

**PARENTS BE AWARE: HEALTH CONCERNS ABOUT
DIETARY SUPPLEMENTS FOR OVERWEIGHT
CHILDREN**

HEARING
BEFORE THE
SUBCOMMITTEE ON
OVERSIGHT AND INVESTIGATIONS
OF THE
COMMITTEE ON ENERGY AND
COMMERCE
HOUSE OF REPRESENTATIVES
ONE HUNDRED EIGHTH CONGRESS
SECOND SESSION

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JUNE 16, 2004
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Serial No. 108-93

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Printed for the use of the Committee on Energy and Commerce



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**PARENTS BE AWARE: HEALTH CONCERNS
ABOUT DIETARY SUPPLEMENTS FOR OVER-
WEIGHT CHILDREN**

WEDNESDAY, JUNE 16, 2004

HOUSE OF REPRESENTATIVES,
COMMITTEE ON ENERGY AND COMMERCE,
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
Washington, DC.

The subcommittee met, pursuant to notice, at 10:10 a.m., in room 2123, Rayburn House Office Building, James C. Greenwood (chairman) presiding.

Members present: Representatives Greenwood, Stearns, Bass, Walden, Ferguson, Barton (ex officio), DeGette, Schakowsky, and Waxman.

Staff present: Kelli Andrews, majority counsel; Mark Paoletta, majority counsel; William Harvard, legislative clerk; Bud Albright, majority staff director; Andy Black, majority policy coordinator; David Nelson, minority senior investigator; and Jessica McNiece, minority research assistant.

Mr. GREENWOOD. The hearing will come to order.

The Chair recognizes himself for the purposes of making an opening statement.

Reports concerning the increase of obesity in America's children have been broadcast throughout the media in recent weeks and months. The June 7 issue of Time magazine has a cover story on obesity problems facing Americans both young and old. Today the committee will examine the exploitation of parents desperate to find a solution to their children's weight problems. These parents are sometimes persuaded to turn to dietary supplements marketed with the promise of weight loss for their kids. What we have learned from our investigation is that these promises are at best empty or at worst, dangerous.

Today we focus on several products that have been marketed and manufactured for the express purpose of providing a weight loss benefit for children as young as 6 years of age. These products with names that invite certain weight loss in children, Skinny Pill for Kids, PediaLean and PediaLoss have been represented to America's parents to be safe and effective for weight loss in children. None, I repeat none of these products has been tested in any scientifically credible manner in children. None of these products has any legitimate basis upon which to claim that they would be effective in helping children lose weight.

Several of these products also contained ingredients which would be harmful to children. For example, we've learned that an herb called uva ursi was contraindicated for children under 12 years of age, yet this ingredient found its way into a dietary supplement called the Skinny Pill for Kids and was promoted to millions of parents on national television by Edita Kaye. The fact that this product was being marketed at all for children when it contained an ingredient children should not take is outrageous.

I have watched the tapes of Ms. Kaye and her laboratory formulator defending this product, a product that thankfully a child has never ingested.

And let me be clear to Ms. Kaye, PAL Labs and anyone else there who is deciding whether to put an ingredient contraindicated for children in a product for kids: It is no answer to the American public that only small amounts of these ingredients were incorporated in the pills.

The company that testify at our hearing today provided false hope and promises and parents and children in the marketing of their respective products. Given the delicate nature of children's health, this type of misleading advertising is even more egregious.

One of the dietary supplements for children that the committee investigated, PediaLean, is still available for purchase today. The fact that two of these products, the Skinny Pill for Kids and PediaLoss I am told are not being sold anymore in no way changes the larger issues at stake here today.

These companies, Edita Kaye and her Fountain of Youth Group DBS Labs and Basic Research, promoted and offered for sale products for young children to take by doing little if any of their own legitimate research on the health effects of their products on children. Nor did any company even attempt to determine that the products worked before promoting it for purpose. They did this simply to make money at the expense of desperate parents, parents hoping against all hope for a safe and effective magic solution for their children's weight problems.

The fact that some of these companies ultimately made little or no money on these products does not alleviate the concern that the rapid rise from obesity will be exploited by dietary supplement manufacturers for monetary benefit.

It is also important to point out that while Edita Kaye's Skinny Pill for Kids was pulled before it ever hit the shelves, sparing children around the country the ill effects of ingesting this product and that her national promotional efforts for her product were a year and a half ago, she refused to voluntarily cooperate with the committee's investigation every step of the way.

I expect that Ms. Kaye will stand by her statements made on national television that she is happy that the promotional launch of her ill-fated Skinny Pill for Kids opened up the debate on this issue of finding a solution to the increasing number of overweight children in the U.S. If Ms. Kaye believes she opened this debate, it is only fitting that she be present at this public forum to continue the debate. I am disappointed that she was not willing to voluntarily aid the committee in our investigation into this matter.

Several agencies have extensive work relating to obesity in children. I look forward to hearing about the work the Centers for Dis-

ease Control has done in this arena and the information it believes is useful to aid parents and their children in combating weight related problems.

The Federal Trade Commission has done extensive to combat misleading advertising in the dietary supplement industry, and in particular in supplements marketed to children. We know that they recently settled an action with Ms. Kaye regarding her promotional efforts with respect to the Skinny Pill for Kids and other of her products. We look forward to hearing more about this settlement and look forward to hearing about other work the Commission has done in this area.

In addition, we are joined by some medical experts who will be able to shed light on some of the problems associated with taking these dietary supplements designed for use by children and the problems that can arise when young children are led to believe that there is a magic pill.

I am hopeful that at the end of this hearing the public, particularly parents, are more informed about what little science and research goes into these products before they are marketed for children. I hope that parents after hearing testimony today will turn skeptical eyes toward claim of weight loss from a pill.

The uniqueness of this subcommittee's oversight function is its ability to promote change by providing the public with information. The more information that parents have about these dietary supplements promoted for their children, the more informed will be their decisions regarding their children.

The Chair now recognizes the gentlelady from Colorado, Ms. DeGette for her opening statement.

Ms. DEGETTE. Thank you, Mr. Chairman.

Today's hearing addresses a topic of great concern, the potential dangers of dietary supplements for pediatric populations and the extent to which these products are being marketed to some uninformed parents and adolescents and children. This hearing is of particular interest to me because it highlights the substantial differences between how we treat claims about dietary supplement versus pharmaceuticals, and also how we treat products for children versus adults. There is a substantial difference in both of these cases.

Dietary supplements such as the three products that we are examining today, the Skinny Pill for Kids, PediaLean and PediaLoss are not subject to the same stringent regulations as food additives or drugs. This, of course, is because of the Dietary Supplement Health Education Act, DSHEA, which has greatly limited the power of the FDA to stop sales of dangerous substances, only until after substantial public harm has occurred. Nor does that agency have the same power they exercise over drugs to assure that labeling and advertising are not false or misleading.

Some say that the law has allowed "buyer beware" to replace and "safe and effective when used as directed." I am concerned that consumers do not have enough understandable information under this law and that the law loosens the oversight that could prevent marketing of dangerous or ineffective substances to children and adults. These dietary supplements for overweight children are a tragic example of how loose the oversight is, but they are not the

only example. We had another hearing earlier this spring on ephedra and other dietary supplements that are providing a real risk to consumers.

The Federal Trade Commission, today represented by Mr. Beales, is here to provide information about the credibility of advertising claims about weight loss effects and the safety of those products. The FTC will discuss its recent filing of a complaint against one of the witnesses today Basic Research. I'm very interested to learn from the FTC about the extent of false and deceptive advertising in the dietary supplement industry and whether the FTC's current enforcement powers are sufficient.

This hearing also highlights the substantial difference between testing requirements in pediatric versus adult populations. I, like many of my colleagues on the subcommittee, have worked hard on the pediatric rule which requires testing for drugs that are given to pediatric populations and on post market surveillance of medical devices used by children. The FDA has worked with Congress and the pharmaceutical industry to improve testing for these drugs and devices, so we have made significant progress for a majority of products. But yet for dietary supplements like this PediaLean which the box and bottle look to me like remarkably like an FDA approved drug, I think that's probably the intention, we have a disturbing situation in which the product, at least with the Skinny Pill for Kids which thank goodness is not being sold, it included a substance that was determined to be dangerous to children.

The Skinny Pill for Kids was widely advertised, but as the chairman said, it was never distributed.

The situation remains that we do not have adequate information on the effects of supplements in children. This committee's work on the pediatric role was based on a determination that children are not just mini adults and that medical products for children must be tested for efficacy and toxicity.

The committee does not take the protection of children lightly, nor does it formulate policy based on dubious science. Two of the witnesses today will speak to the science behind these dietary supplements, and I am pleased that they are with us today because I think, frankly, there is too much junk science receiving credence. The Federal Government plays a substantial role in protecting consumers from these invalidated claims, and this science I believe warrants an examination. The hearing is an opportunity to learn about the science, and I thank the chairman for holding it.

I just want to add one more thing. I understand the purposes behind DSHEA, and I support many of those goals. But given the last hearing and now this hearing, Mr. Chairman, I really think we need to look at DSHEA to see whether or not there are ways we can make distribution of these dietary supplements more safe for the health of our constituents.

And I yield back the balance of my time.

Oh, Mr. Chairman, before I yield, I'd ask unanimous consent to put Mr. Dingell and Mr. Waxman's opening statements, and any other members opening statements in the record.

Mr. GREENWOOD. Without objection, that will be the order.

The gentlelady from Chicago, Ms. Schakowsky.

Ms. SCHAKOWSKY. Let me begin by thanking Chairman Greenwood for holding this hearing on such an important topic.

The issue of childhood obesity has become one of great concern for all of us as it has become clear that we are now faced with an epidemic in this country that threatens the future health of millions of American children and adults.

It is also clear that, as a result of the increased media attention on this issue, parents have become more aware of this problem and the significant risks that it poses to their children. For that reason, we have a responsibility to make sure that parents in their efforts to provide remedies to this very complex and chronic problem do not give their children dietary supplements that, despite their marketing and labels, have been proven to be neither effective nor safe.

In addition to what appears to be a significant lack of resources and funding made available to the Federal Trade Commission and the Food and Drug Administration to screen these products, it should be recognized that the ability of these agencies to protect families from the unethical manufacturing and marketing of dietary supplements has been weakened considerably by the limited authority provided to them by the 1994 Dietary Supplement Health and Education Act, DSHEA.

It is evident that under the current system outlined by DSHEA, manufacturers of dietary supplements can get around current guidelines, allowing them to not only move their product into the market but also make health claims that mislead desperate parents who are searching for solutions to help their children.

I feel, then, that it is important to ask what steps the Bush Administration and Congress have taken and should take to strengthen the current law and subsequently address the roadblocks that exist which prevent the FTC and FDA from doing more to protect consumers from these untested products.

There is a significant amount of research available from the CDC and the World Health Organization that outlines steps that parents, children, physicians and communities can take in their efforts to address the increasing prevalence of childhood obesity. It is these proven effective interventions such as improved nutrition education, increased access to healthy foods and increased opportunities for children to engage in physical activities that we should be actively promoting to families and within schools.

In addition to promoting what we know to be effective in the fight against obesity, I believe that it is our responsibility to make sure that families are protected from the manufacturing and marketing of products that are not only unproven in regards to their efficacy in inducing weight loss, but also unproven to be safe for both children and adults.

I look forward to hearing from today's panelists about how we can best inform and protect consumers from business practices that are not credible and jeopardize consumer safety.

Thank you, Mr. Chairman.

[Additional statements submitted for the record follows:]

PREPARED STATEMENT OF TOM ALLEN, A REPRESENTATIVE IN CONGRESS FROM THE
STATE OF MAINE

I am pleased that Chairman Greenwood and Ranking Member Deutsch called this hearing today to look at the marketing and distribution of dietary supplements targeted at children.

We all recognize that obesity in the U.S. is reaching epidemic proportions. In Maine, nearly 27 percent of high school students are overweight and nearly 59 percent of Maine adults are overweight or obese. Nationally, approximately two-thirds of American adults are overweight and 15 percent of 6- to 19-year-olds are overweight—a number that has tripled over the past two decades. Obesity represents a tremendous burden on our health care system—costing Americans more than \$117 billion per year. Obesity is associated with an increased risk for heart disease, the leading cause of death in the U.S., as well as cancer, diabetes, and muscle problems.

Overweight children and their parents, often desperate for an easy solution to weight loss, are lured by the bold, exaggerated marketing claims of dietary supplement manufacturers and their so called “clinical studies.” The average American does not know that there are virtually no standards regulating how these supplements are made, ingredients are often not fully disclosed—disguised behind “scientific-sounding” trademarks, and there is no requirement—or national database—for adverse event reporting. And yet parents are being encouraged to give these pills to children as young as six. It is certainly a case of “buyer-beware.” But do parents, and their children know this? In the case of dietary supplements marketed as “diet aids,” it is often impossible to figure out exactly what you are getting, what the side effects could be, and whether there is any evidence that the supplement will have the desired effect.

A 2002 Harris poll determined that most people believe that if a supplement is on the market it must have been approved by “some government agency”; that manufactures are prohibited from making claims for their products unless they have the data to back up those claims; and that companies are required to include warnings about potential risks and side effects. In the case of dietary supplements, all of these assumptions are false. In 2002, the FTC found that at least half of all weight-loss ads contained false or misleading statements. These companies thrive by playing on people’s desperate search for a quick-fix to lose weight.

Thank you to our panelists for joining us today. I particularly look forward to hearing from our expert witnesses about their views of the safety and efficacy of these products, and the appropriateness of promoting these supplements to children as young as 6.

PREPARED STATEMENT OF HON. JOHN D. DINGELL, A REPRESENTATIVE IN CONGRESS
FROM THE STATE OF MICHIGAN

Mr. Chairman, thank you for continuing the investigation into the unfortunate consequences of the Dietary Supplement Health Education Act. Last summer this investigation exposed the statutory limitations and regulatory failures in dealing with ephedra, the herbal form of a stimulant drug that caused death and a number of serious health problems. As a direct result of pressure from this Committee, the Food and Drug Administration (FDA) finally decided that enough damage had been done to the public health and banned that so-called dietary supplement.

I am also pleased with another positive achievement of this investigation. Our inquiries to the Drug Enforcement Administration (DEA) and FDA regarding the sale of dangerous steroid precursors as dietary supplements ultimately helped produce Administration support for H.R. 3866, the “Anabolic Steroid Control Act of 2004.” The bill passed the House with almost unanimous support and is currently pending Senate action.

Today, we look at another category of products that may potentially cause not only physical harm to the public but also make a serious dent in the wallets of American consumers desperate to find an “easy way” to treat their overweight children. Again we will see how unscrupulous operators ignore public health consequences as they bend, break, and otherwise abuse a weak law to sell products that could seriously injure the uninformed user. Further, their advertising claims attract the most vulnerable: parents and children who hope to lose pounds easily without undergoing important lifestyle changes, such as diet and exercise.

Given current judicial interpretations, weak statutory language, clever uncovering of legal loopholes, and shoddy enforcement, the current law cannot adequately protect the public from these modern-day patent medicine peddlers. I therefore joined Rep. Susan Davis and Rep. Henry Waxman, in introducing H.R. 3377, the “Dietary Supplement Access and Awareness Act of 2004.” Passage of this bill would be the

first step toward undoing the harm to the public health and the personal pocket-books of millions of Americans who, because of the fraudulent claims which dominate this industry, have endangered their health and squandered billions of dollars on products that have not the slightest scientific evidence to support manufacturers' claims.

Mr. Chairman, thank you again for this Subcommittee's focus on the public health threats posed by certain dietary supplements. I look forward to the testimony presented today.

Mr. GREENWOOD. The Chair thanks the gentlelady and will now introduce our first panel.

We're pleased to have with us and we welcome Mr. Howard Beales, who is the Director of the Bureau of Consumer Protection of the Federal Trade Commission.

Good morning, sir.

Mr. BEALES. Good morning. And thank you very much for the opportunity to—

Mr. GREENWOOD. Well, I am not ready. I am just saying good morning and I have not asked you to speak yet.

Mr. BEALES. I am sorry.

Mr. GREENWOOD. But I will. Thank you.

We have Dr. Howell Wechsler, who is the Acting Director, Division of Adolescent and School Health for the Centers for Disease Control and Prevention.

Good morning, sir. Good to have you here.

We also have Dr. Alison Hoppin. Am I saying that right? Who is the Associate Director for Pediatric Services at MGH Weight Center in Massachusetts General Hospital.

And we expect shortly to have with us Dr. Keith Ayoob, who is the Associate Professor of Pediatrics at the Albert Einstein College of Medicine.

The Chair recognizes the presence of the gentleman from Florida, Mr. Stearns. Do you have an opening statement you would like to make? The Chair would recognize the gentleman from Florida.

Mr. STEARNS. Thank you, Mr. Chairman. Obviously, I am very, very excited that you are holding this hearing.

I Chair the Subcommittee on Commerce, Trade, and Consumer Protection and we also deal in major league sports. And I am glad that you are investigating dietary supplement issues for the year or so.

And I am very interested in how Howard Beales from the Federal Trade Commission will testify today on its actions before us. Basic Research, for one, has provided us that the active ingredient in their products has been hyped up, some sort of hyper fiber which I think they sell for about \$40 a bottle on the Internet and I guess the real question is does it work. Is there validity and research and support to support their advertising claims and what is the Federal Trade Commission to make sure that it has been demonstrated? Can the parents feel comfortable buying this product? And are they better off, perhaps, just with a salad and perhaps with fiber from fruit?

As a member of the Florida delegation I'm struck by the prevalence of connections to Florida by some of our witnesses and some of the manufacturing distribution. So, I would be curious to see how that works out.

So, Mr. Chairman, I appreciate your hard work here and I look forward to the hearing.

Mr. GREENWOOD. The Chair thanks the gentleman from Florida.

And before we swear in the first panel, I would like to, for the benefit of the members of the committee, have you view a brief video that I think illustrates this issue if our technical people are ready to do that.

[Video shown, interview of Edita Kaye and Dr. Ayoob done by Katie Couric.]

Ms. COURIC. Obesity in children has reached epidemic proportions. According to the Centers for Disease Control, more than 6 million kids in the United States are severely overweight, that is 15 percent of our children and adolescents. But is a diet pill for children the answer? Edita Kaye is the creator of skinny.com and the new Skinny Pill for Kids. And Dr. Keith Ayoob is an Associate Professor of Pediatrics at Albert Einstein College of Medicine.

Good morning to both of you.

Dr. AYOOB. Good morning.

Ms. COURIC. Let me start with you, if I could, Edita Kaye.

Ms. KAYE. Good morning to you.

Ms. COURIC. Good morning. Nice to see you.

Ms. KAYE. Thank you.

You have been marketing a Skinny Pill for adults on a website and now you have a Skinny Pill for Kids. Why?

Ms. KAYE. Yes.

Ms. COURIC. Obviously for the reasons I just outlined?

Ms. KAYE. Well, I will tell you why. Because in the past 36 months that I have been selling the Skinny Pill, which is a dietary nutritional supplement for women and men, I have had requests; we have almost 500,000 people who have used our product and it is safe and successful. And there is a wonderful food plan that goes with it. And moms have been writing to me, emailing me, calling me saying "Edita, what can I do for my kids." And children have called me. And it breaks your heart, Katie, the letters and emails that I get. Kids get thrown into garbage cans. They have no self-esteem. They are afraid to go to school. They cannot play with their friends. They cannot eat in the restaurants that their friends eat in.

So I thought, okay, I will come up with something that I am going to call the Skinny Pill for Kids, and to me I am ringing a great big bell out there across America.

Ms. COURIC. What is in this pill?

Ms. KAYE. In this pill we have B vitamins, which are wonderful and they help with energy, right? We have dietary fibers which are wonderful because what they do is they give you a feeling of fullness so you do not eat as much.

Ms. COURIC. Right.

Ms. KAYE. Or as often.

Ms. COURIC. In other words, it is all natural ingredients, right?

Ms. KAYE. Absolutely. These are—no one has questioned the contents of the Skinny Pill.

Ms. COURIC. There is no ephedra—

Dr. AYOOB. Excuse me. Excuse me.

Ms. KAYE. No, no, no, no.

Ms. COURIC. Wait for a second, Doctor. You're going to get to—I am going to get to you in a second because I am sure you have some serious issues with the whole notion of marketing a Skinny Pill for children, and what are they?

Dr. AYOOB. Yes, I do, big time issues. First of all, I work with this issue every single day and kids are the most important people in the world to me.

I have a real issue when somebody is marketing a bogus product that has no scientific evidence behind it and when it includes herbs that are essentially diuretics and that have never been tested on kids. I would never recommend this product for anybody.

Ms. COURIC. And, in fact, it contains, niacin folate, vitamin B12—

Dr. AYOOB. And can—

Ms. COURIC. Wait a second. Pectins, clumodin, uva ursi, whatever that is, Berchu leaves and juniper berry. And you say it is based on scientific research done in Australia and the U.K.?

Ms. KAYE. Yes. It comes together with a food plan. We know that pectins, such as the fibers that are in this product, are ways of helping satisfy children's fullness.

The B vitamins are—you know, there is nothing in this product that you cannot get in other vitamins.

But what I am saying here is you have got it—you know, I will tell you what the experts are saying to our kids. They are saying, “Look, you are fat, here is what you have to do. Turn off the TV and stop eating fast foods.” How real is there? It is not going to happening—

Ms. COURIC. Doctor?

Dr. AYOOB. Excuse me.

Ms. KAYE. What I am saying is—

Dr. AYOOB. Excuse me. I have a real issue with that. I am sorry. But ingredients in this product have never been tested on kids. Edita, you do not have any evidence and until you do have evidence, you should not be making bogus claims. This pills is not going to help anybody lose weight. A balanced eating plan and a lifestyle change that parents can gradually work on is what is going to help kids lose weight.

Ms. COURIC. Has this been tested on children?

Ms. KAYE. I produce this in a lab. It has formulators—

Ms. COURIC. Has it been tested on children?

Ms. KAYE. This particular product, some of the ingredients have and I do not know about the others.

Ms. COURIC. But this particular substance—

Ms. KAYE. I do not know—

Ms. COURIC. Excuse me, Dr. Ayoob. Does that not make you—give you real cause for concern?

Ms. KAYE. No. Because what happens, Katie, is what I am saying is you need to take some supplements and you need to eat skinny foods. And no one is saying that I am not doing that. In fact, I welcome that Dr. Ayoobs of the world come and help me, help me do something about this problem. Let us get doctors working on this with me, dieticians, nutritionists, parents, grown ups—

Dr. AYOOB. Katie, the only way—Katie, the only way this—

Ms. COURIC. Go ahead, Dr. Ayoob.

Dr. AYOOB. The only way you are going to lose from this product is from your pocketbook, not from your body.

Ms. KAYE. No, that—

Dr. AYOOB. And I take kids much more seriously than this. And, Edita, if you want me to help you, I will.

Ms. KAYE. Oh, thank you. Thank you.

Dr. AYOOB. I will help you take it off the market.

Ms. COURIC. Okay. He wants you to take it off the market—

Dr. AYOOB. I will help you take it off the market.

Ms. COURIC. [continuing] though, that is way of—

Dr. AYOOB. Absolutely. I am not even sure this is legal—these are legal herbs to put and to give to kids.

Ms. COURIC. Let me ask you both—

Dr. AYOOB. FTC had a press conference last week about making—

Ms. COURIC. Go ahead. I'm sorry.

Dr. AYOOB. [continuing] bogus claims for health products. And I think this has never been tested on kids. I would not give these herbs. They're diuretic herbs. You do not give those to 6 year old children.

Ms. COURIC. Let me just ask you about the psychological impact of this. To tell children that frankly there is a magic bullet, yes you say there is—

Ms. KAYE. That is not what I am saying.

Ms. COURIC. [continuing] and an eating plan.

Ms. KAYE. That is not what I am saying.

Ms. COURIC. But in the adult website you do say “magic will happen.” And frankly—

Ms. KAYE. Well, magic happens when you take—

Ms. COURIC. [continuing] is this not misleading and psychologically difficult for kids?

Ms. KAYE. Because, Katie, I will tell you what happens, okay. Here is what happens. I say to kids, look, let us use this time that you have blessed me with. Let us say to kids, look, this morning when you are having that glass of orange juice, have an orange. An orange has fiber in it. I am saying tonight at bedtime—

Dr. AYOOB. Katie?

Ms. KAYE. [continuing] have some peanut butter. That is wonderful.

Dr. AYOOB. Katie—

Ms. KAYE. That is when the magic happens.

Ms. COURIC. Dr. Ayoob—

Dr. AYOOB. Excuse me.

Ms. KAYE. And there are foods—

Ms. COURIC. [continuing] we are almost out of time. You get the last word, Dr. Ayoob.

Dr. AYOOB. Thank you very much, Katie.

Katie, this is a bogus product. There are ingredients that I would never give to kids. I am not even sure it is legal to have this in and give this to kids. And a sensible eating plan with a lifestyle, a healthy eating style is the way to get kids to lose weight.

Ms. COURIC. All right.

Dr. AYOOB. Pills are not the answer.

Ms. COURIC. That will be the last word.

Thank you both very much. We will be back after this.

Ms. KAYE. Thank you, Katie.

Mr. GREENWOOD. Bogus products or miracle pill, that is what this hearing is about. And we are now about ready to hear testimony for our first panel.

First let me inform our witnesses that pursuant to the rules of this committee you are entitled to be represented by counsel. Do any of the witnesses wish to be represented by counsel today? Okay.

It is the practice of this subcommittee to take our testimony under oath. Do any of you object to giving your testimony under oath. Okay.

In that case, I am going to ask if you will stand and raise your right hands, please.

[Witnesses sworn.]

Mr. GREENWOOD. Okay. Thank you. You are under oath.

And, Mr. Beales, you are now recognized for your opening statement.

TESTIMONY OF J. HOWARD BEALES III, DIRECTOR, BUREAU OF CONSUMER PROTECTION, FEDERAL TRADE COMMISSION; HOWELL WECHSLER, ACTING DIRECTOR, DIVISION OF ADOLESCENT AND SCHOOL HEALTH, THE CENTERS FOR DISEASE CONTROL AND PREVENTION; ALISON HOPPIN, ASSOCIATE DIRECTOR FOR PEDIATRIC SERVICES, MGH WEIGHT CENTER, MASSACHUSETTS GENERAL HOSPITAL

Mr. BEALES. Thank you, Mr. Chairman. And good morning to you and the members of the subcommittee.

I am the Director of the FTC's Bureau of Consumer Protection. And I would like to thank the subcommittee for taking a leadership role to ensure the truthfulness and accuracy of marketing for dietary supplements to children.

There is little doubt that the dietary supplement industry is a large and growing segment of the consumer health care market. According to a recent CDC study, more than a third of American adults use some form of complementary and alternative medicine. Although similar statistics are not available for children, children's supplements comprise a niche market with estimated sales of over a half a billion dollars as of July 2002.

Over the past decade we have filed 15 law enforcement actions challenging false or unsubstantiated claims about the efficacy or safety of children's dietary supplements, including five this year. Among the kinds of problems we've seen are zinc lozenges sold to reduce the severity of cold symptoms in children when, in fact, the

one study that focused on children failed to find any benefit in reducing their cold symptoms.

We have also challenged unproven claims that dietary supplements can improve or even cure AD/HD, a condition that NIH estimates affects 3 to 5 percent of school-aged children in the United States.

We have taken action against marketers of body building supplements containing steroid hormones popular among teenage athletes and required them to place strong warnings in their future advertising and labeling about the potential risks of using steroid hormones.

FDA recently notified specific companies that the sale of these products is prohibited by the Food, Drug and Cosmetic Act.

Finally, given the concern about the increasing rate of childhood obesity, we are vigorously investigating and bringing cases against marketers of dietary supplements for weight loss in children who promise dramatic, easy, rapid or weight loss without any basis for their claims.

For example, earlier this year the FTC challenged advertising that allegedly claimed that "Skinny Pill for Kids" safely burned fat, blocked new fat deposits, normalized insulin and blood sugar levels and reduced the risk of obesity-related diseases. Prompt Commission action stopped this marketing campaign before the children's product actually entered the marketplace.

Yesterday, the Commission issued two new complaints against marketers whose products include weight-loss products marketed specifically for children. The Commission's complaints alleged that Basic Research, which sold a product called, "PediaLean," and DBS Labs and Dynamic Health which sold a product called "PediaLoss" made deceptive weight loss claims in their advertisements.

The Commission will continue to actively challenge deceptive marketing of dietary supplements, both to children and adults.

Thank you for focusing attention on this important consumer health issue and for giving the FTC an opportunity to discuss its role. We look forward to working with the subcommittee on initiatives concerning our dietary supplement program, and I look forward to your questions.

[The prepared statement of J. Howard Beales III follows:]

PREPARED STATEMENT OF J. HOWARD BEALES III, DIRECTOR, BUREAU OF CONSUMER PROTECTION, FEDERAL TRADE COMMISSION

Mr. Chairman and members of the Subcommittee, I am J. Howard Beales, Director of the Bureau of Consumer Protection, Federal Trade Commission ("FTC" or "Commission"). The Commission is pleased to have this opportunity to provide information concerning our efforts to ensure the truthfulness and accuracy of the marketing of dietary supplements for children.¹

The mission of the Federal Trade Commission is to prevent unfair competition and to protect consumers from unfair or deceptive practices in the marketplace. As part of this mission, the Commission has a longstanding and active program to combat fraudulent and deceptive advertising claims about the health benefits and safety of dietary supplements, especially those products marketed to or for children.²

¹ The written statement presents the views of the Federal Trade Commission. Oral testimony and responses to questions reflect my views and do not necessarily reflect the views of the Commission or any Commissioner.

² The Commission's authority in this area derives from Section 5 of the Federal Trade Commission Act, which prohibits "unfair or deceptive acts and practices in or affecting commerce,"

The dietary supplement industry represents a substantial and growing segment of the consumer healthcare market with industry sales for 2002 estimated to be \$18.8 billion.³ A recent survey of complementary and alternative medicine use in the United States shows that more than one-third of U.S. adults age 18 and over are turning to alternative medicine, including herbal products, enzymes and other dietary supplements.⁴ The market for children's supplements has also been growing. Industry analysts estimate annual sales of children's supplements reached \$510 million as of July 2002 and represented one of the top niche markets in the supplement industry.⁵

The supplement category encompasses a broad range of products, from vitamins and minerals to herbals and hormones. Products promoted specifically for children extend beyond traditional multivitamins to include preventives and cures for a variety of childhood ailments ranging from colds to more serious conditions like attention deficit/hyperactivity disorder (AD/HD). Most recently, the Commission has seen the appearance of a few children's products promoted for weight loss.

Certainly, some supplements offer the potential for real health benefits to consumers. The scientific research on the associations between supplements and health is accumulating rapidly. A 2001 NIH conference on Dietary Supplement Use in Children, however, found that little is known about the evidence base to support appropriate indications for use in children or about the safety of children's supplements.⁶

Commission law requires that claims about the safety and efficacy of any health-related product, including dietary supplements, be substantiated by competent and reliable scientific evidence before the claims are made. The Commission seeks to ensure that consumers get accurate information so that they can make informed decisions about how to manage their own healthcare. Bad information can pose a threat to the health and well-being of consumers. In recent years the Commission has brought several actions against deceptive promotions of supplements to children as part of its broader supplement law enforcement program. The agency also has made an effort to educate parents about the appropriate and safe use of children's supplements. The Commission's testimony today will highlight some of those enforcement and education efforts.

The FTC's Dietary Supplement Advertising Program

The agency has committed a significant portion of its consumer protection resources to combating false, misleading, or unsubstantiated claims in advertising for healthcare products, including dietary supplements. Over the past decade the Commission has filed or settled more than 100 law enforcement actions challenging allegedly false or unsubstantiated claims about the efficacy or safety of a wide variety of supplements. The Commission has focused its enforcement priorities on national advertising claims for products with unproven benefits; products promoted via the Internet and elsewhere to treat or cure serious diseases; and products that may present significant safety concerns to consumers.

As in all its advertising programs, the Commission works to make sure its enforcement actions have a strong impact, for example, by holding accountable not just the supplement manufacturer but other parties that play a role in deceptive marketing, such as ad agencies, infomercial producers, distributors, and catalog companies.⁷ The Commission has sought to obtain meaningful relief for consumers, going beyond the basic cease and desist orders in many cases, to require substantial mon-

and Section 12, which prohibits the false advertisement of "food, drugs, devices, services or cosmetics." 15 U.S.C. §§45, 52.

³Source: *Nutrition Business Journal*, Supplement Business Report 2003.

⁴Barnes, P. et al., *CDC Advance Data Report #343. Complementary and Alternative Medicine Use Among Adults: United States, 2002* (May 27, 2004). Reprint available at <http://www.nccam.nih.gov>. The study found that 36% reported using some form of complementary and alternative medicine, and that 19% specifically used natural products such as herbs, other botanicals and enzymes, most without consulting a healthcare practitioner.

⁵Source: *Nutrition Business Journal* (July 2002).

⁶The conference was sponsored by the National Institute of Child Health and Human Development and the Office of Dietary Supplements of NIH. See *Dietary Supplement Use in Children: Who, What, Why, and Where Do We Go From Here* (Feb. 2001). Executive Summary available at: http://www.nichd.nih.gov/about/od/prip/pastevents/executive_summary.htm.

⁷See, e.g., *Vital Basics, Inc. et al.*, Dkt. No. C-4107 (2004) (consent); *Creative Health Institute, Inc. and Kyl L. Smith*, Dkt. No. C-4108 (2004) (consent) (Respondents included the marketer, the individual who developed the product and others); see also *The Quigley Corp.*, Dkt. No. C-3926 (2000) (consent); *QVC, Inc.*, Dkt. No. C-3955 (2000) (consent) (Respondents included the products' manufacturer and marketer as well as the home shopping channel on which the products were advertised). The Commission's cases generally are available at www.ftc.gov.

etary relief for consumer redress or disgorgement of profits.⁸ Finally, when the marketing of a supplement raises safety concerns, the Commission has required that strong warning statements be placed in labeling and advertising and, in certain cases, has imposed limits on how and to whom the product can be marketed.⁹

The Commission coordinates all of its enforcement efforts closely with the Food and Drug Administration (FDA). As you know, the two agencies have overlapping authority over the marketing of dietary supplements and operate under a long-standing liaison agreement whereby the FTC has primary responsibility for claims made in advertising and the FDA for claims made in labeling.¹⁰ Since December 2002, the FTC and FDA have intensified the level of this cooperation with stepped-up enforcement against deceptive supplement marketing. The staff of the two agencies have formed a joint enforcement task force that has led to improved information sharing and more effective joint actions that make the best use of the unique enforcement tools available to each agency. Both agencies have benefitted. For the FTC's part, the joint effort has helped us to bring more than 40 actions targeting fraudulently marketed supplements and other health products in the 18 months since the inception of the task force.¹¹

Actions Involving Children's Supplements

The agency's efforts to police the supplement marketplace include especially close scrutiny of products marketed for use in children or otherwise targeted to appeal to young consumers. In the last ten years, thirteen of the Commission's actions against deceptive supplement advertising have addressed children's products, including three actions to date in 2004.¹² These actions have involved products making allegedly unfounded promises to prevent colds, products allegedly deceptively touted as safe and natural alternatives for the treatment of attention deficit/hyperactivity disorder (AD/HD), and, most recently, products promoted to help children lose weight. Some of the challenged products have contained stimulants or hormones that raise safety concerns or herbs with known toxicity.

1. Substantiation of Claims for Children's Dietary Supplements

The Commission has made it clear to the supplement industry that it will carefully evaluate the research for supplements marketed to children or to any other specific population, to make sure that the evidence supports safety and efficacy for the population to whom the product is marketed.¹³ In some instances, research that has been conducted on children has failed to find the same effect as research conducted for the same product using an adult population.¹⁴

For example, the Commission's 1999 action against **Quigley Corporation** focused, in part, on claims made about the benefits of the company's "Cold-Eeze" zinc lozenges and "Kids-Eeze" zinc bubble gum for reducing the severity of cold symptoms and even preventing colds in children. In fact, although there was some limited evidence at the time on the effect of zinc on cold symptoms in adults, there was

⁸See, e.g., *Vital Basics, Inc. et al.*, Dkt. No. C-4107 (2004) (consent) (\$1 million in consumer redress); *FTC v. Seasilver USA, Inc., et al.*, Civil Action No. CV-5-0676-RHL-LRL (D. Nev. Mar. 4, 2004) (final stipulated order) (\$4.5 million in redress). The Seasilver defendants also agreed in a separate settlement with FDA to destroy \$5.3 million in misbranded products.

⁹See, e.g., *Global World Media Corp.*, Dkt. No. C-3772 (1997) (consent) (warning on ephedra risks and ban on marketing of certain products in media with majority youth audience); *Christopher Enterprises, Inc., et al.*, Civil Action No. 2:01 CV-0505 ST (D. Utah 2001) (final stipulated order) (ban on marketing of comfrey products for internal use and application on external wounds).

¹⁰See Working Agreement Between FTC and FDA, 3 Trade Reg. Rep. (CCH) ¶9,859.01 (1971).

¹¹See *Federal Trade Commission Attacks \$1 Billion in Deceptive Health Marketing Since December*, FTC Press Release (July 10, 2003), available at <<http://www.ftc.gov/opa/2003/07/diethealth.htm>>.

¹²A complete list of FTC cases involving children's supplements, including citations, is attached as Attachment A. The Commission files a complaint in a case when it has "reason to believe" that the practices cited in the complaint violate the FTC Act. A consent order that is reached in settlement of such allegations does not constitute an admission by the respondent that a law violation has occurred.

¹³See, e.g., *Dietary Supplements: An Advertising Guide For Industry*, Part B.5., available at <<http://www.ftc.gov/bcp/online/pubs/buspubs/dietsupp.htm>>.

¹⁴Last December the NIH's National Center for Complementary and Alternative Medicine (NCCAM) announced the results of research it had funded on echinacea, an herb popularly used to treat colds and other upper respiratory infections. The placebo-controlled study involved 534 children ages 2 to 11 and found no benefit in children, either for shortening the duration or lessening the symptoms of colds. Further, the study found that echinacea use was associated with an increased risk of rash. James A. Taylor *et al.*, EFFICACY AND SAFETY OF ECHINACEA IN TREATING UPPER RESPIRATORY TRACT INFECTIONS IN CHILDREN, 290 J. OF THE AM. MED. ASS'N 2824 (Dec. 3, 2003).

no evidence on cold prevention, and the one zinc study using a children's population failed to find any benefit in reducing cold symptoms in children.¹⁵

2. Purported AD/HD Treatments

It has been estimated that AD/HD affects 3 to 5 percent of school-aged children in the United States.¹⁶ A variety of supplement products and ingredients on the market are promoted with claims ranging from increasing concentration, improving behavior, or enhancing school performance, to promises of complete cures for AD/HD. Due to the prevalence of these promotions and the serious nature of the health condition at issue, the Commission has focused much of its enforcement efforts on this category of children's supplements. To date, the Commission has settled six actions against companies marketing a variety of supplements for the treatment of AD/HD or its symptoms, focusing on the most widely promoted products and those making claims that allegedly far exceed any scientific evidence of a benefit.¹⁷

The first two actions involved a multi-level marketer, **New Vision International, Inc.**, and **Max F. James**, a high level distributor for New Vision, both charged with making unsubstantiated claims for a combination of dietary supplements called "God's Recipe" that included an herbal drink containing grape seed extract, a mineral capsule, and a multi-enzyme tablet containing alfalfa and barley sprouts. The package was promoted through compelling testimonials as a cure for AD/HD and a natural alternative to Ritalin. Subsequent actions included a consent order with **J&R Research** settling charges that the company made unsubstantiated claims that its pycnogenol supplement was effective in treating not only AD/HD, but also cancer, heart disease, arthritis, diabetes, and multiple sclerosis; a consent order with **Efamol Nutraceuticals, Inc.** settling charges of unsubstantiated claims that two essential fatty acid supplements, "Efalex" and "Efalex Focus," could treat or cure AD/HD; and a consent order with **Natural Organics, Inc.** challenging the deceptive marketing of a multi-ingredient supplement called "Pedi-Active A.D.D."

Most recently, the Commission settled charges against **Vital Basics, Inc.** relating to the marketing of "Focus Factor," a multi-ingredient supplement purported to improve focus, memory, concentration, and academic performance in children, teenagers, adults, and senior citizens alike. The campaign for Focus Factor involved widely disseminated television and radio infomercials and Internet marketing. The Commission's consent order included a \$1 million consumer redress payment.¹⁸ The Commission also obtained a consent order against **Kyl Smith**, the developer of Focus Factor, and his company **Creative Health Institute**, along with an additional \$60,000 payment for consumer redress.

3. Bodybuilding Supplements Appealing to Young Athletes

Dietary supplements marketed to increase athletic performance and strength may be particularly attractive to young athletes and bodybuilders. For that reason, in 1999 the Federal Trade Commission challenged ads promoting a category of bodybuilding supplements that raised safety concerns and were popular among teenage athletes. The Commission brought action against two marketers of supplements containing androstenedione and other steroid hormones, **MET-Rx USA, Inc.** and **AST Nutritional Concepts**. Both companies were charged with making unsupported safety claims for their products, and were required to place strong warnings in future advertising and labeling warning against the potential risks of using steroid hormones, including potential unwanted changes in male and female sexual characteristics and increased danger for persons at risk of prostate or breast cancer.¹⁹ The orders in both of these cases also required an additional warning for certain prod-

¹⁵The Commission also challenged other claims as unsubstantiated and beyond the existing science, including claims, not specific to children, that the products would relieve allergies and reduce the risk of contracting pneumonia.

¹⁶Attention Deficit-Hyperactivity Disorder Information Page, NIH National Institute of Neurological Disorders (Mar. 21, 2003), available at <http://www.ninds.nih.gov/health_and_medical/disorders/adhd.htm>.

¹⁷Although not directly marketed for AD/HD, an earlier Commission case, **Zygon International, Inc.**, challenged, as unsubstantiated, claims that the company's "SuperBrain Nutrient Program" would enhance intelligence and memory. Marketing for the product included claims that pregnant women taking the product would enhance the intelligence of their children.

¹⁸The Vital Basics case also challenged safety and efficacy claims for "V-Factor," a supplement marketed as a male sexual performance enhancer.

¹⁹Specifically the consent orders required that the following statement be displayed prominently in advertising and labeling: "**WARNING:** This product contains steroid hormones and may cause breast enlargement, testicle shrinkage, and infertility in males, and increased facial and body hair, voice deepening, and clitoral enlargement in females. Higher doses increase these risks. *If you are at risk for prostate or breast cancer you should not use this product.*"

ucts that contained the powerful cardiovascular and central nervous system stimulant, ephedra, which has since been banned by the Food and Drug Administration.

In bringing these actions, the Commission coordinated closely with the Food and Drug Administration, as well as the Department of Justice's Drug Enforcement Agency and the White House Office of National Drug Control Policy, to better understand the risks these products posed and how young athletes used them. The agency also worked with the National Federation of State High School Associations to help raise awareness among student athletes about the dangers of using any performance-enhancing substances. In addition, earlier this year, the FDA sent 23 companies warning letters indicating that the agency considers the marketing of products containing androstenedione to be prohibited. Specifically, the FDA warning letters indicated that such products are adulterated under the Federal Food, Drug, and Cosmetic Act because androstenedione is a new dietary ingredient for which there is not adequate evidence of safety.

4. Other Cases Raising Safety Concerns

When necessary, the Commission will impose additional remedies, beyond warning requirements, to ensure that potentially dangerous supplements do not harm young consumers. In the Commission's 1997 action against **Global World Media Corp.**, for example, the agency challenged the marketing of a supplement named "Herbal Ecstasy," a product containing a high dosage of ephedra, that was promoted as an "absolutely safe" natural alternative to street drugs to get "high." The product was advertised with psychedelic print and television ads in media with large youth audiences, including even MTV and Nickelodeon in some markets. The Commission's order required strong warning statements in advertising and labeling.²⁰ And, to further protect young consumers to whom the marketing had been targeted, the order also prohibited any future advertising of Herbal Ecstasy and similar ephedra products in media with a predominantly young audience.²¹ Since that time, FDA has banned ephedra products because of serious safety risks.

In another matter, the Commission addressed the marketing of several products containing comfrey, an herb associated with severe liver toxicity. **Christopher Enterprises, Inc.** used the Internet and other media to market various cure-all remedies containing comfrey. Some of these comfrey products were promoted for use in young children as a cough and cold remedy and even for use in babies and pregnant women for treatment of a variety of infections. The Commission alleged that the company's safety claims were false. Because of the severe risks associated with this herb, the Commission's 2001 consent order banned the company from marketing any comfrey product either for internal use or for application to open wounds. The consent order further required that products sold for external use were required to be labeled and advertised with warning statements making it clear that comfrey can cause serious liver damage and even death.²²

Most recently, the Commission charged **Direct Marketing Concepts, Inc.** with making several false and unsubstantiated claims about the safety and efficacy of two dietary supplements marketed through widely-aired infomercials. In addition to challenging claims that the products could prevent or cure cancer and other diseases and cause substantial weight loss, the Commission also challenged a claim relating to the safety of one product for children and pregnant women. Specifically, the Commission complaint charged the marketers with making unfounded claims that "Supreme Greens," a combination of numerous plant and herbal ingredients, was safe for everyone, including pregnant women, children, and persons on medication.

5. Weight Loss Supplements

Given the concern about the increasing rate of childhood obesity, marketing of dietary supplements for weight loss in children is another subject of ongoing FTC investigations and law enforcement. With weight loss advertising in general, the Com-

²⁰The specific warning for the 1997 order was: "**WARNING:** This product contains ephedrine which can have dangerous effects on the central nervous system and heart and could result in serious injury. Risk of injury increases with dose."

²¹The consent order prohibited dissemination of ads for Herbal Ecstasy and similar products containing ephedra in any media where more than 50% of the audience is under 21 years of age.

²²The warning reads: "**Warning:** External Use Only. Consuming this product can cause serious liver damage. This product contains comfrey. Comfrey contains pyrrolizidine alkaloids, which may cause serious illness or death. This product should not be taken orally, used as a suppository, or applied to broken skin. For further information contact the Food and Drug Administration: <http://vm/cfsan.fda.gov>." The final stipulated order also included a \$1.4 million judgment that was suspended pro

mission is concerned that consumers not be misled by ads promising dramatic, easy, rapid weight loss without diet or exercise.

In one recent case, involving a product called “Skinny Pill for Kids,” the FTC challenged advertising by **The Fountain of Youth Group, LLC** and its principal **Edita Kaye**. The company claimed on its web site and in other media that Skinny Pill for Kids was the “First thermic and herbal formula ever developed for weight loss for children 6 to 12.” According to the ads, Skinny Pill for Kids would burn fat, block new fat deposits, normalize insulin and blood sugar levels, reduce the risk of obesity-related diseases including heart disease, high blood pressure and diabetes, and was proven safe by scientific research. The complaint alleged that these claims were unfounded or outright false. Prompt Commission action stopped this marketing campaign before the children’s product actually entered the marketplace. Currently, the Commission also is pursuing two other non-public law enforcement matters that include weight loss products marketed specifically for children.

The Commission’s efforts to stop the deceptive marketing of weight loss products to children is part of a larger ongoing effort to stop weight loss scams. Going back more than a decade, the agency has maintained an aggressive law enforcement program against weight loss scams, bringing more than 100 cases against false and misleading weight loss claims. In November 2002, the Commission held a public workshop to explore approaches, in addition to traditional law enforcement, to curb ongoing weight loss fraud.²³ Based, in part, on the workshop, the Commission launched a new initiative to enlist the media in screening out facially false weight loss ads before they are run. As part of this effort, the Commission has published, and widely disseminated to television, newspapers and magazine publishers, its *Red Flag: Bogus Weight Loss Claims*²⁴ brochure, which provides media outlets with easy guidelines for spotting and stopping false claims. Thus far, the response from media has been encouraging.

Consumer Education Efforts

As the *Red Flags* brochure exemplifies, the Commission’s consumer protection activities are not limited to law enforcement. The agency complements traditional cases with a variety of creative and effective education and outreach for both consumers and industry. In May 2000 the FTC published a feature article on promotions for children’s dietary supplements.²⁵ That article described the FTC’s enforcement efforts against various deceptive promotions of children’s supplements and detailed some of the concerns surrounding the safety and efficacy of these products. It also provided practical pointers for parents about safe and responsible use of supplements, urging parents to consult with a pediatrician before starting their child on any supplement. The article was reprinted in large and small markets, and was featured in numerous local and regional radio broadcasts, reaching parents throughout the country. The Commission will continue to look for opportunities for consumer education, in partnership with other health and law enforcement authorities. This approach can help parents better protect their children against ineffective and sometimes dangerous health products.

Conclusion

The Commission will continue to have an active program to challenge deceptive marketing of dietary supplements in general and children’s supplements specifically. The agency will continue to monitor promotions of children’s products, staying alert for new categories of supplements, such as children’s weight loss products, and taking action as warranted against unfounded safety and efficacy claims. The Commission thanks this Subcommittee for focusing attention on this important consumer health issue and for giving the Federal Trade Commission an opportunity to discuss its role. The Commission looks forward to working with the Subcommittee on initiatives concerning our dietary supplement program.

²³The November 2002 workshop brought together government officials, scientists, public health groups, marketers of weight loss products, advertising professionals, and representatives of various media outlets. A report describing the results was issued in December 2003. “Deception in Weight-Loss Advertising Workshop: Seizing Opportunities and Building Partnerships to Stop Weight-Loss Fraud,” FTC Staff Report (Dec. 2003). <http://www.ftc.gov/reports/index.htm>.

²⁴Available at <http://www.ftc.gov/bcp/online/pubs/buspubs/redflag.pdf>.

²⁵FTC Consumer Feature, *Promotions for Kids’ Dietary Supplements Leave Sour Taste*, (May 2000), available at <http://www.ftc.gov/bcp/online/features/kidssup.htm>.

APPENDIX A

FTC ADVERTISING CASES—CHILDREN’S SUPPLEMENTS

- Direct Marketing Concepts, Inc., d/b/a Today’s Health and Direct Fulfillment, et al., No. 04-CV-11136-GAO (D. Mass.) (Complaint filed June 1, 2004)(Alleged false and unsubstantiated claims that “Supreme Greens,” a multiple ingredient plant and herbal supplement, could cure or prevent cancer, heart disease, diabetes, and arthritis, could cause substantial weight loss, and was safe for everyone, including pregnant women, children, and persons on medication. Also, alleged false and unsubstantiated claims that “Coral Calcium Daily” could prevent, treat, or cure cancer and other serious diseases.)
- Vital Basics, Inc., Robert B. Graham, and Michael B. Shane, C-4107 (Apr. 26, 2004) (Consent Order) (Alleged unsubstantiated efficacy claims for the dietary supplement “Focus Factor” and safety claims for the dietary supplement “V-Factor Natural Pack,” which contains yohimbine and L-arginine. Focus Factor was marketed to improve memory, mood, and concentration in children and adults. V-Factor was marketed to improve male sexual performance. Failure to disclose materials connections with endorsers of the products. \$1 million in consumer redress is required by the order.)
- Creative Health Institute, Inc., and Kyl L. Smith, C-4108 (Apr. 26, 2004) (Consent Order) (Alleged unsubstantiated efficacy claims for the dietary supplement “Focus Factor.” Dr. Smith developed Focus Factor and advertised and sold it through CHI at least from 1997 to 2000. \$60,000 in consumer redress is required by the order.)
- The Fountain of Youth Group, LLC, and Edita Kaye, No. 3:04-CV-47-J-99HTS (M.D. Fla.) (Feb. 10, 2004) (Stipulated Final Order for Permanent Injunction)(Complaint alleged false and unsubstantiated weight-loss and health claims for their dietary supplement products—Skinny Pill AM, Skinny Sleep PM, Skinny Carbs, and Skinny Pill for Kids. The Order contains a judgment of \$6 million, which was suspended due to defendants’ inability to pay.)
- Natural Organics, Inc., et al. D. 9294 (Sept. 6, 2001) (Consent Order) (Alleged unsubstantiated claims that company’s dietary supplement, “Pedi-Active A.D.D.,” treats or mitigates Attention Deficit Hyperactivity Disorder and improves attention span and scholastic performance of children who have difficulty focusing on their schoolwork.)
- Christopher Enterprises, Inc., et al., No. 2:01 CV-0505 ST, (D. Utah) (Stipulated Final Order for Permanent Injunction and Settlement of Claims for Monetary Relief (Dec. 3, 2001) (Alleged false safety claims and unsubstantiated efficacy claims for products containing the herbal ingredient comfrey. Order includes judgment for \$1.4 million, which is suspended provided respondents pay \$100,000 for consumer redress. The order prohibits the defendants from marketing any comfrey product for ingestion, for use as a suppository, or for external use on open wounds, unless they have evidence that the product is free of pyrrolizidine alkaloids and that it is safe. The defendants are also required to place a warning disclosure in any ad, promotional material or product label for any comfrey products intended for topical use. The specific claims challenged in the complaint are also prohibited by the order.)
- Efamol Nutraceuticals, Inc., C-3958 (June 22, 2000) (Consent Order) (Alleged unsubstantiated efficacy claims for the products Efalex and Efalex Focus, marketed and sold by the company for the mitigation or cure of the effects of Attention Deficit Disorder(ADD) or Attention Deficit Hyperactivity Disorder(ADHD)
- J & R Research, Inc., C-3961 (July 19, 2000) (Consent Order) (Alleged unsubstantiated efficacy claims for the product Pycnogenol, marketed and sold by the company for the mitigation or cure of the effects of Attention Deficit Disorder(ADD) or Attention Deficit Hyperactivity Disorder(ADHD).)
- New Vision International, Inc., et al., 127 F.T.C. 278 (1999) (Consent Order) (Alleged unsubstantiated claims that dietary supplements called “God’s Recipe” would cure ADD/ADHD.)
- Max F. James, 127 F.T.C. 324 (1999) (Consent Order) (Alleged unsubstantiated claims for “God’s Recipe” by James, a high level distributor of the product; see New Vision International, Inc.)
- AST Nutritional Concepts and Research, Inc., et al., No. 99-WY-2197 (D. Colo.) (May 4, 2000) (Permanent Injunction)(Alleged unsubstantiated safety claims made for purported body-building supplements that contain androstenedione, “androgen,” and other steroid hormones, and in some cases, stimulants.)
- Met-RX USA, Inc., et al., No. SACV99-1407 DOC(ANX) (C.D. Cal.) (Nov. 24, 1999) (Stipulated Final Order For Permanent Injunction and Other Equitable Relief)

- (Alleged unsubstantiated safety claims made for purported body-building supplements that contain androstenedione, "androgen," and other steroid hormones, and in some cases, stimulants.)
- Global World Media Corp., 124 F.T.C. 426 (1997) (Consent Order) (Alleged explicit safety and no side effects claims for Ecstasy supplement advertised to produce a natural "high," in media with large youth audiences, and without disclosing health and safety risks.)
- The Quigley Corp., C-3926 (Feb. 10, 2000) (Consent Order) (Alleged unsubstantiated claims by Quigley that Cold-Eezer and Cold-Eeze brand zinc lozenges that it manufactures can prevent colds and alleviate allergy symptoms and that Kids-Eeze Bubble-Gum can reduce the severity of cold symptoms in children.)
- QVC, Inc., C-3955 (June 14, 2000) (Consent Order) (Alleged unsubstantiated claims on its "home shopping" network that Cold-Eezer or Cold-Eeze brand zinc lozenges can prevent colds and alleviate allergy symptoms.)
- Zygon International, Inc., 122 F.T.C. 195 (1996) (Consent Order and up to \$195,000 in consumer redress for all products) (Alleged unsubstantiated claims that SuperBrain Nutrient Program improves memory and enhances the intelligence of children and also benefits pregnant women; that Fat Burner pills cause weight loss; and that Day and Night Eyes pills improve day vision and night blindness.)

Mr. GREENWOOD. Thank you, Dr. Beales. And we thank you for the good work of the Commission.

Dr. Wechsler, you are recognized for your opening statement.

TESTIMONY OF HOWELL WECHSLER

Mr. WECHSLER. Mr. Chairman, members of the committee, thank you for the opportunity. I am the Acting Director of the Division of Adolescent and School Health at the Centers for Disease Control and Prevention, which is part of the U.S. Department of Health and Human Services. Today, I will summarize for you the latest scientific information we have on the overweight epidemic among children and adolescents, and highlight HHS' comprehensive strategy for combating this epidemic.

The latest data, in fact, were released just yesterday by CDC, and they show that between 1999 and 2002, 16 percent of children and adolescents were overweight, and another 15 percent were at risk for overweight. Since 1980 the prevalence of overweight has more than doubled among children, among adolescents it has tripled. The increases in overweight cut across all regions, ages and racial and ethnic groups. However, more African-American and Mexican-American youth are overweight compared to white youth.

An estimated 400,000 adult deaths and a cost of \$117 billion in each year in the United States are associated with obesity. Most of this disease occurs in adults, but children who are overweight often develop risk factors for diseases such as Type 2 diabetes, high blood pressure and elevated cholesterol. Sixty percent of overweight children have at least one additional risk factor for cardiovascular disease, 25 percent have two or more.

Type 2 diabetes, which is strongly associated with obesity, was virtually unknown in children and adolescents 10 years ago. Today it accounts for almost 50 percent of new cases of diabetes among youth in some communities.

Overweight adolescents have a 70 percent chance of becoming overweight or obese adults and childhood overweight that persists into adulthood is typically more severe than overweight or obesity that developed during adulthood.

Overweight and obesity represent a major long-term public health crisis that if not reversed, the gains in life expectancy and

quality of life seen in recent decades will erode and more health-related costs will burden the Nation.

Many factors have contributed to the unfavorable trends in physical activity and nutrition that have fueled the obesity epidemic. Consequently, there will be no silver bullet, no single change strategy to end the epidemic. Multiple strategies addressing multiple factors will be needed. The critical challenge is to help young people and their families adopt healthy eating and physical activity behaviors.

Addressing overweight and obesity is a top priority for HHS, and I'll briefly describe seven key components of the Department's comprehensive strategy for reducing overweight and obesity.

First, is providing strong national leadership through President Bush's HealthierUS Initiative and Secretary Thompson's Steps to a HealthierUS initiative which promotes community programs to support responsible health choices.

Second is delivering clear effective health messages to ensure that consumers have the information they need to improve their health. Some ways we do that include the Dietary Guidelines for Americans, the nutrition facts label, 5 A Day for Better Health Program to promote food and vegetable consumption and the President's Council on Physical Fitness and Sports.

HHS is communicating health messages directly to children through "VERB," CDC's media campaign to increase physical activity among 9 to 13 year olds. We do this through advertising and marketing promotions using television, radio, print and websites. After just 1 year, campaign impact has been demonstrated by reports of increased free-time physical activity among girls, 9-10 year olds, and children from low- to moderate-income households. It is showing effectiveness.

The third component is monitoring the problem and programs to address the problem. We have nationally representative data on overweight and diet and physical activity among young people through the National Health and Nutrition Examination Survey. In addition, we have surveillance systems in place that allows us to collect not only national, but State and city data on height and weight among high school students on physical activity and nutrition, as well as what programs are in place in schools to address those issues.

The fourth component is identifying and addressing research gaps. The National Institutes of Health is funding the studies that evaluate interventions designed to prevent childhood overweight and promote physical activity and healthy eating.

The fifth component, we synthesize research findings to identify effective policies and programs to figure out for the public what works.

The sixth component is developing and disseminating research-based tools to help schools and community based organizations implement effective policies and programs.

And the seventh and final component is helping community and State agencies and organizations implement effective programs.

Secretary Thompson's Steps to a HealthierUS initiative is enabling community based agencies to implement effective programs to address obesity as well as diabetes and asthma.

With 2004 funding, CDC is supporting obesity prevention programs in 28 States. What are the State health departments doing? They're helping children and adolescents by encouraging restaurants to make fruit and vegetables more available, to improve lighting, sidewalks and crosswalks in neighborhoods, to clean up vacant lots for use as play areas, to train health care professionals to promote behavior changes.

In addition, CDC provides funding to 23 States to implement school based physical activity and nutrition programs where the State education agencies are strengthening policies, improving curricula, implementing professional development activities and involving families and community.

In conclusion, CDC, NIH and all the HHS agencies are leading the Nation in conducting the research necessary to learn more about strategies to prevent overweight among children and adolescents. We know, however, there are no quick fixes when it comes to losing weight. It is only through proper diet and physical activity that we can maintain and improve our health. We know that no one strategy alone will be sufficient and our chances for success will be greater if we use multiple strategies to address multiple factors, and if we involve multiple sectors of society at the community, State and national levels.

HHS is leading the national effort to combat overweight in children through a comprehensive multifaceted, multilevel approach. We are committed to doing all that we can to help our young people enjoy good health now and for a lifetime.

I thank you for your interest.

[The prepared statement of Howell Wechsler follows:]

PREPARED STATEMENT OF HOWELL WECHSLER, ACTING DIRECTOR, DIVISION OF ADOLESCENT AND SCHOOL HEALTH, CENTERS FOR DISEASE CONTROL AND PREVENTION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

INTRODUCTION

Mr. Chairman, Members of the Committee, thank you for the opportunity to participate in today's hearing. I am Dr. Howell Wechsler, Acting Director of the Division of Adolescent and School Health at the Centers for Disease Control and Prevention (CDC), which is part of the U.S. Department of Health and Human Services. Today, I will present an overview of the overweight epidemic among children and adolescents; describe the scientific information available on effective interventions to prevent overweight among young people; and identify a number of Department of Health and Human Services (HHS) initiatives and programs designed to combat this epidemic.

The National Institutes of Health defines obesity and overweight using a Body Mass Index (BMI), which is a calculation of a person's weight in kilograms divided by the square of their height in meters. Health professionals often use a gender and age specific BMI "growth chart" to help them assess whether a child or adolescent is overweight. Children are considered overweight if they are at or above the 95th percentile of the sex-specific BMI for age growth charts. Doctors and other health care professionals are the best people to determine whether an overweight child or adolescent's weight and growth patterns place the individual at risk for health problems. At the current time, there is no definition of obesity for children and adolescents, because BMI is not a reliable measure of fatness for children, especially across varying ages and degrees of maturity, in contrast to adults who have already reached their peak height. There is also concern related to the potential stigma associated with using the term "obesity" for children.

OVERVIEW OF OVERWEIGHT AMONG CHILDREN AND ADOLESCENTS IN U.S.

In the United States, obesity and overweight has risen at an epidemic rate during the past 20 years. The prevalence of overweight has more than doubled among chil-

dren and has tripled among adolescents since 1980. Approximately 15.3 percent of children aged 6 to 11 years and 15.5 percent of adolescents aged 12 to 19 years were overweight in 1999-2000. There are no signs that the rapid increase in overweight seen over the past two decades is abating. The latest data, which cover the period from 1999-2002, is being released today by CDC in the Journal of the American Medical Association.

The increases in overweight among children and adolescents cut across all regions of the Nation, ages, and racial and ethnic groups. However, the prevalence of overweight has been growing at a much faster rate among certain populations. For example, more African-American and Mexican-American youth are overweight compared to white youth, and this disparity has grown dramatically over the past two decades. An economic disparity in the prevalence of overweight is seen among white adolescents: those from lower income families have a greater prevalence of overweight compared with white adolescents from higher income families.

The primary concern of overweight and obesity is one of health and not appearance. An estimated 400,000 adult deaths each year in the U.S. are associated with obesity. Total costs (medical costs and days lost from work because of illness, disability or premature death) from obesity in 2000 were estimated to be \$117 billion.

We have already begun to see the impact of the obesity epidemic on the health of young people. Although most of the death and disease associated with overweight and obesity occurs in adults, children who are overweight often develop risk factors for diseases such as type 2 diabetes, high blood pressure, and elevated cholesterol levels. Sixty percent of overweight children have at least one risk factor for cardiovascular disease, in addition to overweight, and 25 percent have two or more. Type 2 diabetes, which is strongly associated with obesity, was virtually unknown in children and adolescents 10 years ago; today, it accounts for almost 50 percent of new cases of diabetes among youth in some communities. A CDC report predicted that one in three Americans born in 2000 will develop diabetes during his or her lifetime. Childhood overweight is also associated with discrimination, poor self-esteem, and depression.

Furthermore, overweight adolescents have a 70 percent chance of becoming overweight or obese adults. This increases to 80 percent if one or more parent is overweight or obese. Adults who are overweight or obese are at increased risk for premature death, heart disease, type 2 diabetes, certain types of cancer, breathing problems, arthritis, and psychological problems, such as depression. One final concern is that childhood overweight that persists into adulthood is typically more severe than overweight or obesity that develops during adulthood.

Overweight and obesity represent a major long-term public health crisis. If it is not reversed, the gains in life expectancy and quality of life seen in recent decades will erode, and more health-related costs will burden the nation.

GOVERNMENT'S ROLE IN COMBATING THE OBESITY EPIDEMIC

Eating a healthy diet and increasing physical activity reduces weight which is shown to reduce the risk for many chronic diseases. Often small changes—such as physical activity for 30 minutes a day or consuming 100 fewer calories a day—can result in large health benefits. In order for individuals to take action, they must have the right information to empower their lifestyle choices. The government can support individual action by:

- Providing leadership;
- Establishing a framework for understanding issues related to overweight and obesity;
- Coalescing and coordinating efforts to address the issues;
- Developing clear, coherent and effective health messages to ensure that consumers have accurate and adequate information to make informed decisions about improving their health;
- Identifying and addressing research gaps;
- Bringing diverse stakeholders together to address the epidemic (e.g., food industry, consumer organizations and the medical community);
- Coordinating private/public campaigns;
- Providing training and education materials to address the epidemic; and
- Working to improve the health-promoting nature of the environments in which individuals make their decisions.

HHS has made addressing the problems of overweight and obesity top priorities for the Department. In fact, HHS has a large number of current initiatives and programs underway to address these issues. They include programs in education, communication and outreach, intervention, diet and nutrition, physical activity and fitness, disease surveillance, research, clinical preventive services and therapeutics,

and policy and web-based tools. These programs are targeted to a variety of populations including infants and breastfeeding mothers, children and adolescents, women, minorities, the elderly, the disabled, rural, and the general population.

HHS has adopted a comprehensive, multi-component approach to address the complex epidemic of obesity among children and adolescents. HHS strategies include:

- Providing strong, national leadership
- Developing and delivering clear, coherent, and effective health messages to ensure that consumers have accurate and adequate information to make informed decisions about improving their health;
- Monitoring the problem and programs to address the problem so that we can better understand its causes, consequences, and how it changes over time;
- Identifying and addressing research gaps;
- Synthesizing research findings to identify effective policies and programs;
- Developing and disseminating tools to help schools and community-based organizations implement effective policies and programs; and
- Helping national, state, and local agencies and organizations implement effective programs.

DEPARTMENT OF HEALTH AND HUMAN SERVICES STEPS INITIATIVE

In June 2002, President Bush launched the *HealthierUS* initiative designed to help Americans, especially children, live longer, better, and healthier lives. The President's *HealthierUS* initiative helps Americans take steps to improve personal health and fitness and encourages all Americans to: 1) be physically active every day; 2) eat a nutritious diet; 3) get preventive screenings; and 4) make healthy choices concerning alcohol, tobacco, drugs and safety.

In 2003, Tommy Thompson, Secretary of the Department of Health and Human Services, further advanced the President's initiative by introducing *Steps to a HealthierUS (Steps)*. At the heart of this program lies both personal responsibility for the choices Americans make and social responsibility to ensure that policy makers support programs that foster healthy behaviors and prevent disease. The *Steps* initiative envisions a healthy, strong, U.S. population supported by a health care system in which diseases are prevented when possible, controlled when necessary, and treated when appropriate.

The *Steps* Cooperative Agreement Program is one part of Secretary Thompson's larger *Steps* initiative. This program aims to help Americans live longer, better, and healthier lives by reducing the burden of diabetes, obesity, and asthma and addressing three related risk factors—physical inactivity, poor nutrition, and tobacco use. In FY 2003, \$15 million was provided to 23 communities to support innovative community-based programs that are proven effective in preventing and controlling chronic diseases. In FY 2004, \$44 million will be used to increase funding to existing *Steps* communities, fund new communities, and fund one or two national organizations to enhance the capacity of *Steps* communities.

As part of the *Steps* initiative, HHS also recently released a report titled *Prevention: A Blueprint for Action*, which outlines simple steps that individuals and interested groups can take to promote healthy lifestyles and encourage healthy behavior. The Department's efforts to promote health and prevent disorders such as obesity rests, in large part, on developing effective messages that are appropriate for individuals and groups in ways that they can understand and act upon. An example of this is the CDC's youth media campaign demonstration, "*VERB. It's what you do.*" *VERB's* goal has been to promote social norms that support physical activity and portray fitness as fun and healthy. HHS/CDC has enlisted partner organizations in the campaign, such as 4-H, Boys and Girls Clubs and the National Hockey League to brand the *VERB* message and make it appealing to its pre-teen audience. *VERB* also reaches out to parents and other adults influential to young people, encouraging them to support and participate in physical activity with pre-teens.

Campaign strategies include multimedia advertising and marketing promotions using television, radio, print, and Web sites; contests and community events; and partnerships with youth organizations, schools, national professional associations, and entertainment media that are popular with youth. Reported preteen (or "tween") awareness of *VERB* is high at 74 percent, with 90 percent of these youth understanding the campaign's messages. After one year, campaign impact has been demonstrated by reports of increased free-time physical activity among several important population subgroups, including the nation's 10 million tween girls, 8.6 million 9-10 year olds, and 6 million tweens from low- to moderate-income households. For example, after one year of the campaign, the average 9-10 year old in the nation

engaged in more sessions of free-time physical activity when compared to children who were unaware of VERB.

Other important HHS programs that communicate nutrition and physical activity messages to the American public are the National Cancer Institute's 5 A Day for Better Health Program and the President's Council on Physical Fitness and Sports (PCPFS). The 5 A Day program seeks to increase to 5 or more the number of daily servings Americans eat of fruits and vegetables. In addition to its widely known slogan, the 5 A Day program reaches many individuals through health care provider networks, the internet, and print media. It also has sponsored the development and evaluation of a number of school-based interventions to promote fruit and vegetable consumption among children and adolescents.

The PCPFS promotes physical activity for all ages, backgrounds and abilities with information and publications (www.fitness.gov) and physical activity/fitness motivational awards programs (www.presidentschallenge.org). The Council advises the President and the Secretary of HHS about issues related to physical activity, fitness, and sports, and recommends programs to promote regular physical activity for the health of the nation.

CDC SURVEILLANCE EFFORTS

Through its ongoing National Health and Nutrition Examination Survey, CDC produces nationally representative data on the prevalence of overweight among children and adolescents based on measured height and weight, as well as on their dietary and physical activity behaviors. In addition, CDC's biennial Youth Risk Behavior Survey provides national, state, and city data on self-reported height and weight, physical activity, and dietary behaviors among high school students.

CDC's School Health Policies and Program Study (SHPPS) is a national survey periodically conducted to assess school health policies and programs of state education agencies and of nationally representative samples of school districts, schools, and health and physical education classrooms. SHPPS provides national data on what schools are doing in relation to physical education, after school physical activity programs, recess, nutrition education, school food service, and vending machine policies and practices. CDC's School Health Profiles survey, conducted every other year, tells us about the extent to which schools are implementing physical activity and nutrition-related policies and practices in different states and cities.

CDC'S NATIONAL NUTRITION AND PHYSICAL ACTIVITY PROGRAM TO PREVENT OBESITY

With 2004 funding, the CDC will support obesity prevention programs in a total of 28 states. Of these, 23 states will be funded at the capacity-building level to hire staff with expertise in public health nutrition and physical activity, build broad based coalitions, develop state plans, identify community resources and gaps, implement small-scale interventions, and work to raise public health awareness of changes needed to help state residents achieve and maintain a healthy weight. The other five states are funded at the basic-implementation level to put their state plans into action, conduct and evaluate nutrition and physical activity interventions, train health care and public health professionals, provide grants to communities, make environmental changes, and strengthen obesity prevention programs in community settings. In addition, CDC provides funding to 23 states for the implementation of school-based policies and programs to help young people avoid behaviors that increase their risk for obesity specifically unhealthy eating and inadequate physical activity.

Additionally, the CDC is developing a mechanism to quickly deploy staff (rapid deployment teams) into communities, worksites and schools to facilitate evaluation of promising strategies aimed at improving nutrition, increasing physical activity, and preventing obesity. Each team would collect baseline data, and provide evaluation consultation and technical assistance, identify methodologic gaps, and provide recommendations to improve the quality of program evaluation.

OTHER HHS EFFORTS

Working groups within the Department's agencies have recently evaluated current HHS programs and activities, made recommendations to better coordinate these efforts, and identified areas of opportunity for new initiatives. Two recent major initiatives tied to obesity are the Food and Drug Administration's (FDA) Obesity Working Group, which will advise the Agency on innovative ways to deal with the increase in obesity and identify ways to help consumers lead healthier lives through better nutrition, and the National Institute of Health's (NIH) development of an Obesity Research Task Force, to develop a strategic plan for obesity research.

This past year the FDA made a major change in the nutrition label on foods to include a separate listing of trans fatty acids. This was the first significant change in the Nutrition Facts panel since it was established in 1993.

The FDA has also undertaken a broad effort to crack down on misleading information and/or unsafe dietary supplements, and has proposed new regulations to establish good manufacturing practice requirements for dietary supplements. FDA has focused its enforcement efforts over the past year to ensure consumers are not being harmed as a result of claims that overstate the effectiveness of dietary supplement products. The Agency took steps to remove dietary supplements containing ephedrine alkaloids from the market. These products were extensively promoted for aiding weight control and boosting sports performance and energy. The totality of the available data showed little evidence of benefit from dietary supplements containing ephedrine alkaloids except for modest, short-term weight loss insufficient to improve health, while confirming that ephedrine alkaloids raise blood pressure and otherwise stress the circulatory system. These effects are linked to significant adverse health outcomes, including heart attack and stroke. In March of this year, the Agency announced various efforts to crack down on products containing androstenedione, or "andro." This class of products poses substantial safety risks to all Americans, particularly our nation's youth and athletes.

One of the key messages of this effort is that there are no safe quick fixes when it comes to losing weight and improving athletic performance, and it is only through proper diet, nutrition and exercise that we can improve our physical performance and, more importantly, maintain and improve our health.

Also, in the school setting, the Health Resources and Services Administration's Healthy Schools, Healthy Communities program promotes and establishes comprehensive school-based health centers to improve the health of at-risk school aged children. Services provided by the centers include nutrition education and counseling, support groups for overweight children, dietary surveillance, and nutrition screening.

NATIONAL DIETARY GUIDELINES

HHS is collaborating with the U.S. Department of Agriculture to review the Dietary Guidelines that were published in 2000 and to draft new *2005 Dietary Guidelines for Americans*. In light of the growing number of overweight and obese Americans, a major focus of the new guidelines will be providing guidance to the public on maintaining a healthy weight and creating lifestyles that balance the number of calories eaten with the number of calories expended. These guidelines must: (1) contain nutritional and dietary information and guidelines for the general public, (2) be based on the preponderance of scientific and medical knowledge current at the time of publication, and (3) be promoted by each Federal Agency involved in a Federal food, nutrition, or health program.

STRATEGIES FOR COMBATING OVERWEIGHT IN CHILDREN

Overweight and obesity result from an imbalance between caloric intake and caloric expenditure. Many factors have contributed to the unfavorable trends in physical activity and nutrition that have fueled the obesity epidemic. Consequently, there will be no silver bullet, no single change strategy to solve these problems. Multiple strategies addressing multiple factors will be needed to successfully combat the obesity epidemic.

Reviews of research conducted to date indicate that there are at least three behavioral strategies for reducing rates of overweight and obesity that appear to be justified by the current state of knowledge. These are: (1) increased physical activity for the population, (2) reduced sedentary behaviors, such as television viewing and video gaming, for children and adolescents, and (3) the promotion of breast feeding and efforts to increase its duration.

Increased physical activity for overweight patients reduces many of the comorbidities associated with obesity such as hypertension, hyperlipidemia, and glucose intolerance; maintains weight after weight loss; and prevents weight gain. The dose of physical activity necessary to prevent weight gain among normal or overweight children, adolescents, or adults has not been established, although one hour of daily, moderate intensity physical activity appears required for weight maintenance in adults after weight loss.

A factor in the prevalence of overweight among our youth may be the amount of time children and adolescents are sedentary, watching television or playing video games, for example. One school-based study demonstrated a two percent decrease in overweight as a result of a curriculum that included reduced television time. A

second school-based study demonstrated reduced rates of weight gain in children who reduced television time.

Breastfeeding is the most appropriate form of feeding for most infants and clearly reduces the incidence of acute diseases of infancy and early childhood. In addition, recent studies indicate that breastfeeding reduces the risk of childhood overweight by 15-20 percent.

While we have good ideas about the types of behaviors we need to promote, the critical challenge before us is to identify how we can effectively help young people and their families to adopt these behaviors. g189Tools to help schools and community-based organizations

HHS has developed, and is continuing to develop, a variety of tools that schools can use to implement policies and practices recommended by the CDC guidelines. These include:

- *CDC's School Health Index for Physical Activity and Healthy Eating*, a widely used self-assessment and planning tool that enables schools to identify the strengths and weaknesses of their health promotion policies and programs, develop an action plan for improving student health, and involve teachers, parents, students, and the community in improving school policies and programs.
 - *Fit Healthy and Ready to Learn*, a school health policy guide, developed with CDC support by the National Association of State Boards of Education, that provides education policymakers and administrators with sample physical activity and nutrition policies and information to support the policies.
 - *CDC's Building a Healthier Future Through School Health Programs* describes promising practices that states should consider when planning school-based policies and programs to help young people avoid behaviors that increase their risk for obesity and chronic disease, especially tobacco use, unhealthy eating, and inadequate physical activity.
 - *Power of Choice*, an after-school program jointly developed by FDA and the US Department of Agriculture (USDA) that guides pre-teens toward a healthier lifestyle by motivating and empowering them to make better food and physical activity choices in real-life settings.
 - *Fruit and Vegetables Galore*, developed by USDA in collaboration with HHS, provides tips to school foodservice professionals on planning, purchasing, preparing, presenting, and promoting fruits and vegetables. It also includes suggestions for working with teachers by providing them with teaching tools and by supporting their educational efforts, making daily meal offerings competitive with other commercial options available to students, and getting students excited about healthful eating.
 - *Kids Walk to School*, a user-friendly manual developed by CDC that provides information and resources for community partners to increase opportunities for daily physical activity by encouraging children to walk to and from school in groups accompanied by adults and by encouraging collaboration among partners to create an environment supportive of walking and bicycling to school safely.
- In addition, HHS agencies are developing important new tools, to be released in the coming months that will help schools promote healthy eating and physical activity.

- *Making It Happen—School Nutrition Success Stories (MIH)*, a joint product of CDC and USDA, tells the stories of 32 schools and school districts that have implemented innovative strategies to improve the nutritional quality of foods and beverages offered and sold on school campuses. The most consistent theme emerging from these case studies is that students will buy and consume healthful foods and beverages—and schools can make money from healthful options.
- *The Health Education Curriculum Analysis Tool* is a user-friendly checklist designed by CDC to help schools select or develop curricula based on the extent to which they have characteristics that research has identified as being critical for leading to positive effects on youth health behaviors. The companion Physical Education Curriculum Analysis Tool will help school districts develop state-of-the-art physical education curriculum based on insights gained from research and best practice.
- *Media Smart Youth: Food, Fitness, and Fun* is a curriculum with supporting materials developed by the National Institute of Child Health and Human Development for youth ages 11-13 years old. It is designed to create awareness of the role that media play in shaping values concerning physical activity and nutrition, while building skills to encourage critical thinking, healthy lifestyle choices, and informed decision making, now and in their future.

CONCLUSION

Successfully combating the overweight epidemic among children and adults will require the involvement of many sectors and levels of society. Although national initiatives can play an important role, they are not sufficient by themselves. Community-based initiatives are critical for reaching Americans where they live, work, go to school, and play. State-level programs are critical for supporting and disseminating community-based activities. HHS is implementing a comprehensive approach to reach the American people through these various levels.

There is a great deal more that we need to learn about intervention strategies to prevent overweight among children and adolescents. Key research questions that need to be addressed include:

- Which are the most important behaviors to target to influence overweight and obesity?
- Which mediating variables should be targeted to influence obesity-related behaviors?
- Which are the types of interventions that have the greatest impact on the most critical mediating variables and behaviors?
- How do we translate efficacy study findings into real-world policies and programs?
- How do we effectively and efficiently disseminate effective policies and programs?
- Do the effects of overweight and obesity prevention policies and programs last over time?

CDC, NIH and other HHS agencies will lead the Nation in conducting the research necessary to answer these questions.

We have, however, learned a great deal about effective strategies for promoting physical activity and healthy eating among young people. We know that no one strategy alone will be sufficient and that our chances for success will be greater if we use multiple strategies to address multiple factors that contribute to caloric imbalance and if we involve multiple sectors of society at the community, state, and national levels. HHS is leading the national effort to combat the overweight epidemic in children through a comprehensive, multi-faceted, multi-level approach. We are committed to doing all that we can to help our young people enjoy good health now and for a lifetime.

I thank you for your interest and the opportunity to share information about strategies to combat the overweight epidemic in children, and would be happy to answer your questions.

Mr. GREENWOOD. Thank you very much, Dr. Wechsler.

Dr. Hoppin, you are recognized for your opening statement. Good morning.

TESTIMONY OF ALISON HOPPIN

Ms. HOPPIN. Good morning. Chairman Greenwood, members of the committee. Good morning.

My name is Alison Hoppin, and I am a physician specializing in Pediatric Obesity Medicine. I am grateful for the opportunity to speak with you today about the “dietary supplements” that are marketed as weight loss agents for overweight children. I am concerned about the lack of scientific standards displayed in the marketing tactics of some members of this industry. The marketing claims are misleading at best, sometimes patently false, and these issues are of particular concern for the products that are marketed for use in children.

My specialty training is in Pediatric Gastroenterology and Nutrition, and for the past 8 years the focus of my research and patient care has been on the problems associated with obesity in children and adolescents. I direct the Pediatric services at the Weight Center at Massachusetts General Hospital, one of the academic medical centers associated with Harvard Medical School. The MGH Weight Center is a multidisciplinary program for clinical treatment of adults and children with obesity. It is also a center for research into the underlying causes, consequences, and treatment of obesity.

I am an instructor on the faculty of Harvard Medical School, where I teach medical students, residents, and fellows in Nutrition and Pediatric Gastroenterology. I am also the mother of two children, 10 and 12 years old. And it is with this dual perspective of a physician and parent that I speak today.

Our country is now facing an epidemic of obesity. It affects all socioeconomic and ethnic groups in our society, and all age groups. Indeed, rates of obesity in children have tripled over the past 30 years. This is not a benign or cosmetic problem. Obesity causes or worsens more than 40 different medical diseases, including diabetes and heart disease, depression, breast cancer, colon cancer, and prostate cancer. It is responsible for over 400,000 premature deaths annually in the United States, and over \$100 billion dollars in health care costs each year. Added to this enormous disease burden is a heavy emotional burden from obesity, due to pervasive cultural preferences for thin body types. This leads to criticism, negative stereotypes, ridicule, and outright bias against individuals with obesity.

There are no consistently successful low-risk treatments for obesity. Many individuals with obesity lose weight in the short term with a wide variety of diets, exercise, and behavioral approaches. However, fewer than 5 percent of adults keep this weight off for 5 years or more, past and current diet fads notwithstanding. Against these odds, people that are facing the emotional and physiological burden of obesity understandably feel discouraged and desperate, and are therefore very vulnerable to products making claims of success.

Children and adolescents are unique in the field of obesity. They are particularly vulnerable to the emotional consequences of obesity, as the impact of teasing from peers or criticism from adults is particularly damaging to their self-esteem. As they go through puberty, adolescents are acutely aware of their changing bodies and are strongly influenced by the images of their idols in the entertainment world, professional sports, and in the popular press. They tend to act impulsively and often fail to consider long-term risks. They are therefore particularly prone to risky dieting behavior, including eating disorders.

I am very concerned about the misinformation that has permeated the field of obesity in the past, and in particular by the companies marketing “dietary supplements” that take advantage of the frustration, fears, and desperation that frequently arise in individuals fighting obesity, or in those who are merely dissatisfied by their body size. Some members of the dietary supplement industry develop products based on a very shaky foundation of pseudoscience. They then market these products to a vulnerable population. They frequently claim pharmacological effects of the products, but then take no responsibility for assessing or communicating the possibility of pharmacological side effects or toxicities. In their marketing, many members of the dietary supplement industry display scientific standards that are well below that of companies in the pharmaceutical, food, or cosmetic industries.

Three “dietary supplements” were recently marketed as “weight loss” treatments for children. Each used combinations of herbal medicines that were previously marketed to adults with claims for

weight loss. The very names of these products; the Skinny Pill for Kids, PediaLoss, and PediaLean make claims of pharmacological effects, and supplementary marketing materials go further. The claims that the Skinny Pill “works overnight with a thermic formula to burn fat while you sleep” and “prevents starch from turning into sugar and then into fat” have no basis in scientific fact. I have reviewed the scant scientific material available to support or refute these claims. In most cases, the data consist of small studies in adults using single-ingredient preparations. The study designs fall short of standards required for scientific proof. Frequently, two studies on the same compound give contradictory results. Extrapolation of results from one study or group of studies is difficult due to highly variable nomenclature and lack of measurement standards for active ingredients. Moreover, one cannot assume that results of studies on a single-ingredient preparation will be valid for multiple-ingredient preparations, in which different active ingredients may interact to change effectiveness or danger from toxicity.

In my review of the literature, I found no studies that tested the particular combinations of dietary supplements used in the Skinny Pill for Kids or PediaLoss, in either adults or children. Moreover, most of the individual ingredients in these preparations have not been adequately tested for safety in children. Children are not just small adults, and their responses to drugs or toxins may be quite different from those seen in adults. This raises serious concerns about the effects that ingesting these products could have in young children.

One of these products, PediaLean, makes its claim based on a purported clinical study of the product in Italian children over 10 years ago, published in an Italian medical journal. It appears that someone, presumably the company that makes PediaLean, had the study translated into English. Selected excerpts from the study were then published in marketing materials for PediaLean, under the statement that this product is “Clinically Proven Safe and Effective.” However, I have serious concerns about the study design, particularly the lack of a true control group, and therefore I have serious doubts about the validity of the authors’ conclusions. There is no placebo control, and no discussion of how the control group was selected, so apparently there was no randomization process. Thirty-eight percent of the subjects dropped out of the study, and results from these drop-outs was apparently ignored. The study states that at least 14 percent of patients given PediaLean “stopped taking the fiber capsule because they complained of abdominal discomfort or because they had not noticed any reduction in appetite.” Ignoring drop-outs like these can greatly bias the results of a study, and is not an accepted approach to analysis.

The Italian study makes no effort to assess for side effects or toxicity from this product, although it does mention, in passing, that a significant number “complained of abdominal discomfort.” The active ingredient, glucomannan, is known to swell in the body after it is taken, and several cases of esophageal and gastrointestinal obstruction have been reported in the literature. I have concerns about the possibility of esophageal obstruction in patients taking a compound containing glucomannan, but the Italian study makes no

mention of monitoring their subjects for this side effect or other toxicities. The so-called “micronization” process with which the glucomannan is treated provides no reassurance against the possibility of obstruction. A compound can swell and stick together in an obstructive mass regardless of the size of the particles. I have seen no evidence, in the company’s own materials or elsewhere, that micronization changes the tendency of glucomannan to clump together to form an obstructive mass when mixed with water.

Despite these obvious flaws in study design, the marketing claims for this product include such inappropriately definitive statements as “Klein-Becker’s proprietary micronization process guarantees that PediaLean is not only safe, but is the one and only weight-control compound designed, manufactured, and clinically proven safe and effective for use by overweight children and adolescents.” On the contrary: there is no valid clinical proof here that the product is either safe, or effective for weight loss.

Another product, the Skinny Pill for Kids, includes Uva Ursi also known as bearberry, an ingredient that in several objective sources is specifically not recommended for children under 12 years of age because of concerns for liver toxicity. A second ingredient, Juniper Berry, may cause kidney damage with “prolonged use” or if high doses are used. These and one other ingredient are considered weak diuretics, meaning that they increase water loss in the urine, and this might conceivably cause a transient minor loss of water weight, which might deceive a patient into thinking that it was helping with weight control. However, there is no biological reason to believe that this diuretic effect would cause any loss of fat, which would be the only “real” type of weight loss.

Another product, PediaLoss, contains just one ingredient that might conceivably cause weight loss, HCA, although two studies on this ingredient give contradictory results. A second ingredient, lecithin, has no support for use as a weight loss agent, and indeed weight gain has been reported as a possible side effect of this ingredient.

I am not here to make statements disparaging alternative medicine in general, or the fields of herbal medicine or dietary supplements in particular. The field of herbal medicines struggles with issues such as lack of standardized nomenclature and dosing standards, and suffers from a dearth of data on which to base clinical decisions. However, I applaud the trend toward creating such standards and improving evidence-based techniques for determining effectiveness and toxicities of medicines in this field.

My concerns are specific to the marketing practices that have been used for some dietary supplements, including those that I mentioned earlier. There is no scientific reason to believe that any of these supplements have true effectiveness for short- or long-term control of obesity. Children and adolescents are particularly influenced by advertising or marketing and are less likely than adults to take a skeptical view of unproven advertising claims. To market these products to the public with claims of effectiveness is therefore exploitative. The absence of carefully collected follow-up data provides little reassurance about the safety of these preparations when used in large numbers of children and adolescents. To target children and adolescents, a group particularly likely to engage in un-

tested or extreme dieting practices, and a group particularly likely to be influenced by advertising, is particularly irresponsible. This, combined with the lack of safety standards in this field, is certainly risky, and possibly downright dangerous.

I am pleased to see that preliminary inquiries by this committee requesting further information on these products were met by abrupt withdrawal of the product from the market in two of the three cases. However, these events do not alter the legislative climate that allows for unbridled and irresponsible marketing of dietary supplements with minimal standards of accountability for potential hazards. In each of the instances noted above, there is inadequate information to provide a reasonable assurance that the ingredient does not present a significant or unreasonable risk of illness or injury in children. I support stronger regulation of these products, based on at least some minimal scientific standards. Stronger regulation is particularly important when products are marketed to vulnerable populations such as the elderly, or the children and adolescents targeted by the products described here.

Thank you for your time and attention to this matter, and I am happy to answer questions about any of these issues that I raised. [The prepared statement of Alison Hoppin follows:]

PREPARED STATEMENT OF ALISON HOPPIN

My name is Alison Hoppin, and I am a physician specializing in the field of Pediatric Obesity Medicine. I am grateful for the opportunity to speak with you today about the “dietary supplements” that are marketed as weight loss agents for overweight children. I am concerned about the lack of scientific standards displayed in the marketing tactics of some members of this industry. The marketing claims are misleading at best, sometimes patently false, and these issues are of particular concern for the products that are marketed for use in children.

My specialty training is in Pediatric Gastroenterology and Nutrition, and for the past eight years the focus of my research and patient care has been on the problems associated with obesity in children and adolescents. I direct the Pediatric services at the Weight Center at Massachusetts General Hospital, one of the academic medical centers associated with Harvard Medical School. The MGH Weight Center is a multidisciplinary program for clinical treatment of adults and children with obesity. It is also a center for research into the underlying causes, consequences, and treatment of obesity. I am an instructor on the faculty of Harvard Medical School, where I teach medical students, residents, and fellows in Nutrition and Pediatric Gastroenterology. I am also the mother of two children—10 and 12 years old. It is with the dual perspective of a physician and parent that I speak today.

Our country is now facing an epidemic of obesity. It affects all socioeconomic and ethnic groups in our society, and all age groups. Indeed, rates of obesity in children have tripled over the past 30 years. This is not a benign or cosmetic problem. Obesity causes or worsens more than 40 different medical diseases, including diabetes and heart disease, depression, breast cancer, colon cancer, and prostate cancer. It is responsible for over 400,000 premature deaths annually in the United States, and over \$100 billion dollars in health care costs each year. Added to this enormous disease burden is a heavy emotional burden from obesity, due to pervasive cultural preferences for thin body types. This leads to criticism, negative stereotypes, ridicule, and outright bias against individuals with obesity.

There are no consistently successful low-risk treatments for obesity. Many individuals with obesity lose weight in the short term with a wide variety of diets, exercise, and behavioral approaches. However, fewer than 5% of adults keep this weight off for five years or more, past and current diet fads notwithstanding. Against these odds, people that are facing the emotional and physiological burden of obesity understandably feel discouraged and desperate, and are therefore vulnerable to products making claims of success.

Children and adolescents are unique in the field of obesity. They are particularly vulnerable to the emotional consequences of obesity, as the impact of teasing from peers or criticism from adults is particularly damaging to their self-esteem. As they go through puberty, adolescents are acutely aware of their changing bodies

and are strongly influenced by images of their idols in the entertainment world, professional sports, and in the popular press. They tend to act impulsively and often fail to consider long-term risks. They are therefore particularly prone to risky dieting behavior, including eating disorders.

I am very concerned about the misinformation that has permeated the field of obesity in the past, and in particular by the companies marketing “dietary supplements” that take advantage of the frustration, fears, and desperation that frequently arise in individuals fighting obesity, or in those who are merely dissatisfied by their body size. Some members of the dietary supplement industry develop products based on a very shaky foundation of pseudo-science. They then market these products to a vulnerable population. They frequently claim pharmacological effects of the products, but take no responsibility for assessing or communicating the possibility of pharmacological side effects or toxicities. In their marketing, many members of the dietary supplement industry display scientific standards that are well below that of companies in the pharmaceutical, food, or cosmetic industries.

Three “dietary supplements” were recently marketed as “weight loss” treatments for children. Each used combinations of herbal medicines that were previously marketed to adults with claims for weight loss. The very names of these products—the “Skinny Pill for Kids,” “PediaLoss,” and “PediaLean,”—make claims of pharmacological effects, and supplementary marketing materials go further. The claims that the Skinny Pill “works overnight with a thermic formula to burn fat while you sleep” and “prevents starch from turning into sugar and then into fat” have no basis in scientific fact. I have reviewed the scant scientific material available to support or refute these claims. In most cases, the data consist of small studies in adults using single-ingredient preparations. The study designs fall short of standards required for scientific proof. Frequently, two studies on the same compound give contradictory results. Extrapolation of results from one study or group of studies is difficult due to highly variable nomenclature and lack of measurement standards for active ingredients. Moreover, one cannot assume that results of studies on a single-ingredient preparation will be valid for multiple-ingredient preparations, in which different active ingredients may interact to change effectiveness or danger from toxicity.

In my review of the literature, I found no studies that tested the particular combinations of dietary supplements used in “The Skinny Pill for Kids” or “PediaLoss,” in either adults or children. Moreover, most of the individual ingredients in these preparations have not been adequately tested for safety in children. Children are not just small adults, and their responses to drugs or toxins may be quite different from those seen in adults. This raises serious concerns about the effects that ingesting these products could have in young children.

One of these products, **“PediaLean®”** makes its claim based on a purported clinical study of the product in Italian children over ten years ago, published in an Italian medical journal. It appears that someone, presumably the company that makes PediaLean, had the study translated into English. Selected excerpts from the study were then published in marketing materials for PediaLean, under the statement that this product is “Clinically Proven Safe and Effective.” However, I have serious concerns about the study design, particularly the lack of a true control group, and therefore I have serious doubts about the validity of the authors’ conclusions. There is no placebo control, and no discussion of how the control group was selected, so apparently there was no randomization process. Thirty-eight percent of the subjects dropped out of the study, and results from these drop-outs was apparently ignored. The study states that at least 14% of patients given PediaLean “stopped taking the fiber capsule because they complained of abdominal discomfort or because they had not noticed any reduction in appetite.” Ignoring drop-outs like these can greatly bias the results of a study, and is not an accepted approach to analysis.

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materials or elsewhere, that micronization changes the tendency of glucomannan to clump and form an obstructive mass when mixed with water.

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Another product, the “**Skinny Pill for Kids®**” includes Uva Ursi (also known as bearberry), an ingredient that in several objective sources is specifically not recommended for children under 12 years of age because of concerns for liver toxicity.^{1,2,3} A second ingredient, Juniper Berry, may cause kidney damage with “prolonged use” or if high doses are used. These and one other ingredient are considered weak diuretics, meaning that they increase water loss in the urine, and this might conceivably cause transient minor loss of water weight, which might deceive a patient into thinking that it was helping with weight control. However, there is no biological reason to believe that this diuretic effect would cause any loss of fat, which would be the only “real” type of weight loss.

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Mr. GREENWOOD. Thank you Dr. Hoppin, and we are very happy to have you with us. It is a big help.

The Chair recognizes himself for 5 minutes for questions, and let me start with Mr. Beales. You have announced today that you have

¹ PDR for Herbal Medicines, 2000 pp 779-782;

² McGuffin M et al: American Herbal Products Association’s Botanical Safety Handbook. CRC Press, Boca Raton FL; 1997

³ AltMedDex, accessed through MICROMEDEX(R) Healthcare Series Vol. 120, 6/7/04

filed a complaint against the manufacturer of PediaLean, is that correct?

Mr. BEALES. Yes, sir.

Mr. GREENWOOD. Let me understand something. Unlike a pharmaceutical product that has a gargantuan burden of proof going before the FDA to prove that the product is in fact safe and effective. Under the DSHEA Act products like PediaLean have no burden of proof whatsoever. Help me understand where the burden of proof comes when the Federal Trade Commission takes an action. Do you have to prove that the product doesn't work or do you simply challenge the manufacturer to prove the claims?

Mr. BEALES. Under the FTC Act a manufacturer has to have evidence to substantiate a claim before it makes that claim. And for products like these, the evidence has to be competent and reliable scientific evidence. If they do not have that kind of evidence, then it's a deceptive practice to make the advertising claim at all. And what we have to show, our burden is to show that the evidence they produced is not enough to meet that standard.

Mr. GREENWOOD. Now, you have filed against individual officers of these companies as well as the company as an entity. Can you explain to the committee why you have taken that action?

Mr. BEALES. What we generally do in most of our cases is we will look for any individuals that were actively involved in the practices and in control of what the company was doing, and name those individuals as well. And that is pretty much true across the board in our cases.

Mr. GREENWOOD. Looking at the PediaLean box, at the very first sentence in the back panel says "There is nothing more effective than PediaLean in helping your child lose weight." I mean that, in and of itself, seems to be so patently false given all of the science tells us that it is diet control and exercise that is most effective in having anyone lose weight.

Let me turn to Dr. Hoppin for a moment. A number of these products boast about the fact that they have fiber in them, and fiber is supposed to suppress appetite. How much fiber does it take, and can you put enough fiber in a pill to actually have the affect that eating an apple would have or fiber that is available in cereal and so forth?

Ms. HOPPIN. I do not believe that you can. There are some very borderline evidence of studies of fiber supplements in adults that perhaps suggest a weight loss effect, but it is very shaky and there is no such evidence in children.

Mr. GREENWOOD. Thank you.

Dr. Beales, tell us what the like sequence of events is going to be with the complaint that you filed now, how will this play out with regard to PediaLean?

Mr. BEALES. In both PediaLean and PediaLoss we filed administrative complaints. They will go to trial in front of an administrative law judge at the Commission. And then after the administrative law judge makes a decision, that would be subject to appeal by either the staff or the respondent to the Commission itself, and then appeal to the Circuit Courts of Appeals.

Mr. GREENWOOD. Have you gathered information with regard to the volume of sales of these products and do you know anything about the revenues generated to the companies by these products?

Mr. BEALES. The information that we get in the course of an investigation pursuant to our compulsory process is confidential. And if we have sales information, I mean we could talk about it in a non-public briefing but we do not have a public estimate of what their sales are.

Mr. GREENWOOD. Okay. According to your testimony the FTC brought charges against Edita Kaye and her company, the Fountain of Youth Group, LLC alleged false and deceptive advertising claims. These charges arose out of several of her products, including the Skinny Pill for Kids. I think you have notebooks in front of you. Look at tab 3, page 3. There's an ad for a Skinny Pill for Kids taken off the website, www.skinny.com. And under No. 4 on that page it states it "offers very real weight loss help through supplements that metabiotically assist children to burn more fat pounds and inches, block new fat deposits and help regulate insulin levels to help mitigate fat factors." Did the FTC find this statement to be false and misleading advertising and if so, why?

Mr. BEALES. We challenged a series of seven different claims about Skinny Pill for Kids in addition to an eighth claim that the other claims were scientifically proven. And what we alleged was that they did not have adequate substantiation to support those claims and they were, therefore, deceptive.

Mr. GREENWOOD. Okay. Let me just quickly go to Dr. Hoppin. Do you have that in front of you as well, ma'am? I just ask for your professional opinion if you think that this product could offer very real weight loss help through supplements that metabolically assist children to burn more fat pounds and inches, block new fat deposits and help regulate insulin levels to help mitigate fat factors.

Ms. HOPPIN. Absolutely not—

Mr. GREENWOOD. Would you turn your microphone on, please.

Ms. HOPPIN. Absolutely not. There is no evidence of a regulatory role of any of these ingredients. Certainly fiber can help slow gastric emptying slightly, so can fat. That is part of the diet. And with slower gastric emptying, you may have smaller swings in blood sugar. But that is not a regulatory role for insulin.

Mr. GREENWOOD. Okay. Chair recognizes the gentlelady from Colorado for 5 minutes.

Ms. DEGETTE. Thank you, Mr. Chairman.

I just want to ask some questions, Dr. Hoppin, about some of these products because it seems to me that they are supposed to work in different ways. The Skinny Pill for Kids, the main way it was supposed to work was through a diuretic effect, is that correct?

Ms. HOPPIN. I am not sure which component of the ingredients they claim is the main affect, I am afraid. But that would be one plausible concept.

Ms. DEGETTE. Did that pill also have fiber in it, do you know?

Ms. HOPPIN. Yes, it does.

Ms. DEGETTE. Okay. So it had both.

Now, this PediaLean, it does not have any diuretic, the active ingredient is this glucomannan. How do you say it?

Ms. HOPPIN. Glucomannan.

Ms. DEGETTE. Glucomannan. And it does not have diuretics in it, though, right?

Ms. HOPPIN. Correct.

Ms. DEGETTE. So the way that that one is supposed to work it is in a capsule and then someone takes it, and then it theoretically expands in the stomach and makes the child less hungry, right?

Ms. HOPPIN. I suppose so. I have not seen their claims of how they say it will work. But that would be the idea behind of taking fiber as a supplement.

Ms. DEGETTE. Now, one of the side effects of this, I think in an attachment to your testimony you talk about some studies on adults using this glucomannan of esophageal obstruction, right?

Ms. HOPPIN. Yes.

Ms. DEGETTE. Now, would that be a problem if a capsule was swallowed and expanded in the stomach?

Ms. HOPPIN. Until it is tested, we have no way of knowing.

Ms. DEGETTE. Okay.

Ms. HOPPIN. In other words, it is the same product that has caused the esophageal obstruction in the past in some adults. But until proven otherwise, I do not think that you can say that the micronization process or encapsulating it makes any difference in that risk.

Ms. DEGETTE. All right. So we do not know because, as you say, there is just this one Italian study on children, at least.

Ms. HOPPIN. And they did not even bother to look for toxicity, as far as I can tell.

Ms. DEGETTE. Okay. Well, I was sitting here reading over the insert in the PediaLean box, and what it said is if your child has difficulty swallowing the capsules, they can sprinkle on bread or onto a spoonful of applesauce, peanut butter or yogurt; just about in food. It says it on the box, too. So do you think that would cause an issue if it expanded in the esophagus of that side effect?

Ms. HOPPIN. Well, thinking hypothetically, if the capsule was at all protective against the esophageal obstruction, then you have just gotten rid of that protection. So, yes.

Ms. DEGETTE. Okay. And now in the Italian study that you referenced, did they test for the delivery study in that Italian study, do you know?

Ms. HOPPIN. No. No.

Ms. DEGETTE. They did not?

Ms. HOPPIN. They only mentioned vaguely and in passing these 14 percent of people that stopped, the subjects that stopped taking it because of abdominal discomfort.

Ms. DEGETTE. Now, there were 23 subjects and 30 controls in the Italian study, right?

Ms. HOPPIN. Yes. They started out with quite a few more treatment subjects, and then they just plain ignored those that dropped out, which is not a—

Ms. DEGETTE. If you were doing a study, how would you conduct that study?

Ms. HOPPIN. One does what is called an intention to treat approach to analyses, meaning that anybody who is enrolled into the treatment arm needs to be considered in the final analysis.

Ms. DEGETTE. And that would be so like if they did not get any benefit from the substance or if they had side effects, you just do not let them go away. You take that into account in your final results, right?

Ms. HOPPIN. Exactly. You have to analyze everybody because they may well have dropped out because they had side effects or because it was not effective.

Ms. DEGETTE. Okay.

Mr. Beales, I wanted to ask you a couple of questions about FTC enforcement actions that it takes. Now, you talked briefly in your written and oral testimony about the Skinny Pill for Kids product. And I wanted to ask you what your basis for the FTC's complaint that the claims were unfounded or outright false were? What was the basis for those claims?

Mr. BEALES. Well, what we do in a typical investigation like this is we will ask the company to produce its substantiation, the evidence that it believes substantiate the claim.

Ms. DEGETTE. Right.

Mr. BEALES. And then we will evaluate the adequacy of that evidence.

Ms. DEGETTE. And what happened in that situation with the Skinny Pill for Kids?

Mr. BEALES. We alleged that the evidence they had was not adequate to substantiate those claims.

Ms. DEGETTE. I know. Did they produce the evidence then?

Mr. BEALES. I am not sure exactly what they produced. I mean, what is—

Ms. DEGETTE. But the result was that obviously it was not enough because the sale was halted, right?

Mr. BEALES. Yes, ma'am. The evidence—well, sometimes people do not produce anything, sometimes they produce evidence that we think is inadequate, and I am not sure which is the case for Skinny Pill.

Ms. DEGETTE. I see. Okay. Now in that particular case were there any other fines or punishments taken against either the company or the propriety of that pill, Ms. Kaye?

Mr. BEALES. There was a judgment of \$6 million which was suspended due to the defendant's inability to pay. There is an injunction that would prohibit any future unsubstantiated safety or efficacy claims for this or other related kinds of products or claims.

Ms. DEGETTE. Is there any ongoing effort to collect the \$6 million judgment or is it just gone now?

Mr. BEALES. It is—the money is gone. It was suspended because the defendants did not have the money.

Ms. DEGETTE. Well, what I am saying is you get this judgment against them and you suspend it because they do not have any money to pay, but what happens if they start marketing another product on the Internet or the proprietors are going on TV and making more money, do you come back and try to collect that?

Mr. BEALES. No, we do not.

Ms. DEGETTE. Do you think that creates a deterrent effect against these folks doing it in the future?

Mr. BEALES. Well, if they do it in the future, that would violate the injunction and would be contempt of court and we would pro-

ceed that way, and there would be financial consequences for the future conduct—

Ms. DEGETTE. How did the Commission determine a \$6 million fine?

Mr. BEALES. Typically what we do is it's redress as opposed to a fine. I mean, it is money that would go back to consumers if we collected the money. And typically what we do is that amount would be based on what we thought was total sales or total revenue for the product.

Now, that case covers not just Skinny Pill for Kids but also some adult products because the Skinny Pill for Kids was never actually marketed.

Ms. DEGETTE. Well, that is what I was just about to say. There is over \$6 million of profit that anybody got from the same Skinny Pill for Kids, is that right?

Mr. BEALES. No, that is right. And the \$6 million is resolving—is the judgment in the entire case which involves several adult products as well as Skinny Pill for Kids.

Ms. DEGETTE. Yes. Okay. Thank you.

Mr. GREENWOOD. The time of the gentlelady has expired.

The gentleman from Florida is recognized for 10 minutes.

Mr. STEARNS. Thank you, Mr. Chairman.

Dr. Wechsler, and I guess Dr. Hoppin, this is a question for you. Adults take Metamucil. And they use this in many ways, but in many ways it acts as a bulk in which it prevents them from eating. Does that work as a dietary supplement for adults?

Ms. HOPPIN. It works very well for constipation. It does not work for weight control.

Mr. STEARNS. It has no bearing then on weight control, in your opinion?

Ms. HOPPIN. Except for the shaky evidence on guar gum and glucomannan and in two studies that disagree with each other in adults where there was a minor weight loss effect.

Mr. STEARNS. What's the difference between glucomannan and what's in Metamucil?

Ms. HOPPIN. Different types of vegetable fibers.

Mr. STEARNS. But there is still the husk of these fibers, so to speak?

Ms. HOPPIN. That is correct.

Mr. STEARNS. Okay. So the glucomannan is basically the product that adults are taking everyday?

Ms. HOPPIN. It is a different fiber.

Mr. STEARNS. Different fiber, but a fiber. So, okay—is that, Dr. Wechsler do you agree with that, that basically adults—

Mr. WECHSLER. I have no comment. I defer to her. I defer to her.

Mr. STEARNS. Okay. Okay. So we have established that what is in this glucomannan is pretty much the same product that adults are taking everyday for regularity, but you indicated there is some debate whether it could be used a dietary supplement. Is that a fair statement of what you said?

Ms. HOPPIN. I guess so. I would be much more skeptical about the actual use in weight loss.

Mr. STEARNS. Okay.

Ms. HOPPIN. It works very well for mild constipation.

Mr. STEARNS. Yes, I understand.

Mr. BEALES, has anyone been hurt by the Skinny Pill or any of these products that you are claiming false advertising, has anyone been hurt at all? I know the Skinny Pill has not been sold to anybody. But I guess Basic Research and these other products, has anyone been hurt?

Mr. BEALES. Well, I think in these cases, as in many of our cases, the injury is economic. People spend money for a product that was not going to do anything for them.

Mr. STEARNS. Okay. Okay. Of course, I see that on QVC a lot. I mean, I see all these products—not necessarily on QVC, excuse me. But on different advertisements for television you can just see the list of products that they say are going to do these things.

So do you feel that you have enough law in the Federal Trade Commission regarding deceptive and misleading advertising or do we in Congress need to help you out with any additional legislation to avoid these false claims dealing with children that are overweight or possibly deceptive advertising in weight loss supplements?

Mr. BEALES. We think we have ample authority to address these problems and that we can and have done so quite successfully. For us DSHEA changed nothing. The approach that the Commission has always taken to claims about the efficacy of any product is to examine whether or not there was a reasonable basis to support that claim. And that remains the case.

Mr. STEARNS. So at this point you have sufficient legislation? You do not need additional?

Mr. BEALES. We think we do. Yes, sir.

Mr. STEARNS. Is it the FTC's position that even if a bottle, let us say, the Skinny Pill for Kids was never sold by virtue of the advertising and marketing, that the owner had violated the law?

Mr. BEALES. If the company has made representations that are not truthful or not substantiated, that is in and of itself a law violation. And ideally, in a great many cases, we would like to stop that violation and enjoin that violation before it actually happened. Before it actually causes injury to the public.

We did that in Skinny Pill. There is one other case that is fairly recent where we did that as well. It was an anthrax home test kit that actually if you had anthrax, it said you did not. And if you did not, it said you did. We stopped sale of that product before any sales had been made. And I think that is what we strive for. Obviously, most of the time the product has been sold and we are there at least somewhat after the fact, but that is our goal.

Mr. STEARNS. In the case of Skinny Pill it looks like you got there sufficiently in advance so that none of these pills were sold, and that is I think a compliment to the Federal Trade Commission that you did that.

Is there any indication that these pills would have gone ahead if you had not gotten involved?

Mr. BEALES. Well, you know, that is always difficult to assess. There was obviously a reaction from here, apart from us, that would presumably have influenced in their plans. And I do not really know. We thought there was enough risk of it going forward

that we needed an injunction that would make sure if they did go forward, they had the evidence they needed to support the claims.

Mr. STEARNS. And I notice as the chairman pointed out going to the website, a Skinny Pill they had advertised it and talked about their intent to sell it.

Do you find that when you find these false advertising claims by different companies that they are first time offenders or are these people that maybe shutdown their corporation their proprietorship and go somewhere else and start it up again, or are most of these people first time offenders?

Mr. BEALES. We see both. We bring a number of cases against first time offenders. We also see recidivists. And we see both. I would have to look at exactly what the mix is.

Mr. STEARNS. Okay.

Mr. Chairman, I think I will yield back the balance of my time.

Mr. GREENWOOD. The Chair thanks the gentleman.

The gentlelady from Illinois, Ms. Schakowsky.

Ms. SCHAKOWSKY. What I am really concerned about here is not only the potential adverse effect, the fact that there may be harm as well as the fact that they do not work, but what is seemingly the impotence of our government to do anything serious about them. And that is what I really wanted to talk about.

In regards to the case that was brought against Edita Kaye, you say that the fines were dropped because there is no ability to pay, I understand that there is still income from related activities. She is still selling her book, as I understand it.

I am trying to understand what penalties are involved. And let me continue. On the issue of whether anything ever happens to anyone, were there any adverse effects? My understanding is that the Federal Trade Commission is not required to keep any adverse effect reports, that would be required for drugs but it is not required for supplements. And let me go on and then you can answer.

We are also going to hear testimony from Mr. Mitchell Friedlander, who in 1986 was found to make material false claims regarding a number of weight loss products. But we cannot even recall those products. We can say that you cannot sell them anymore, but I understand that the enforcement even on that is not very stringent. He is back. He is still involved in the sale of similar products, PediaLoss and PediaLean. So what are we doing to protect the public and particularly our children in a serious way from access to these products? Our activities of enforcement and regulation seem pretty inadequate.

Mr. BEALES. Well, I think we have been very aggressive in this area and that we have done a very good job of keeping products off the market and keeping sales for products that have been on the market as low as we could.

What we do for a case that's initial violation as opposed to a violation of an existing order, is we do not have civil penalty authority in those cases. We do have equitable remedies available to us. And, in particular, we can get redress for consumers. That is typically the total sales of the product. Total sales of a product are substantially greater than profitability on virtually any product, and that is the amount of money that we will seek in judgment in court.

In cases where companies plead the inability to pay, we require a sworn financial statements to identify the assets and the income that might be available to satisfy that judgment. That if there are misstatements on those sworn financial statements, our orders typically include an avalanche clause, we call it, that would trigger the full judgment amount.

Ms. SCHAKOWSKY. How does a Friedlander come back today?

Mr. BEALES. In any case when we get an injunction to cover future conduct, we get an injunction that we think is appropriate in terms of—or we seek an injunction that we think is appropriate in terms of its claims and product coverage in order to fence in future violations.

Ultimately what injunction we get is up to a district court judge, that was the source of the injunction in the Friedlander case in 1986. It was Federal District Court case where the judge entered his own order.

Ms. SCHAKOWSKY. That applied to what? What was the jurisdiction? You are saying he could go somewhere else and do it and that would be okay?

Mr. BEALES. Well, it covered—it was a narrow order in terms of what it covered. We would have liked a broader order, but it was not what we got from the judge. And we did not think we had a case that would involve violation of order here. So we proceeded on a new case in this matter. And that is always a choice we have to make.

We seek broad enough orders to be able to cover likely future conduct and other places where the deceptive practice might be employed. And, you know, that is certainly our goal in every case.

Ms. SCHAKOWSKY. Let me just read a quote. According to Richard Cleland, as quoted in May 2004 “Consumer Reports,” who is the Assistant Director of the FTC’s Division of Advertising Products, “There are literally hundreds, perhaps of thousands” he was referring to dietary supplement manufacturing companies out there, “that probably deserve scrutiny.” Cleland cited lack of resources for the reasons why the FTC cannot adequately review all products.

I hear what you are saying that there are these kind of enforcement cases, but there are perhaps thousands out there that are not even being looked at. And, when we do, here we are with a case from 1986. Now it is 2004, same person, same product back again. It seems to me that we need to do something to strengthen our capacity to go after these cases, no?

Mr. BEALES. Well, what we do—I mean I do not think it is a problem of capacity to go after the cases. I mean, it is, you know, there are ultimately resource limits on how many cases we can bring, that is certainly right. We think we have—I mean dietary supplements in general has been one of my top priorities. In the time I have been at the Commission we have devote substantial resources to that effort. In the last year in mostly dietary supplements and health related claims, we have enjoined product sales that are more than a billion dollars of products that were out there where we have stopped it.

when we get an order, and particularly a Federal district order, where we have an order like that we can proceed under a civil contempt theory. And in appropriate cases, we an proceed under crimi-

nal contempt for violations of that order. And we can and have put people in jail for ongoing violations or repeat conduct of those kinds of orders.

Ms. SCHAKOWSKY. Thank you.

Mr. GREENWOOD. The gentlelady yield back?

The gentleman from New Hampshire, Mr. Bass.

Mr. BASS. Thank you, Mr. Chairman.

Mr. Beales, we have all kinds of documents here, all dated, time lined. I am curious to know how the FTC got involved in the two cases that we are examining here today. Was it a result of a process that you had in place whereby you could identify possible deceptive advertising or unsafe—advertising unsafe products or just deceptive advertising and begin a process of review or did this whole thing occur in both instances as a result of the investigative work of either a network or a news outlet, or this subcommittee's staff?

Mr. BEALES. It is a little bit of both. We get our cases in a wide variety of different ways. We get referral from other law enforcement agencies. We do pay attention to the media. We get complaints from consumers. We monitor advertising on our own, and particularly in an area that we are interested in like dietary supplements. And any and all of those ways produce cases.

Mr. BASS. Do you feel that the FTC has the capacity—you will never be able to monitor everything. But do you feel that you have the capacity to catch this kind of deceptive advertising as appears to have occurred here before, the products are actually consumed or is it based, as you said a minute ago, based on catch as catch can. Well, you did not say that, I am saying that; discovery of problems?

Mr. BEALES. Well, in most cases we are after the fact. In most cases people do not pre-announce their products and they do not start marketing them until they are ready to sell them. And so the marketing and the sales start at more or less the same time.

There are some cases, and Skinny Pill is one of them, were people will begin the marketing before the product is there. And in those cases we would try very hard to prevent the product from ever being sold based on those particular claims. And in Skinny Pill for Kids we were successful. But in most cases, the marketing has already started, the sales have already started and what we try to do is to stop it as quickly as we can and get money back for consumers who may have been injured—

Mr. BASS. Is there a program in the FTC where people just review ads all day long or not?

Mr. BEALES. Not in that sense. I mean, we do not have specialists in ad review. WE do have people who review advertising on an ongoing basis. But, I mean, we do not have a room where we lock people up and make them watch all the advertising that is out there.

Mr. BASS. I think that it might be a good opportunity for you to make it clear to all the various supplement companies out there that may think that standards for supplements are unclear, can you state in simple and clear terms what is required of companies, dietary supplement companies included in terms of substantiation of any advertising or marketing claim that they made?

Mr. BEALES. Anybody who wants to make claims about the efficacy of a dietary supplement needs to have competent and reliable scientific evidence to support that claim. There is an extensive pamphlet that we have on dietary supplements that offers guidance to industry that has got 36 different examples of ways that you can go astray. And I think, frankly, the industry understands what the competent and reliable scientific evidence standard means.

Certainly when there are studies that are critical of dietary supplements, they know what questions to ask. Is it a big enough sample, is it the right dosage, is it the right formulation; those are the same questions that the industry needs to ask about studies that support efficacy.

Mr. BASS. Does the FTC publish any kind of guidelines that potential marketers can use to make sure that their products comply with this?

Mr. BEALES. Well, that's what this pamphlet is.

Mr. BASS. Okay. I did not see that.

Mr. BEALES. It is "Dietary Supplements and Advertising Guide for Industry."

Mr. BASS. Fine. And I believe you answered this before. You are not recommending any changes in policy or law that would make the job of stopping misleading or deceptive advertising in weight loss supplements necessary, is that right?

Mr. BEALES. We are not. We think we have adequate authority to proceed as we are.

Mr. BASS. Dr. Hoppin one question for you. First of all, I would like to compliment you on your testimony. Just from a structural standpoint, it was extremely clear and understandable, and I was able to read it in about 30 seconds and understand it. And that really helps.

My overall question for you is when you get right down to it, are there any pills—have you found that anything works to reduce weight that is the market today?

Ms. HOPPIN. Do you mean from the dietary supplement industry?

Mr. BASS. Anywhere?

Ms. HOPPIN. There are—

Mr. BASS. You can start with dietary supplements. You can go to diets, if you want, I do not care. But I just want to know, you know, seat-of-the-pants opinion that you have should consumers believe anything that they see about pills that you can buy or diets that you can go on that are really going to work over the long term, or even the short term?

Ms. HOPPIN. There are not great solutions in this field yet. There may be at some point in the future.

Weight loss surgery is one of the few effective approaches, and that comes with some very substantial risks. And so that is not without its problems.

I have seen nothing in the dietary supplement industry that is suggestive that it would be useful. Certainly there are very important lifestyle factors that can be changed and must be changed, both in individuals' lives but also as a public commitment and a public change, which is something that Dr. Wechsler is alluding to.

There are two pharmaceuticals on the market for long term weight control, and both of those are very weak but they are well

supported by science that they have an effect on weight loss, just a wee effect.

Mr. BASS. And these are pharmaceuticals that are available by prescription?

Ms. HOPPIN. Correct.

Mr. BASS. I see.

Ms. HOPPIN. Yes.

Mr. BASS. All right.

Thank you, Mr. Chairman.

Mr. GREENWOOD. The Chair thanks the gentleman.

The gentleman from California, Mr. Waxman is recognized for 10 minutes.

Mr. WAXMAN. Thank you very much, Mr. Chairman. And I want to commend you for holding this hearing on this important subject.

I want to move off the subject just a little bit, but it is connected, and ask Dr. Wechsler about the dubious products we are confronting today that find a market when obesity among children is a serious ongoing problem in our country. Some have suggested that the dramatic rise in the consumption of sugar containing soft drinks is contributing to obesity among children. What does the research say about the impact of soft drinks on calorie consumption?

Mr. WECHSLER. Well, we know that there is not single factor that is responsible for this epidemic. There are many, many different factors involved, and it is really impossible to identify how much of it is due to any individual factor.

We do have several studies that indicate an association between soft drink consumption and children becoming overweight or adults putting on weight.

We also have a very recently published solid study that showed a school-based program that tries to educate children to reduce their soft drink consumption, which did lead to a reduction in the prevalence of weight among the child.

So the evidence is still limited, but somewhat promising.

We also know that on average teenagers consume about 11 percent of their calories from full caloric soft drinks. So it seems prudent to take the advice of the dietary guidelines which state that Americans should choose beverages and foods to moderate their intake of sugars.

Mr. WAXMAN. Are you concerned about the steep rise in soft drink consumption by children?

Mr. WECHSLER. It is one of many dietary and physical activity factors that there are of some interest for us as possible contributors.

Mr. WAXMAN. What sort of policies have you considered to address the issue?

Mr. WECHSLER. Well, my particular area is in the area of school health, and we think it is important for schools to offer a choice to make sure that students have an opportunity to have access to beverage choices in the schools that perhaps have no calories or much fewer calories.

Mr. WAXMAN. You also advocate that we have less junk food available and some other alternatives for children in schools?

Mr. WECHSLER. Well, we would have to define what we mean by junk food. But certainly we think it is important for children to

have more access to appealing fruits, vegetables, whole grains, low fat dairy products. They cannot make the healthy choices unless the healthy choices are there.

Mr. WAXMAN. Well, how would you define junk food?

Mr. WECHSLER I do not use that term. But we do talk about as the dietary guidelines do, about moderating our intake of saturated fats and foods high in cholesterol and sugar.

Mr. WAXMAN. Thank you.

Well, I thought this was very helpful. I wanted to ask these questions, get them on the record as part of this overall hearing. And I thank you for your responses.

I yield back my time, Mr. Chairman.

Mr. GREENWOOD. The gentleman from Oregon is recognized for 10 minutes.

Mr. WALDEN. Thank you, Mr. Chairman.

Mr. Beales, in your statement you mentioned that in the FTC's enforcement actions efforts have been made to hold not just the manufacturer accountable, but other parties involved in deceptive marketing. In the complaint filed against Basic Research today, did you hold additional persons involved in marketing accountable, and if so who and why?

Mr. BEALES. We did. We named Basic Research, A. G. Waterhouse, Klein-Becker, USA, Nutrisport, Sauvage Dermologic Laboratories, BAN LLC. We named Dennis Gay, the CEO of the limited liability corporations, Daniel Mowrey who is an expert endorser and represented to be a medical doctor in some of the challenged ads, and Mitchell Friedlander, who is a marketing consultant and subject to a previous FTC order.

Mr. WALDEN. You said one of those gentleman represented himself as a medical doctor.

Mr. BEALES. We alleged that one of the advertisements represented him as a doctor, yes sir.

Mr. WALDEN. And do you know whether or not he is a doctor?

Mr. BEALES. He is not.

Mr. WALDEN. And the ad represented him that way?

Mr. BEALES. That is what we allege, yes.

Mr. WALDEN. Your allegation? Interesting.

You referenced in your early opening statement some red flags that the FTC has shared with media outlets regarding dietary weight loss supplements. What are some of those red flags?

Mr. BEALES. Well, there is a list of seven claims that we think are claims that are always false and for which there is no scientific basis. And we have asked the media to screen out advertising that includes those claims. And that is what this publication is, it is our media guidance to the media on claims that they should avoid. That includes claims that a product will cause weight loss of two pounds or more a week for a month or more without diet and exercise; claims that a product will cause substantial weight loss no matter what or no matter how much the consumer eats; claims that a product will cause permanent weight loss even when the consumer stops using the product; claims that a product will block the absorption of fat or calories to enable consumers to lose substantial weight; claims that a product will safely enable the consumer to lose more than three pounds a week for more than a

month; claims that a product will cause substantial weight loss for all users. And finally, claims that a product will cause substantial weight loss by wearing it on the body or rubbing it into the skin.

Mr. WALDEN. Ah.

Mr. BEALES. Earrings, jewelry, sandals. You have to walk for them to work.

Mr. WALDEN. Well said.

How do you approach the proliferation of these claims on the Internet? I am amazed every time I log onto the Internet the online pharmacies that offer everything, the claims that come in as emails. Are you able to track those? Do you need a national standard?

I mean, consumers are told that everything can be fixed now if you just buy whatever the product is, and that it has all been clinical tests, and yet you are finding that is not the case. What should we be doing about that?

Mr. BEALES. Well, the Internet and email in particular poses its own set of challenges. I mean, the biggest challenge for us with deceptive email, and there is an enormous amount of it out there, is finding people. The anonymity of email, unfortunately, makes it very easy to sellers and spammers alike to hide. And that's exactly what they do. But I mean it's a technological problem of finding people.

What we have done about websites in general is we have pursued with some frequency, a strategy of surfing the web to identify sites that make particular claims and then we will issue, if we see claims that we think are deceptive in a particular area, we will issue a warning letter to that website advising them of what we think are the problems. And then we will come back again and follow-up and try to see whether or not they have made changes.

Our most recent surf was to address products, dietary supplement products that claim to be cures or treatment for SARS and there was an earlier one that addressed anthrax cures. We got very good cooperation in both of those cases, in both of those instances, from websites where we brought the problems to their attention.

Mr. WALDEN. Were the owners of the websites the ones selling the product or were they just an intermediary?

Mr. BEALES. It is probably some of each. In some cases it is an intermediary, but you are—if you are a retailer or a catalogue seller offering products to the public, we would hold that catalogue seller liable when we think the operator of a website is in essentially that same posture, as well as the manufacturer.

You know, in some cases we go after the manufacturer. In some cases we go after the seller who is holding it out to the public. In some cases we go after both.

Mr. WALDEN. See, Mr. Davies and I are working on some legislation that would, hopefully, help address this problem on the internet by establishing some national standards. But I think the only way you can get at this problem is getting at the money. And the way you get at the money, is you cannot buy something on the internet generally unless you give them a credit card number. Now maybe you can send a check in, and that is a different deal. But I think ultimately we got to chance the money, and that is what this is all about. These are companies exchanged in false adver-

tising promoting products that in some cases either do nothing or nothing good, and then they run and hide and they change their names and they change their claims. And they do not do anything until a congressional hearing gets called or you show up at their doorstep. And it needs to stop.

Mr. BEALES. I agree. And actually, what we do in almost all these cases is follow the money. What we find, and you know to take spam as an example, typically the spam will promote a link to some website. We will buy the product and that is sort of the first step in our investigation. We will look at who owns that domain name. All too often we find it is one of the many that is registered to Mr. M. Mouse who lives in Orlando or other false registration information.

We will use subpoenas to the financial institutions who are processing the credit cards to try to find out who really owns this website and proceed to follow the money. And sometimes that is relatively short and sweet, and sometimes it is a long and winding road.

Mr. WALDEN. Okay. In the complaint that was filed, the one today, is that right, with the FTC naming Dennis Gay and Dr. Mowrey and Mitchell Friedlander individually, looking at the products listed in the complaint, and you will have to forgive my pronunciations here perhaps, but dermalin, APG, Cutting Gel, Tummy Flattening Gel, Leptoprin, Anorex, a weight control compound and PediaLean a weight control compound. Do any of these contain ephedra, especially Anorex?

Can you turn on your mike? I do not think your mike is on.

Mr. BEALES. I'm sorry.

Leptoprin and Anorex at one point did contain ephedra. My understanding is that the formulations that are being sold now no longer contain ephedra. But at one point, originally—originally those were ephedra, caffeine and aspirin combination products Mr. WALDEN. And do you know if the companies recalled the products that did contain ephedra?

Mr. BEALES. I do not.

Mr. WALDEN. So they could still be out on the market on shelves?

Mr. BEALES. I do not know.

Mr. WALDEN. All right. But if they have not been recalled, I mean I will make the supposition that they could be out on the market today or sold—

Mr. BEALES. Well, I do not know at what point the formulation was sold. I do not know to what extent—

Mr. WALDEN. I see.

Mr. BEALES. [continuing] they are sold through retail as opposed to direct marketing. I mean, those factors would matter on is it still out there.

Mr. WALDEN. All right. And the products I read off, do you—are all these on your list of allegedly false and misleading advertising?

Mr. BEALES. What we have alleged in this case is unsubstantiated claims and that for each of those products we have identified claims about what the product will do that we think are not supported by competent and reliable scientific evidence.

Mr. WALDEN. Dr. Hoppin, in your field of expertise, let us cut to the chase here, Tummy Flattening Gel work? Are you aware of any tummy flattening gel that actually flattens one's tummy?

Ms. HOPPIN. Absolutely not. It's ludicrous.

Mr. WALDEN. All right.

My time has expired, Mr. Chairman.

Thank you for your testimony today.

Mr. GREENWOOD. The Chair thanks the gentleman and recognizes himself for 10 minutes for a second round of questioning.

Dr. Hoppin, if you would look at tab 39 in that notebook there. There is an advertisement for PediaLoss from the website. And it says "PediaLoss is an appetite suppressant for child 6 years and older allowing children to enjoy their favorite foods without gaining weight. This revolutionary new formula slows the absorption of carbohydrates allowing more to be burned for energy and less to be stored as fat."

So the question I have, and that is the claim for PediaLoss, based on your medical expertise is there any basis for that claim based on the ingredients that are listed?

Ms. HOPPIN. Not only is there no basis for the claim, it actually is a pretty bad claim because it is also encouraging lack of dietary changes, which I think is very damaging.

The only ingredient that in my research looked like it might have a weight loss effect is the HCA or garcinia cambogia that's in the PediaLoss. And as I mentioned, there is actually another ingredient that has a side effect of weight gain. So I think when you put multiple ingredients together, you simply cannot draw any adequate conclusions or any support for the claim that it causes weight loss.

Mr. GREENWOOD. Okay. Dr. Wechsler, what recommendations would you give parents who are trying to help their overweight children? And we hope that those parents watching this hearing will never be tempted to buy these phony pills. But what would you recommend to them?

Mr. WECHSLER. Everything that is recommended in the Dietary Guidelines for Americans; wiser food choices and more physical activity.

Mr. GREENWOOD. In any CDC or HHS guidelines for recommendations is the use of unregulated dietary supplements for weight loss considered an actual answer to the problem of child obesity?

Mr. WECHSLER. Not at all that I am aware of.

Mr. GREENWOOD. Okay. Dr. Hoppin, would you also turn to tab 40. And there has been some reference, and you have talked about the Italian study. Do you believe the study provides a sound conclusion that the product in that study was safe and effective for children?

Ms. HOPPIN. Not at all.

Mr. GREENWOOD. Tell us again why not.

Ms. HOPPIN. The three very important flaws in the study design, one being that there is no placebo control. We all know that there are important placebo effects of just about any medication including pain killers and certainly a weight loss medication. And so to have no placebo control completely invalidates any results that they got in addition to ignore the dropout, a very substantial group

of dropouts from the original study and simply analyze those that were left in at the end is very inappropriate and invalidates any findings.

Mr. GREENWOOD. Okay. And what in your opinion are the dangers of these products when they are marketed to children as young as six?

Ms. HOPPIN. Each may have a different specific medical danger, so I cannot really say that altogether. The only blanket statement I can say is that we just do not know. There is no good evidence that these have been shown to be safe.

Mr. GREENWOOD. And certainly in a case for a product like PediaLoss where they say allow children to enjoy their favorite foods without gaining weight. I mean, to tell a parent that it is okay for your kid to sit there and eat a half dozen cream donuts as long as he is taking PediaLoss and he is not going to gain weight, I mean that it seems to be, if anyone would be crazy enough to believe that but apparently people do, I mean that is dangerous because it is probably going to allow the problem to get far worse for the kids.

Ms. HOPPIN. I agree completely. It is actively undermining the only thing that we know is really important, which is to improve diet and lifestyle with the increased exercise.

Mr. GREENWOOD. All right. Okay.

Mr. Beales, a final question for me to you. I was very delighted to hear that when you went after PediaLean, you went after as Klein-Becker, an array of products. Is that correct, is that the response that you gave to the gentleman from Oregon, that you went after—

Mr. BEALES. Yes, sir. I believe there is about six products where we challenged claims and PediaLean is one of them.

Mr. GREENWOOD. Okay. And is that typical if you see a company marketing an array of products, that rather than simply focus on one that you try to scoop them all up?

Mr. BEALES. Well, typically—I mean it is a resource tradeoff and a litigation tradeoff for us. We will try to challenge enough products to get a broad enough order to cover, but we will not examine or challenge every product where we might have problems because it just makes the litigation unmanageable and way too costly. So that is the tradeoff that we make, and we make it differently in different cases. But typically we will challenge more than just one if there are other products that have problems, and less than everything we might—

Mr. GREENWOOD. The Chair will yield back his time.

Does the gentlelady from Colorado have questions?

Ms. DEGETTE. Yes.

Mr. GREENWOOD. She is recognized for 10 minutes.

Ms. DEGETTE. Thank you, Mr. Chairman. I was very interested in Mr. Stearns' line of questions, and I wanted to kind of clear up the record because I think a misimpression may have been left in the record, although no one in this room thinks that there is a misimpression.

Mr. Beales, when you were talking about the FTC's legal authority to take actions and how you did not think that that authority

needed to be augmented or new laws needed to be passed, you were referring simply to the extent of the FTC's legal authority, right?

Mr. BEALES. Yes, ma'am. That is right.

Ms. DEGETTE. And that authority is to take actions against purveyors of different products, not just herbal products or dietary supplements, but all products when there are false claims being made about the efficacy of those products, right?

Mr. BEALES. Yes, ma'am.

Ms. DEGETTE. The FTC does not have any authority before the product is marketed to assess the product to see if it has any efficacy, correct?

Mr. BEALES. That is correct.

Ms. DEGETTE. You are really talking about the FTC's authority for false claims, right?

Mr. BEALES. Yes. Well, I mean, our authority is broader than just false claims.

Ms. DEGETTE. Right.

Mr. BEALES. But, yes. I am only talking about the FTC's authority—

Ms. DEGETTE. Not, say, the FDA's authority under DSHEA or under any other Federal statute, right?

Mr. BEALES. Right. We do not have a position on FDA's authority or a recommendation.

Ms. DEGETTE. Okay. And when you were responding to Mr. Stearns' questions, you were not talking about authority for authorization of these supplements or any of that kind or that body of law, were you?

Mr. BEALES. No. I understood Mr. Stearns to be asking me about the FTC's authority—

Ms. DEGETTE. Right. I think he was. I am just trying to clear up the record now.

Dr. Hoppin, you probably know if, for example, a pharmaceutical manufacturer wanted to have FDA approval of a drug designed to give obese children, they would have to go through rigorous approval process, right?

Ms. HOPPIN. Very rigorous, very expensive approval process.

Ms. DEGETTE. Right. And do you have some sense of what the general parameters of that process?

Ms. HOPPIN. No very accurate sense, but I am happy to give you a broad idea. Often several thousand patients and several different types of studies in order to get an initial indication. And then perhaps some smaller studies to get follow-up indications for a drug.

Ms. DEGETTE. Okay. Now, for dietary supplements under DSHEA, that kind of rigorous approval process does not happen within the FDA, correct?

Ms. HOPPIN. That's correct.

Ms. DEGETTE. Do you know, actually does anybody on the panel know, Dr. Wechsler you might know also, if the FDA suspects that a dietary supplement may have some components that would be harmful to health, do they have authority before the marketing of those dietary supplements to stop those from going to the market or, again, is that after the fact?

Mr. WECHSLER. I am not aware of the answer to that, but I can get that information for you.

[The following was received for the record:]

The Food and Drug Administration (FDA) regulates dietary supplements under a different set of regulations than those covering “conventional” foods and drug products (prescription and Over-the-Counter). Under the Dietary Supplement Health and Education Act of 1994 (DSHEA), the dietary supplement manufacturer is responsible for ensuring that a dietary supplement is safe before it is marketed. FDA is responsible for taking action against any unsafe dietary supplement product after it reaches the market. Generally, manufacturers do not need to register with FDA nor get FDA approval before producing or selling dietary supplements. Manufacturers must make sure that product label information is truthful and not misleading.

FDA’s post-marketing responsibilities include monitoring safety (e.g. voluntary dietary supplement adverse event reporting) and product information, such as labeling, claims, package inserts, and accompanying literature. The Federal Trade Commission regulates dietary supplement advertising.

Two examples of recent post-marketing action taken by FDA involving dietary supplements are ephedra and androstenedione.

First, in February 2004, the FDA issued a final rule prohibiting the sale of dietary supplements containing ephedrine alkaloids (ephedra) because such supplements present an unreasonable risk of illness or injury. Under the Dietary Supplement Health and Education Act (DSHEA) of 1994, FDA may remove a dietary supplement from the market if it presents a significant or unreasonable risk of illness or injury when used according to its labeling or under ordinary conditions of use.

To meet the standard required by the dietary supplement law, the FDA gathered and thoroughly reviewed evidence about ephedra’s pharmacology; peer-reviewed scientific literature on ephedra’s safety and effectiveness; adverse event reports; and a seminal report by the RAND Corporation, an independent scientific institute. The FDA also reviewed tens of thousands of public comments on the agency’s request in March 2003 for information about ephedra-associated health risks.

In recent years, dietary supplements containing ephedrine alkaloids have been extensively promoted for aiding weight control and boosting sports performance and energy. The totality of the available data showed little evidence of ephedra’s effectiveness except for modest, short-term weight loss without any clear health benefit, while confirming that the substance raises blood pressure and otherwise stresses the circulatory system. These effects are linked to significant adverse health outcomes, including heart attack and stroke.

Ephedra, also called Ma huang, is one of the plants that are a source of ephedrine alkaloids, including ephedrine and pseudoephedrine. When chemically synthesized, ephedrine and pseudoephedrine are regulated under the Federal Food, Drug, and Cosmetic Act as drugs. In contrast to the DSHEA-regulated dietary supplements that contain ephedrine alkaloids, the safety and effectiveness of drug products containing ephedrine alkaloids in drug products have to be proven by the manufacturer.

The issuance of the final rule continued a process that started in June, 1997, when FDA first issued a proposal that required a statement on dietary supplements containing ephedrine alkaloids warning that they are hazardous and should not be used for more than seven days. FDA also proposed to restrict the amount of ephedrine alkaloids in dietary supplements and to prevent combining ephedra with other ingredients that have a known stimulant effect.

FDA modified this proposed rule in 2000, and in February 2003 it announced a series of measures that included taking enforcement actions against firms making unsubstantiated claims regarding enhanced athletic performance for their ephedra-containing products. FDA also issued warning letters to firms promoting these products as alternatives to illicit street drugs. Many firms have complied with FDA’s warning against making such claims. FDA has also followed up with seizures and injunctions and joint enforcement actions with the Federal Trade Commission and the Department of Justice. More detail on these actions can be found at <http://www.fda.gov/ola/2003/dietarysupplements1028.html>. As a result, most ephedra-containing dietary supplements advertised for enhanced sport performance have been removed from the market.

Second, in March of this year, the FDA sent a letter to companies that manufacture, market, and distribute products containing androstenedione, or “andro,” which acts like a steroid once it is metabolized by the body, and therefore, can pose similar kinds of health risks as steroids. These products are generally advertised as dietary supplements that enhance athletic performance based on their claimed anabolic and androgenic properties to stimulate muscle growth and increase production of testosterone.

FDA has sent warning letters to 23 companies asking them to cease distributing products sold as dietary supplements that contain androstenedione and warning them that they could face enforcement actions if they do not take appropriate actions. FDA will determine whether further actions are necessary if firms refuse to cease distribution of these products. Such actions could include seizing violative product as well as pursuing injunctions or seeking criminal sanctions against persons who violate the law.

Ms. DEGETTE. Okay. As I understand, like with ephedra when the FDA learned that there were side effects from ephedra, they had the authority to order that off the market. But, again, that was after the fact, correct? You need to answer verbally.

Mr. WECHSLER. Yes.

Ms. DEGETTE. Thank you.

And this is really what I am concerned then, and I want to say I am not opposed to DSHEA. I think that it has many benefits. But as I said in my opening statements, I am concerned when you have these dietary supplements simply being marketed without scientific backing, you are always looking after the fact.

Dr. Hoppin, you are nodding your head. Is this a concern that you share?

Ms. HOPPIN. I certainly do, because as a physician I am very uncomfortable making a decision about treatment with no information. And there is very little science in this field to allow me to make good treatment decisions. So it would be very helpful to all clinicians to have better information. And one of the ways that you encourage that is by requiring it.

Ms. DEGETTE. Right. Thank you.

Thank you, Mr. Chairman. I will yield back.

Mr. WALDEN [presiding]. Mr. Beales, I wanted to ask about the consent decree that the FTC entered into with Jonathan Barash. Could you describe that consent decree, what it contains, what you found, what it means?

Ms. DEGETTE. Yes, sir. The consent decree would require competent and reliable scientific evidence to substantiate weight loss claims or appetite suppression or fat burning, or carbohydrate absorption claims for PediaLoss or any other covered product or service.

Another product that was involved in this case is a product called Fabulously Feminine, and it would require competent and reliable scientific evidence to substantiate claims that that product or any other covered product or service will increase a woman's libido, sexual desire or sexual satisfaction. It would prohibit Mr. Barash from making unsubstantiated efficacy claims for any dietary supplement, food, drug or device and any health related service or program promoting weight loss or sexual enhancement. And finally, it would prohibit him from misrepresenting any tests or study.

Mr. WALDEN. So did he sign this consent decree?

Mr. BEALES. Yes, sir.

Mr. WALDEN. Okay. And he agreed to those conditions?

Mr. BEALES. Yes, sir.

Mr. WALDEN. And in effect then does that hold him responsible for the alleged false and misleading ads for PediaLoss?

Mr. BEALES. Yes, it does. Yes, I mean it is—the complaint that accompanies that order alleges his liability for those deceptive advertising.

Mr. WALDEN. Okay. So he is held responsible for those false and misleading—he has admitted then, am I correct? I am just trying to get this correct?

Mr. BEALES. No. He has not—I mean consent agreements are for settlement purposes. He does not admit to liability. He does agree to be bound by the order.

Mr. WALDEN. Okay. So he does not admit that he was responsible for alleged false and misleading statements for PediaLoss, but he agrees never to issue such statements again, is that for a layperson's interpretation?

Mr. BEALES. That would be right. Yes, sir.

Mr. WALDEN. Was anyone else named in that consent decree?

Mr. BEALES. Not in the consent decree. There are other individuals—

Mr. WALDEN. Or in the complaint?

Mr. BEALES. [continuing] named in the complaint. Yes. Vinit Chabra, Vincent Chabra also known as Vincent Chabra was also named.

Mr. WALDEN. Who are they?

Mr. BEALES. The Chabra Group is one of the companies that we involved in the marketing of these products. And Vinit Chabra is one of the principal of, I presume, of the Chabra Group.

Mr. WALDEN. Do you know if he is under Federal indictment right now, Mr. Chabra?

Mr. BEALES. Yes, he is.

Mr. WALDEN. All right. Was Dynamic Health of Florida also? Dynamic Health?

Mr. BEALES. Dynamic Health is who we named. And I do not know for sure whether they are under the indictment that you are referring to.

Okay. I am sorry. I am told that the indictment names a company named called USA Prescriptions and not Chabra. So he may not be—and I apologize for—

Mr. WALDEN. Wait a minute.

Mr. BEALES. I am told it names Chabra individually and USA Prescriptions. I do not know about Dynamic Health of Florida.

Mr. WALDEN. Okay. Thank you.

That is all the questions I have.

Ms. Schakowsky?

Ms. SCHAKOWSKY. I have just a couple of questions. I want to get at this issue of the health effects a little bit more.

As I understand it, the manufacturer, the distributor or even the Federal Trade Commission if it gets letters that say there was some physical adverse effect, there is no requirement for anybody to get that information to the Food and Drug Administration. The FDA is the only agency, and of course they are not here today to testify about any of this, that potentially would have the authority to ban the product. I understand that with ephedra, that even that decision is now being challenged in court as to whether they have the authority to do that. But there is no requirement for anybody to report adverse effects, is that true?

Mr. BEALES. Any information that came to us about adverse effects, we would certainly bring to the FDA's attention.

Ms. SCHAKOWSKY. But you are not required to do that, are you?

Mr. BEALES. No. I mean, there is nothing that would require the Federal Trade Commission as an institution to do that. We do that as a matter of course, and we do it with a great number of other law enforcement agencies as well.

As far as I know, there is not a requirement for anyone else to report to FDA, but that would be a question better addressed to them than to me.

Ms. SCHAKOWSKY. Yes. The other issue which I would like to ask doctors is that perhaps, unlike ephedra, the potential health effects of supplements may be long term, so we are talking about liver damage or a potential kidney damage. So the fact that there is no pre-screening of these supplements and there is no requirement to do the kind of testing that would determine that could be putting our children and adults at risk from long term health effects. Is that not true? Dr. Hoppin?

Ms. HOPPIN. I would say anything is possible. There is so little information in this field that we simply can't say whether we would expect more short term effects versus long term effects, except that in some of the relatively objective data sources that I looked through with some ingredients in particular there were concerns with long term use for some of the ingredients.

Ms. SCHAKOWSKY. So we just do not know.

Dr. Wechsler, did you want to comment at all?

Mr. WECHSLER. No, I have nothing to add.

Ms. SCHAKOWSKY. Thank you. That is all I have. Thank you. I yield back.

Mr. GREENWOOD. Okay. The Chair thanks the gentlelady.

And the Chair thanks very much our three witnesses for your time and your expertise. We appreciate it. You are excused.

And the Chair will now call forward the witnesses for our second panel and ask them to come to the table.

Ms. Edita Kaye, founder of the Skinny Pill Company; Mr. Jose de la Rocha, Director of Quality Control at PAL Labs; Mr. Jerry Rayman, Vice President of Sales of PAL Labs; Mr. Guy Regalado, a former Vice President of Sales and Marketing at Dynamic Health of Florida; Mr. Jonathan Barash, former President of DBS Labs; Mr. Dennis Gay, President of Basic Research; Dr. Daniel Mowrey, Director of Scientific Affairs at Basic Research; Mr. Mitchell Friedlander, Marketing Consultant, Basic Research; Dr. Nathalie Chevreau of Nutritional Research Center, Basic Research.

And we're going to ask Dr. Keith Ayoob, Associate Professor of Pediatrics at Albert College of Medicine to join this panel as well.

Okay. The Chair welcomes all of our witnesses. Thank you for being with this morning. You may have heard me say to the previous witnesses that it is the practice of this committee to take testimony under oath. And so I ask if any of you object to giving your testimony under oath. Okay.

Also, I need to advise you that pursuant to the rules of this committee and the House you are entitled to be represented by counsel this morning for the hearing. Are any of you represented by counsel?

Ms. Kaye, if you would pull the microphone toward you, bend it down so you can talk right into it and make sure it is on. And if you would identify your attorney.

Ms. KAYE. Mr. Andrew Herman.

Mr. GREENWOOD. And Mr. Herman, would you signify by raising your hand. Okay.

Any other of our witnesses represented by attorney today? Okay. Mr. de la Rocha, would you do the same thing; make sure your microphone is forward and on and identify your attorney?

Mr. DE LA ROCHA. Jeb Hart.

Mr. GREENWOOD. Okay. And Mr. Rayman? Okay. I'm going to ask each of the witnesses that when I ask you to identify your attorney, make sure your microphone is pulled very close to your mouth and that it is on.

Mr. Regalado?

Mr. REGALADO. Mr. Robert Smally.

Mr. GREENWOOD. Thank you. And I see him.

Mr. Barash? Okay.

Mr. Gay?

Mr. GAY. Yes. Stefan Nagan.

Mr. GREENWOOD. Okay. And Mr. Nagan identify yourself? Thank you, sir.

Mr. Friedlander? Not.

And Dr. Chevreau?

Ms. CHEVREAU. Yes. Mr. Nagan.

Mr. GREENWOOD. Okay. Same gentleman.

Very well. In that case—

Mr. BURBAGE. Chairman Greenwood. Mr. Chairman Greenwood, Dr. Mowrey is represented by Richard Burbage. We are on videotape.

Mr. GREENWOOD. Oh, there is. There he is. How do you do, sir. Thank you for joining as well.

Mr. BURBAGE. Thank you.

Mr. GREENWOOD. And you heard me, sir, indicate that we take our testimony under oath. You object to giving your testimony under oath?

Dr. MOWREY. No, I do not.

Mr. GREENWOOD. Even telephonically.

All right. I'm going to ask all of you rise and you, sir, if you are able, I know you have a bad back, but raise your right hands, please.

[Witnesses sworn.]

Mr. GREENWOOD. Okay. You are all under oath.

TESTIMONY OF EDITA KAYE, FOUNDER, THE SKINNY PILL COMPANY; JOSE DE LA ROCHA, DIRECTOR, QUALITY CONTROL, PAL LABS; JERRY RAYMAN, VICE PRESIDENT OF SALES, PAL LABS; GUY REGALADO, FORMER VICE PRESIDENT OF SALES AND MARKETING, DYNAMIC HEALTH OF FLORIDA; JONATHAN BARASH, FORMER PRESIDENT, DBS LABS; DENNIS GAY, PRESIDENT, BASIC RESEARCH; DANIEL MOWREY, DIRECTOR OF SCIENTIFIC AFFAIRS, BASIC RESEARCH; MITCHELL FRIEDLANDER, MARKETING CONSULTANT, BASIC RESEARCH; NATHALIE CHEVREAU, NUTRITIONAL RESEARCH CENTER, BASIC RESEARCH; AND KEITH AYOUB, ASSOCIATE PROFESSOR OF PEDIATRICS, ALBERT COLLEGE OF MEDICINE

Mr. GREENWOOD. And why do we not start with Ms. Kaye. Do you have an opening statement, ma'am?

Ms. KAYE. No, I do not.

Mr. GREENWOOD. Okay. Very well.

Mr. de la Rocha, do you have an opening statement? Okay. All right. Now, first of all, see if your microphone is on. Okay.

TESTIMONY OF JOSE DE LA ROCHA

Mr. DE LA ROCHA. I am the Director of Quality Assurance and Quality Control at PAL Laboratories, Inc. I have been in this position since 1999. Some time in mid- to late October 2002, Jerry Rayman, PAL's Vice President of Domestic Sales & Marketing, informed me that a client had asked PAL to prepare a formulation for a proposed dietary supplement directed at obese children. It was my understanding that the proposed product was to be for children 12 years of age and older.

The initial formulation contained primarily fibers and no diuretics. The second formulation was for "Adults and children more than 12 years old." At Mr. Rayman's request, I modified the formulation. All of Ms. Kaye's requests were given to me through Mr. Rayman. I never personally spoke with her.

On or about November 6, 2002, Mr. Rayman informed me that Ms. Kaye had rejected all our prior drafts and had requested that we draft a formulation for a dietary supplement intended for children 6 years of age and older. I made the requested modifications and forwarded them to Mr. Rayman before I left on vacation, on or about November 27, 2002. Immediately upon my return, on December 9, 2002, Mr. Rayman asked me if there were any medical concerns with the inclusion of Uva Ursi as an ingredient in the Skinny Pill for Kids. I consulted the Physicians' Desk Reference and informed Mr. Rayman that Uva Ursi was contraindicated in children under 12 years of age. At that point, he told me that there was a problem with the formulation that I had proposed because it contained Uva Ursi and his client, Ms. Kaye, had started a marketing campaign with that formulation.

On that same day, Mr. Rayman and PAL's then president, Emilio Ruiz, instructed me to appear on the CNN TV Show, "Connie Chung Tonight," because Ms. Kaye was going to appear on it in order to discuss the Skinny Pill for Kids. Later that afternoon, I appeared on the show as instructed. At this point, PAL had never

produced "The Skinny Pill for Kids." Moreover, PAL then decided it would not produce this product.

Thank you.

[The prepared statement of Jose de la Rocha follows:]

PREPARED STATEMENT OF JOSE DE LA ROCHA

I am the director of Quality Assurance and Quality Control at PAL Laboratories, Inc. ("PAL"). I have been in this position since 1999. Some time in mid- to late October 2002, Jerry Rayman, PAL's Vice President of Domestic Sales & Marketing, informed me that a client had asked PAL to prepare a formulation for a proposed dietary supplement directed at obese children. It was my understanding that the proposed product was to be for children 12 years of age and older.

The initial formulation contained primarily fibers and no diuretics. The second formulation was for "Adults and children more than 12 years old" (Exhibit C). At Mr. Rayman's request, I modified the formulation. All of Ms. Kaye's requests were given to me through Mr. Rayman. I never personally spoke with her.

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Mr. GREENWOOD. Mr. Rayman, do you have an opening statement?

Mr. RAYMAN. Yes. Good afternoon.

Mr. GREENWOOD. Good afternoon. You are recognized for your statement, sir.

TESTIMONY OF JERRY RAYMAN

Mr. RAYMAN. I have been Vice President of Domestic Sales and working for PAL Labs since 2001.

Some time in September 2002, Edita Kaye contacted me in order to discuss a possible proposed formulation for a dietary supplement directed at obese children. In mid- to late October 2002, I asked Jose Diaz de la Rocha, PAL's Director of Quality Assurance and Quality Control, to prepare a formulation for the proposed dietary supplement. Mr. de la Rocha prepared a formulation for a proposed product that was to be for children 12 years of age and older.

I was the only agent or employee of PAL that discussed the formulations for the Skinny Pill for Kids with Ms. Kaye.

On or about November 6, 2002, I informed Mr. de la Rocha that Ms. Kaye had rejected our formulations and had requested that we draft a formulation for a dietary supplement intended for children 6 years of age and older. She specifically requested a diuretic be added to the formula. Edita Kaye's email dated November 7, 2002 confirms her rejection of previous formulations and that she wanted a product for children 6 and up. Edita Kaye approved the product formulated on December 6, 2002. At this point, PAL had never

produced the Skinny Pill for Kids. Moreover, PAL then decided it would not produce this product.

Mr. GREENWOOD. Thank you, sir.

Mr. Regalado, do you have an opening statement, sir?

Mr. REGALADO. No, I do not.

Mr. GREENWOOD. Okay. Mr. Barash, do you?

Mr. BARASH. No, I do not.

Mr. GREENWOOD. Mr. Gay?

Mr. GAY. I do.

Mr. GREENWOOD. Okay. You are recognized for your opening statement, sir.

TESTIMONY OF DENNIS GAY

Mr. GAY. Chairman Greenwood, and members of the subcommittee. Thank you for this opportunity to appear today.

My name is Dennis Gay, and I am the Chief Executive Officer of Basic Research, LLC, which is headquartered in Salt Lake City, Utah. I am accompanied by Dr. Nathalie Chevreau, our Director of Nutritional Research, our Director of Scientific Affairs Dr. Daniel Mowrey, Ph.D. is with us today on a remote basis due to an acute back ailment and possible repeat spinal surgery. Please note that Dr. Mowrey is also currently taking prescription pain medications which will effect his reasoning or response. Also with us is Mr. Mitchell K. Friedlander, a marketing consultant.

Basic Research was started in 1993 with just three people, including myself. We have grown to be a company with an international presence and more than 350 hard working employees, of whom we are very proud.

We are in the business of promoting health and well being for the one out of six Americans who takes some type of dietary supplement every single day as well as millions more who occasionally use supplements or other health and beauty products.

We are appearing here today voluntarily eager to participate in this process and ready to discuss both our product PediaLean and its associated website, [weightlossfor children.com](http://weightlossforchildren.com). Together these resources assist parents in addressing holistically the health, appearance and self-esteem of overweight children, a problem which is laminated daily in the media but about which very little is being accomplished.

PediaLean is a dietary supplement not intended or marketed to diagnose, treat, cure or prevent any disease. There is nothing magically or mystical about its properties. It is quite simply a highly micronized purified form of glucomannan, a substance derived from a tuber known as conjack root. Glucomannan is present in many food products that we and others around the world consume on a regular basis. In fact, humans have consumed for hundreds of years, if not longer.

PediaLean's use as a weight loss aid is simply a new and highly refined application of conjack flour, a well established commodity. To our knowledge there has never been a serious adverse health event involving PediaLean. We are fully satisfied of its safety when used as directly.

Conjack flour is a soluble fiber which has very low caloric content and is not absorbed by digestion. We have provided this committee

with a published peer review clinical trial. That study shows that children who took the active soluble fiber in PediaLean along with normal caloric diet and modest exercise lost significantly more weight than overweight children using diet and exercise alone.

I noted that PediaLean should be used as an adjunct to a program of exercise and improved diet, and we present the product in that context. PediaLean's advertisement specifically state that it is not a miracle pill. In fact, basic research has made it an enormous investment in the area of juvenile overweight, much of which is intended to benefit parents who may never purchase PediaLean. Specifically in addition to developing the product, our company invested in the following:

We selected a panel of credible and highly qualified experts to advise our customers on strategies promoting juvenile weight loss. We developed an interactive website for parents to use as a tool in combating their child's weight problems. We equipped the website with tables, charts, calculators and exercise programs. We provided for information exchanged between parents and our experts as well as a bulletin board on which parents could post questions and support one another.

PediaLean was not the sole focus of our effort, and in fact was not marketed to consumers at all until the website was completed. At considerable expense to our company it was intended to be a complimentary product, a useful tool to be offered along with the website. The product was designed to assist parents in effecting behavior changes.

Basic Research fully backs all of its products including PediaLean based solely on the satisfaction of the customer. If for any reason the customer is not fully satisfied, he or she is invited to return the remaining product for a full refund. It is perhaps worthy of note that PediaLean has enjoyed the highest customer satisfaction among our many products. That said, by no means do we claim to be perfect.

When we have discovered mistakes, some of them in this course of this inquiry, we have worked to correct them at once. As a company we strive to improve our sales daily. It is not at all uncommon for a young and small business experiencing tremendously rapid growth to endure some pains for that growth.

We view today's hearing as an opportunity to contribute in a constructive manner. Even recognizing that we are imperfect, we are proud of our company, our people and our products and are happy to join in this important dialog concerning the issue of overweight children.

Further, Mr. Chairman, we understand that the FTC staff yesterday issued a complaint against us. But as late as this very moment, we still have not seen the complaint. From what little we know, we do not believe allegations have merit and we intend to contest the case vigorously. However, in the interest and the fairness in due process, I trust and hope that you will not expect this morning to address questions bearing directly on a set of allegations we have not yet had a chance to review or analyze.

I appreciate your time, Mr. Chairman.

[The prepared statement of Dennis Gay follows:]

PREPARED STATEMENT OF DENNIS GAY, CHIEF EXECUTIVE OFFICER, BASIC RESEARCH LLC

Chairman Greenwood and Members of the Subcommittee: Thank you for this opportunity to appear today. My name is Dennis Gay, and I am the Chief Executive Officer of Basic Research LLC, which is headquartered in Salt Lake City, Utah. I am accompanied by Dr. Nathalie Chevreau, our Director of Nutritional Research. Our Director of Scientific Affairs, Dr. Daniel Mowrey PhD, is with us today on a remote basis due to an acute back ailment and possible repeat spinal surgery. Please note that Dr. Mowrey is also currently taking prescription pain medications which may affect his reasoning and response. Also with us is Mr. Mitchell K. Friedlander, marketing consultant.

I. BASIC RESEARCH IS A RESPONSIBLE, VITAL COMPANY.

Basic Research was started in 1993, with just three people, including me. We have grown to be a company with an international presence and more than 350 hardworking employees, of whom we are very proud.

That said, by no means do we claim to be perfect. We have made mistakes. When we've discovered those mistakes—some of them in the course of this very inquiry—we have worked to correct them at once. As a company, we strive to improve ourselves daily. It is not at all uncommon for a young and small business experiencing tremendously rapid growth to endure some pains from that growth. We learn from our missteps; this Subcommittee's inquiry has in fact helped us discover ways in which we can improve.

We are in the business of promoting health and wellbeing, particularly for the one out of six Americans who takes some type of dietary supplement every single day, as well as the millions more who use supplements and other health and beauty products on a less frequent basis.

We have hundreds of thousands of satisfied repeat customers who purchase, use, and enjoy our products. We have an excellent reputation with our customers and retail partners. We are known for our extraordinary attention to quality in selecting and processing our raw materials.

We have a real address, a real phone number, and a real headquarters—in short, we are easy to find. We are appearing here today voluntarily, eager to participate in this process and ready to discuss both our product PediaLean and its associated website, weightlossforchildren.com.

Together, these resources assist parents in addressing holistically the health, appearance, and self-esteem of their overweight children—a problem which is lamented daily in the media, but about which very little has been accomplished.

II. PEDIALEAN IS SAFE.

PediaLean is a dietary supplement, not intended or marketed to diagnose, treat, cure, or prevent any disease. There is nothing magical or mystical about its properties. It is, quite simply, a highly micronized and purified form of glucomannan—a substance derived from a tuber known as konjac root. Glucomannan is present in many food products that we and others around the world consume on a regular basis. The substance itself may sound exotic, but humans have consumed it for hundreds of years, if not longer.

In the patented and unique form found in PediaLean, the product is neither a laxative nor a diuretic. Its use as a weight loss aid is simply a new and highly refined application of konjac flour, a well-established commodity. To our knowledge, there has never been a serious adverse health event involving konjac flour. We are fully satisfied of its safety when used as directed.

III. PEDIALEAN IS EFFECTIVE

Glucomannan is a soluble fiber which has very low caloric content and is not absorbed by digestion.

Research has demonstrated that in children and adolescents, a relatively small amount can be a very helpful adjunct to changes in diet and exercise.

The principle is simple and sound. I'm certain we will have the opportunity to share with you more information about PediaLean's development, safety, and efficacy as this hearing proceeds.

IV. PEDIALEAN WAS INTENDED AS PART OF A GREATER WHOLE.

I noted that PediaLean should be used as an adjunct to a program of exercise and improved diet, and we present the product in that context. You will note that in PediaLean's advertisements, it is specifically stated that this is NOT a "Miracle

Pill.” In fact, Basic Research has made an enormous investment in the area of juvenile overweight, much of which can easily benefit parents who never purchase PediaLean. Specifically, in addition to developing the product, our company invested in the following:

- We selected a panel of credible and highly qualified experts to advise us and our customers on strategies for dealing with juvenile weight loss.
- We developed an interactive website for parents to use as a tool in combating their child’s weight problems.
- We equipped the website with tables, charts, calculators, and exercise programs to provide parents with comprehensive assistance.
- We provided for information exchange between parents and our experts, as well as a bulletin board on which parents could post questions and support each other by sharing experiences.

PediaLean was not the sole focus of our effort, and in fact was not marketed to consumers at all until our website was complete—at considerable expense to our company. It was intended to be a complementary product—a useful tool to be offered along with the website. The product was designed to assist parents in effecting these changes.

V. WE BACK OUR PRODUCTS FULLY AND CREDIBLY.

Basic Research fully backs all of its products including PediaLean, *based solely on the satisfaction of the customer*. If for any reason the consumer is not fully satisfied, he or she is invited to return the remaining product for a full refund. It is perhaps worthy of note that PediaLean has enjoyed the highest consumer satisfaction among our many products.

Once again, we fully understand that we have room to improve as a company. We are grateful for the process of self-assessment this inquiry has brought about.

We view today’s hearing as an opportunity to contribute in a constructive manner. Even recognizing our occasional mistakes, we are proud of our company, our people, and our products, and are happy to join in this important dialogue concerning the proper regulation of dietary supplements. Thank you, Mr. Chairman.

Mr. GREENWOOD. Thank you, Mr. Gay.

Mr. Friedlander, do you have an opening statement?

Dr. Chevreau, do you?

Ms. CHEVREAU. No, I don’t.

Mr. GREENWOOD. Okay. Dr. Ayoob, we are glad that you—oh, I’m sorry. I’m sorry. Pardon me. Dr. Mowrey, do you have an opening statement, sir?

Dr. MOWREY. No, I do not.

Mr. GREENWOOD. Okay. Now, Mr. Ayoob.

TESTIMONY OF KEITH AYOOB

Mr. AYOOB. Actually, it is doctor.

Good Morning and thank you for the opportunity to speak with you on a topic of such concern to me: children’s health.

My name is Dr. Keith Ayoob and I do thank you for the opportunity to testify. I hope you will find my comments useful. First, a summary about my credentials and background: I am an associate professor of pediatrics at the Albert Einstein College of Medicine in New York and the Director of the Nutrition Clinic at the Rose F. Kennedy Children’s Evaluation and Rehabilitation Center there.

For 9 years, I served as a volunteer media spokesperson for the American Dietetic Association, and gave over 800 interviews for print, television, radio and the Internet on timely nutrition topics in the media.

I have been on the Board of Editors of the Journal of the American Dietetic Association for approximately 4 years and was an outside reviewer for the Journal for 12 years prior and I am very fa-

miliar with the evaluation of scientific research. During this time, I have reviewed hundreds of proposed articles for publication in the Journal about clinical trials conducted in the field of diet and health research.

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I first learned about the Skinny Pill for Kids back in early December 2002, when Barbara Hoffman, a reporter with The New York Post, asked if I'd heard of a new diet pill being marketed to children 6 to 12 years old. At first I thought she'd misinterpreted a press release, because as a pediatric nutritionist, I could not imagine someone coming up with a pill for young children that promised healthy, safe and effective weight loss. But she referred me to a website called www.skinny.com that had all the details about these supplements. I reviewed the website and was both angry and disgusted by the information contained on the website about the Skinny Pill for Kids. The information was scientifically baseless, blatantly exploitative, and potentially very harmful to children.

When Ms. Hoffman's story ran in the Post on December 6, 2002, the television media picked it up and I was invited to debate the marketer of the pills, Edita Kaye, on NBC's "The Today Show" the following Monday, approximately the same time the product was to begin shipment. I said on that program, and I will reiterate it today, the Skinny Pill for Kids, as well as these other dietary supplements for children that the committee has looked at are "junk science."

Before I say a few words about the Skinny Pill for Kids, I would like to note that I was extremely relieved that, due the pressure put upon Edita Kaye, the creator and marketer of the pill, by the medical community and the media, the Pill was pulled from the market before any child had actually taken it. Further, I also felt vindicated in my efforts to counteract Ms. Kaye's public claims about the product on national television. And now, I'd like to summarize some concerns I had about the ingredients in the product, as well as the marketing claims Ms. Kaye made.

There is no scientific basis for any of the claims made about the Skinny Pill for Kids on Ms. Kaye's website. There is however, scientific evidence against many of the claims she made. The pills were a concoction of a few vitamins and minerals, along with fiber and herbs. A few examples of false claims, in my opinion:

"It contains a proprietary blend of safe natural vitamins, minerals, and fat-fighting nutrients" In my opinion, these pills are not safe. They have never been proven safe. They contain diuretic herbs that should never be given to children.

"It is formulated to help children reduce their risk of obesity-related diseases such as heart disease, high blood pressure, and diabetes." None of the ingredients here will help reduce risk of these diseases. Children with these diseases should be treated by physicians, not Ms. Kaye, and desperate parents should not be given a false sense of confidence that this pill is helping their children in

any way because it cannot help them. What it can do is to delay consumers from seeking real treatments and healthier lifestyles to combat obesity.

“It offers very real weight-loss help through supplements that metabolically assist children to burn more fat pounds and inches, block new fat deposits and help regulate insulin levels to mitigate fat factors.”

In my opinion, all of these claims are absolutely false and without evidence to support them. No studies have been shown to indicate that these claims are true for the ingredients in the Skinny Pill for Kids.

As for the vitamins, the amounts of niacin, folate, and vitamin B12 in the Skinny Pill for Kids, can be obtained far more economically in any standard, over-the-counter multivitamin supplement that would also contain many other vitamins and minerals. There is no need to take separate amounts of them. As for the herbal ingredients, she makes false, unproven claims about many of them, for example: Uva ursi: “Acts as a diuretic and helps diabetes. It has also been shown to strengthen heart muscle.” She’s only right about it being a diuretic herb, and that’s a huge concern. The Physicians’ Desk Reference for Herbs, which is the standard reference text well accepted by health professionals, has stated with scientific backing that uva ursi was contraindicated for children under the age of 12 years, the very population of these pills, as it has been associated with liver damage.

Glucomannan: She says that “This substance actually picks up and removes fat from the colon wall. It is good for obesity because one of its primary functions is the removal of fat. It has been recognized for normalizing blood sugar and it expands up to sixty times its own weight and, in so doing, helps maintain a feeling of fullness and curbs appetite.” Glucomannan is just a food thickener that has never been proven safe or effective for weight loss.

Buchu Leaf: “Aids in controlling diabetes and digestive disorders and fluid retention.” For weight loss, it has never been shown to be effective. It can however, function as a diuretic and should not be given to children.

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Since fiber pills have not been shown to have much effect on weight loss, I am also concerned about another supplement for overweight children called PediaLean. Again, there is no scientific basis for the claims about this product, although the marketers, Klein-Becker, seem to want you to believe otherwise. I have reviewed the website for the product, www.pedialean.com, and have

concerns about their purported “clinical evidence” for safety and efficacy.

These are a few comments I have about the cited “clinical evidence” that PediaLean helps children lose weight. First, the study was not published in any journal I have ever heard of. I have been on the Board of Editors of the Journal of the American Dietetic Association for several years. I read and review numerous manuscripts, good and bad, all the time. I would never have had the chance to review this one however, because this would never have made it to my desk. The associate editor or the editor-in-chief would have screened this and rejected it out of hand, and I am very grateful that they do not waste my time with this type of study.

Second, the study was a single study, done in the early 90’s on a small number of children, many of whom dropped out. The copy I received was translated from Italian and the full name of the journal was not revealed, only an abbreviation. This is highly unusual for a translated study that being used to make specific claims, as it limits the ability of the reader to verify the publication.

Third, there are not even any units assigned to the numbers associated with the claimed weight loss. I have no idea if they are indicating pounds or kilos when they refer to weight loss.

And finally, the study has never been replicated. It has no controls. Without controls, I have no idea if the results were due to the pills, or correction it has no valid controls or placebo controls. Without controls, I have no idea if the results were due to the pills or to the fact that children had to take two pills with a large glass of water before meals. Every researcher knows that you need valid controls to make your study meaningful. This is research 101. When you do not include control groups, it suggests that you may not want the reader to know the results. This study suggests that the researchers didn’t want the results to be accurate. They just wanted them Tuesday, so to speak.

For a company to rely on a study conducted in Italy over 10 years ago, of such poor quality and questionable conclusions, to support their marketing statements that a product is safe and effective for a 6 year old, is disturbing.

The makers of PediaLoss also developed a pill with ingredients that promise but cannot deliver weight loss. The ingredients in PediaLoss, inulin and lecithin, have never been scientifically shown to aid in weight loss. Once again, this is a sham product that cannot deliver what it promises because its claims are baseless and yet another example of junk science.

These supplements are also expensive. The Skinny Pill for Kids was to cost \$40 per month. PediaLean cost almost \$80 a month. I would rather see parents put their hard earned money toward buying healthy food and taking their children for healthy physical activities.

Childhood overweight is a serious issue. It needs a serious solution. True lasting results to the obesity problems of children and adults are not going to be found in an over-the-counter supplement. If they are, then a body of sound, scientific evidence should come before the claims. It is completely inappropriate to allow people to market “supplements” with no evidence that they work, and then

wait until there is a complaint or even harm, before they are investigated.

The loopholes in the laws that permit these types of supplements to be marketed should be closed. They should be closed and nailed shut. My only regret in the judgment imposed on Ms. Kaye is that the multi-million dollar fines attached to their judgment were forgiven for her lack of ability to pay. That makes for a rather weak judgment. Only if she, and others of her ilk, were hit in their pocketbooks, where they'd feel it most, and were held responsible for paying back the fine, even over the course of many years, might they think twice about marketing junk supplements to vulnerable children and their families.

Thank you for your time and I am prepared to answer any questions you may have on these or other matters.

[The prepared statement of Keith Ayoob follows:]

PREPARED STATEMENT OF KEITH-THOMAS AYOOB

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Products like these should never exist. Even if they cause no harm that is reported, they serve only to exploit children and their caregivers by fostering the illusion that these products work, perhaps preventing them from seeking real solutions.

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Thank you for your time and I am prepared to answer any questions you may have on these or other matters.

Mr. GREENWOOD. Thank you, Mr. Ayoob. We appreciate your joining us.

The Chair recognizes himself for 10 minutes for some questioning. I am going to start with you, Ms. Kaye.

And I can well imagine that you are thinking to yourself I never sold one of these pills, why is everyone picking on me. But here is the issue: Somebody else market this same market in the same way tomorrow with the same concerns, raising the same concerns. And so what we are here to do is to understand how this process works so that we can act in the best interests of the American public.

So let me ask you this: In December 2002 you appeared on "The Today Show" and other nationally televised shows promoting a product you called Skinny Pill for Kids. The question is what scientific research did you do on the ingredients in the product before you decided to market it to kids?

Ms. KAYE. I did due diligence, and I thought I acted in a prudent manner by finding a facility, a lab, pharmaceutical company to manufacture such a product and develop a formula that was safe

and effective. My overall concern always was and continues to be the problem of obesity in children, which is an ongoing problem and appears to be getting worse.

As soon as I realized that there were concerns expressed about the formula that was developed by this company on my behalf, I immediately stopped the program and that is really what happened.

Mr. GREENWOOD. Well, were you driving the company to come up with a formula? Your response would indicate that you simply, I do not know whether your randomly chose this company or how you chose this particular company based on its experience or its expertise or research that it had done that enabled you to have confidence that it would be able to do what apparently no one has ever been able to do, according to all of our witnesses, and that is come up with a pill that would actually help children to lose weight. What made you think this company could do that for you, PAL Labs?

Ms. KAYE. Well, PAL Labs assured me that they were an FDA approved facility, that they also manufactured OTC products and that they had high standards of quality control. And, I felt that they were sound, that what they said was in fact correct.

Mr. GREENWOOD. Well, you hold yourself out to be America's favorite nutritionist. Wouldn't it make sense that as a nutritionist with this self-proclaimed crusade to help children, that you would have done some research, you would have looked into what kind of ingredients might work rather than turning to PAL Labs and say you come up with something?

Ms. KAYE. Sir, I am not a chemist or a formulator.

Mr. GREENWOOD. You're a nutritionist?

Ms. KAYE. Hence, I searched for a company that could develop a formula.

Mr. GREENWOOD. And what made you think this company could do that?

Ms. KAYE. For the reasons I just cited.

Mr. GREENWOOD. Well, you said they are FDA approved. That simply means that when they manufacture a product, in this case one that does not have to be approved by FDA, the only thing that matters is whether they're using hygienically correct approaches and there is no chance of a danger that is outside of the ingredients. That does not indicate that they have the tiniest bit of knowledge about what ingredients would actually be beneficial to people.

Did you ask them if they had ever—

Ms. KAYE. They—

Mr. GREENWOOD. Did you ask them if they had any experience whatsoever in producing compounds that would help anyone lose weight, particularly children?

Ms. KAYE. They had told me, and yes they did also in addition to their OTC work, that they did develop formulas for nutritional supplements. That, in addition to the fact that they were FDA certified, that they had a formulator—

Mr. GREENWOOD. You do not know or you are unaware of the fact that nutritional supplements are not required to be able to demonstrate effectiveness before they are marketed?

Ms. KAYE. I am sorry, I do not understand.

Mr. GREENWOOD. Nutritional supplements pursuant to Federal law, makers of nutritional supplements are not required to demonstrate that they have any effectiveness whatsoever. Are you aware of that?

Ms. KAYE. I am really not clear on what you are asking me.

Mr. GREENWOOD. Okay.

Ms. KAYE. I am not sure.

Mr. GREENWOOD. Okay. Do you know the difference between an FDA process where you have to take a pharmaceutical product and you have to go to the Food and Drug Administration and demonstrate that you have clinical trials that have demonstrated the effectiveness and the safety of this product. And that after a very long and sophisticated process, the FDA has to make a decision whether the stuff actually works and whether it actually hurts people, whereas in the nutritional supplement field no such requirement exists. So therefore, PAL Labs could put peanut butter in a capsule and call it a diet pill and you would come along and say, well you are FDA approved, I guess you must be the experts. Do you understand that?

Ms. KAYE. I think so. But I trusted their formulators that they were a company that—

Mr. GREENWOOD. All right. I would like you to turn to that notebook right there to tab 13. Could you open that up to Tab 13, Ms. Kaye? Now there you will find an email that you sent to Jerry Rayman on the subject of Skinny Kids on November 7, 2002. Do you see that?

Ms. KAYE. Yes, sir, I do.

Mr. GREENWOOD. Okay. Would you go down to No. 3 and would you—what was your intent in sending this email?

What I would like you to do, it is tab 13 for the benefit of the members of the committee. Would you just read for us beginning with No. 3 where it says “This is a formula,” and read to the bottom of the page? Out loud, please.

Ms. KAYE. Yes. “This is a formula which was clearly stated to be for children. What you have here in all your disclaimers is 12 years plus. I might just as well put a different label on my far superior existing Skinny Pill formula and sell it to 12 year old children and plus. I need a formula for children 6 years old and up and that is what we have been talking about for months.”

Mr. GREENWOOD. Keep going.

Ms. KAYE. “Well I now have run out of time and I need this formula with price quotes by the end of business today, so please provide the following: A Skinny capsule: 2. For children 6 years of age and older to be taken three times a day, two is better but I can live with three that is also a thermic formula, and I need to be able to say on the label that this is for children 6 years old and up. Jerry, if I cannot get this, I am going to have to go to another formulator. I have an entire campaign built around the belief that you could deliver this type of product for me. I do not want a me too fiber formula like PediaLean, I want something that no one else out there has and I need it by today. I do not mean to sound difficult, but I am very disappointed. Edita.”

Mr. GREENWOOD. So you are clearly involved in the formulation of this product. You were telling them what you want, is that right? Could we not interpret that from your email?

Ms. KAYE. I was telling them that I would like them to come up with a formula. I was not involved in that—

Mr. GREENWOOD. What is a thermic formula? You told them you want a thermic formula, what does that mean?

Ms. KAYE. Something that helps with energy, that is what I had meant.

Mr. GREENWOOD. Okay. And was there any indication that they had ever done that before? Did you believe that they had ever been able to come up with a thermic formula before?

Ms. KAYE. Well, I believed that they had developed formulas for nutritional supplements for weight loss, that they were as they had told me FDA approved, that they had formulators and that they were confident that they could develop such a formula for children. That was what I thought when we had conversations.

Mr. GREENWOOD. Okay. Let me ask Mr. Rayman, when did Edita Kaye first contact PAL Labs about formulating a diet pill for kids?

Mr. RAYMAN. I do not remember the exact date.

Mr. GREENWOOD. Pull that microphone closer to you, please.

Mr. RAYMAN. I do not remember the exact day, but probably sometime in that September/October prior to the actual—

Mr. GREENWOOD. Okay. Did she provide any instructions at that time about the ingredients she wanted in the pills?

Mr. RAYMAN. We talked about a fiber pill. She talked about having a diuretic to get rid of the fiber in the system. And I conveyed that information to—

Mr. GREENWOOD. You specifically remember her asking for a diuretic?

Mr. RAYMAN. Yes, I do.

Mr. GREENWOOD. Did she reject your fiber formulation?

Mr. RAYMAN. She rejected the first formulation, as it was apparent in that email that she sent to us.

Mr. GREENWOOD. Okay. And what was your sense of why she did that?

Mr. RAYMAN. Based on what she said in the email is that she thought that it wasn't different enough from anything else that is out there.

Mr. GREENWOOD. In any of these discussions did Ms. Kaye ever express any concerns about the safety of the product for 6 year old children?

Mr. RAYMAN. No, she did not.

Mr. GREENWOOD. Okay. My time has expired.

The gentlelady from Colorado.

Ms. DEGETTE. Thank you very much, Mr. Chairman.

Following up, Mr. Rayman, your title is Vice President of Domestic Sales and Marketing, correct?

Mr. RAYMAN. That is correct.

Ms. DEGETTE. Do you have any kind of a degree in biology or are you a researcher?

Mr. RAYMAN. No, I am not.

Ms. DEGETTE. You are not in charge of formulating the products?

Mr. RAYMAN. No, I am not.

Ms. DEGETTE. Now, to your knowledge has PAL Laboratories ever formulated weight loss products before?

Mr. RAYMAN. We have made products that people may have marketed as weight loss, but by their direction. They tell us what ingredients they want us to put into a pill, and we put it into a pill.

Ms. DEGETTE. Okay. But Ms. Kaye did not tell you what ingredients to put in there, she simply said she wanted something that was not just a fiber pill, right? And according to your written and verbal testimony, she said she wanted something that was a diuretic, right?

Mr. RAYMAN. She wanted a diuretic added to her fiber product.

Ms. DEGETTE. Now were you her primary contact at PAL Labs?

Mr. RAYMAN. Yes.

Ms. DEGETTE. And what did you do when she came to you and asked you for this product?

Mr. RAYMAN. I went to Jose de la Rocha and told him——

Ms. DEGETTE. And you told Mr. de la Rocha what she wanted, right?

Mr. RAYMAN. That is correct.

Ms. DEGETTE. Mr. de la Rocha, what did you do then when you learned of this request of Ms. Kaye's through Mr. Rayman?

Mr. DE LA ROCHA. Yes. The first formula was——

Ms. DEGETTE. Could you hold that microphone up to your mouth. Thank you.

Mr. DE LA ROCHA. Sorry.

The first formula was fiber formula for children 12 and over.

Ms. DEGETTE. That was what you understood that Ms. Kaye had requested?

Mr. DE LA ROCHA. I understand that it was for—in my mind I never thought for children 12 and—six and over.

Ms. DEGETTE. Now, have you ever developed dietary supplements before?

Mr. DE LA ROCHA. Yes, ma'am.

Ms. DEGETTE. What types of dietary supplements?

Mr. DE LA ROCHA. Vitamin C, vitamin E, simple formulas.

Ms. DEGETTE. And what is your educational background?

Mr. DE LA ROCHA. I'm a chemical engineer. I'm a doctor in technical science.

Ms. DEGETTE. A doctor of?

Mr. DE LA ROCHA. Technical science, that is like a similar or Ph.D. or a master degree here in the States.

Ms. DEGETTE. And is your background in——

Mr. DE LA ROCHA. Chemical engineer.

Ms. DEGETTE. Is in development of dietary supplements?

Mr. DE LA ROCHA. No, ma'am.

Ms. DEGETTE. No. Okay. How long have you been involved in developing dietary supplements?

Mr. DE LA ROCHA. Normally I am not a formulator. I am a quality control guy.

Ms. DEGETTE. Oh, you're a quality—okay. Do you have people at PAL Labs who are in charge of developing the——

Mr. DE LA ROCHA. Right now, yes. Right now in this moment.

Ms. DEGETTE. Right now. But back with this product did you have people in charge of developing some——

Mr. DE LA ROCHA. We got a person in charge of developing, but that person was not in the company in that moment.

Ms. DEGETTE. Right. So the answer is no?

Mr. DE LA ROCHA. No.

Ms. DEGETTE. Thank you.

Now, so you were in charge of—who asked you to be in charge of developing?

Mr. DE LA ROCHA. Mr. Rayman.

Ms. DEGETTE. Mr. Rayman. Okay. And so he said Ms. Kaye wants this weight loss product for children, and he told you to develop the formula, is that right?

Mr. DE LA ROCHA. That is correct.

Ms. DEGETTE. How did you figure out seeing as you have no background in it, how to develop it?

Mr. DE LA ROCHA. Yes. I went to—I did my search and I—

Ms. DEGETTE. You did a search?

Mr. DE LA ROCHA. A search, and I see—

Ms. DEGETTE. On the Internet?

Mr. DE LA ROCHA. Yes. And in PDR and books. And I see a product that was full of fibers and it was approved for children already, it was used in that moment for children. And I propose a similar formula for her product.

Ms. DEGETTE. Now how did you figure out the—and that was for children 12 and over.

Mr. DE LA ROCHA. Yes.

Ms. DEGETTE. How did you know that it should be for 12 and over, from looking on the Internet?

Mr. DE LA ROCHA. I searched the PDR, Physician Desk Reference, to avoid problems and that is why I proposed 12 and over.

Ms. DEGETTE. Yes.

Mr. DE LA ROCHA. That was the first formula. Fibers for children 12 and over.

Ms. DEGETTE. Okay. But then at some point Mr. Rayman said no, that is not what is Ms. Kaye wanted, right?

Mr. DE LA ROCHA. That is correct.

Ms. DEGETTE. And then you developed the new formulation that was eventually used?

Mr. DE LA ROCHA. The second step was a formula with diuretic but still 12 and over.

Ms. DEGETTE. Right. But how did you figure out how to put these compounds together?

Mr. DE LA ROCHA. They—they almost—they will guide and they say, okay—

Ms. DEGETTE. Who guides you?

Mr. DE LA ROCHA. Through Jerry Rayman. I do not know—

Ms. DEGETTE. What?

Mr. DE LA ROCHA. Jerry Rayman. It was—

Ms. DEGETTE. So Mr. Rayman told you—okay. Mr. Rayman, is that true, did you tell Mr. de la Rocha amounts to put in in this formula?

Mr. RAYMAN. Amounts? No. No.

Ms. DEGETTE. Okay. Go ahead, Mr. de la Rocha.

Mr. DE LA ROCHA. Yes, what diuretics, that is it. And I did the second step, the second formula with—

Ms. DEGETTE. But how did you figure out how much of the fiber and how much of each diuretic to put into the formula?

Mr. DE LA ROCHA. Yes, that was using the Physician Desk Reference and what was in the market.

Ms. DEGETTE. I am sorry. The PDR, I mean I am not a scientist. The PDR, that does not tell you what proportions of these various compounds to put together, does it?

Mr. DE LA ROCHA. It has amounts safer and what is the drug amount. They have some amount and some suggestions.

Ms. DEGETTE. Mr. Ayoob, I saw you shaking your head. What is your view as to this proceed?

Mr. AYOOB. I am so glad you asked.

Ms. DEGETTE. I thought you might be.

Mr. AYOOB. Yes. If he had looked at the PDR, he would have known that this is not to be given to people under 12 years of age. And he may have, I do not know. He may have not intended it. I do not know. But the PDR definitely says that can cause liver damage, it should not be given.

Ms. DEGETTE. It says what can cause liver damage?

Mr. AYOOB. I am sorry. Uva ursi.

Ms. DEGETTE. Okay.

Mr. AYOOB. That is the particular diuretic—

Ms. DEGETTE. What about the putting together of all of these substances into the supplement? I mean, does the PDR address that?

Mr. AYOOB. The PDR does not address it. It addresses individual things.

Ms. DEGETTE. Right. Like it says a dose of X amount can cause liver damage?

Mr. AYOOB. Exactly. Or at least in large amounts it can cause liver damager, etcetera.

Ms. DEGETTE. Do you have a concern when you have a lab like this putting together several different things, a fiber and these diuretics, that there might be interactions between those?

Mr. AYOOB. It concerns me that there might be interactions between them. It also concerns me that it might have interactions with prescription medications that children might be taking.

Also, it concerns me anytime there is any amount of a diuretic herb in a over-the-counter supplement directed to very young children that says it is a diuretic and should not be given to them. That is a very big concern for me.

Ms. DEGETTE. Okay.

Mr. AYOOB. In terms of—

Ms. DEGETTE. Now, Mr. de la Rocha, were you concerned about the interaction of this supplement with children taking prescription drugs?

Mr. DE LA ROCHA. Yes. In fact, this was a mistake in the moment because what the original formula was for children 12 and over.

Ms. DEGETTE. Well, okay, I know. Early on I know you said that, but the truth is the way it finally came—Ms. Kaye came back and said she wanted it for kids six and older. And then Mr. Rayman, you went back I assume and told Mr. de la Rocha we want it for six and older, right?

Mr. RAYMAN. That is correct.

Ms. DEGETTE. And so then what happened, Mr. de la Rocha?

Mr. DE LA ROCHA. Then I made a mistake.

Ms. DEGETTE. Okay. What was that mistake?

Mr. DE LA ROCHA. That I did not check the same ingredients for children of that age.

Ms. DEGETTE. You just assumed they would be all right?

Mr. DE LA ROCHA. I just assumed if the client is asking for that and according to Mr. Rayman the client was a nutritionist—

Ms. DEGETTE. It was really based on what the client wanted and not any kind of scientific evidence at all, right?

Mr. DE LA ROCHA. Yes. I agree with you.

Ms. DEGETTE. Okay. Did you do any studies on kids before you gave this formula to Ms. Kaye to market?

Mr. DE LA ROCHA. No. No.

Ms. DEGETTE. Mr. Ayoob, you are eager to say something else?

Mr. AYOOB. Thank you. I appreciate it.

This is sometimes perhaps what happens when you have somebody who is claiming to be a nutritionist who does not have any qualifications. Somebody who did, might have been able to foresee some of this problem.

I know in most States you have to be licensed or certified before you can call yourself a nutritionist, and I am not sure that Ms. Kaye is. And had she had some background and training, this might have been preventable.

Ms. DEGETTE. Well—

Mr. AYOOB. I do not know.

Ms. DEGETTE. It might have been. And let me ask you, Ms. Kaye, did you ever look at the PDR to see if these substances were safe for children under 12? Did you ever do any kind of review of the literature to see if this product was safe?

Ms. KAYE. I ready about fiber, which was something that I thought would be a good thing since children do not get enough fiber and need more. But as far as the actual ingredients in the product and the quantities and so on, my concern was that this company, this laboratory was formulators, as I thought, would develop a safe product. And that is—

Ms. DEGETTE. But you—

Ms. KAYE. [continuing] what I charged them to do.

Ms. DEGETTE. I saw you on national TV holding yourself out to be a nutritionist. Now, you are not certified in nutrition?

Ms. KAYE. I am not a registered dietician, no.

Ms. DEGETTE. Right. See, I mean, I have two kids, 10 and 14. I am worried about their fiber, too. I would never go out and try to develop a dietary supplement. I am not—and—well—Mr. Chairman, I have a lot more questions which maybe I will ask at a second round. I will yield back.

Mr. GREENWOOD. The Chair thanks the gentlelady.

The gentleman from Florida.

Mr. STEARNS. Yes. Thank you, Mr. Chairman.

I am going to direct my questions to Mr. Barash and Regalado, Mr. Regalado.

Mr. Barash, tell me what is your relationship with PediaLoss in the past?

Mr. BARASH. I have no relationship with PediaLoss.

Mr. STEARNS. In the past did you have any relationship?

Mr. BARASH. Yes. I guess it is easier to explain. Dynamic Health placed a purchaser order with a company called Delta Body Systems, Brian Newsome who I had met in Boca Raton. He could not fill that purchase order. I started up a company called DBS Laboratories, LLC.

Mr. STEARNS. Yes.

Mr. BARASH. Overtook the purchase order and was only involved in—working with supplement manufacturing companies in delivering the product to Dynamic Health.

Mr. STEARNS. And what product was that?

Mr. BARASH. Well, PediaLoss was the product.

Mr. STEARNS. Okay. So you were involved with the marketing of PediaLoss?

Mr. BARASH. No.

Mr. STEARNS. You were involved with the distribution of it?

Mr. BARASH. No.

Mr. STEARNS. Were you involved with the manufacturing of it?

Mr. BARASH. I was involved in the manufacturing process of identifying a supplement contract manufacturer to produce the product with the bottle makers, with the packaging and the label. As far as putting the product together and delivering it to the Dynamic Health warehouse.

Mr. STEARNS. Where did the formula come from?

Mr. BARASH. The formula came from Brian Newsome and David Wood.

Mr. STEARNS. Who is David Wood? Now you are saying you got the formula from these people, and then you took this formula or you got—

Mr. BARASH. No. The formula, the purchase order was done before I was in the picture. About 2 months before I got into the picture. That would be a question you would have refer over to Dynamic Health.

Mr. STEARNS. Okay. When you got the formula, what did you do with the formula?

Mr. BARASH. Well, I had gotten one of several formulas. It was my job to go out and find a supplement manufacturer company to product the formula for Dynamic Health.

Mr. STEARNS. Yes. Are you aware of the claims that PediaLoss makes in their website?

Mr. BARASH. I have seen the website, yes.

Mr. STEARNS. Yes. It says here—

Mr. BARASH. For packaging.

Mr. STEARNS. “This revolutionary new formula slows the absorption of carbohydrates allowing more to be burned for energy and less to be stored as fat. This highly effective and natural dietary supplement comes in berry flavor” and so forth.

Where is the justification in your mind coming from or came from for this new all natural health product to deter child obesity? Did—

Mr. BARASH. I am sorry.

Mr. STEARNS. Did David Wood provide this to you?

Mr. BARASH. No. I cannot comment on that.

Mr. STEARNS. But you were involved with PediaLoss in the sense that you took the formula and helped in the distribution of it?

Mr. BARASH. No. What I did was intercept a purchase order that could not be fulfilled from a Brian Newsome Delta Body System which Chabra International, Dynamic Health placed with him for about 15 or 16 different products. They could not get him to deliver product. So what I did is step into the picture and work with contract manufacturers in the—I would say the operations of getting the product from the manufacturer to the warehouse.

Mr. STEARNS. Well, it is funny you mentioned that you do not seem to have any relationship with PediaLoss, but the FTC has charged you with false and misleading advertising for two products.

Mr. BARASH. That is correct.

Mr. STEARNS. One PediaLoss and, you know, this weight loss supplement for kids and some product called an alleged female sexual enhancer. So you have been charged with false and misleading advertising, yet you are saying to me today you do not seem to have any relationship with PediaLoss, and you mentioned—

Mr. BARASH. I did not say I have no relationship—I have any relationship—

Mr. STEARNS. Well, you seem to be equivocating of what you did with PediaLoss. Do you think the FTC charges are groundless?

Mr. BARASH. As far as a concern with Jonathan Barash and—

Mr. STEARNS. That you have been charged with false and misleading advertising by the Federal Trade Commission for PediaLoss, do you think that is true or not? Are these groundless charges or do you accept these charges as fact? Just yes or no, I mean tell me which one. Sorry.

Mr. BARASH. I am involved in a situation that would—

Mr. STEARNS. No, no. The question is do you think the charges by the Federal Trade Commission are groundless? Yes or no. In other words, are they false in your opinion? Is the Federal Trade Commission wrong? Yes or no.

Mr. BARASH. No.

Mr. STEARNS. So you are saying that they are not false, so that you accept them, that you did make false and misleading advertising of the PediaLoss product, that is what you just told me. Is that true?

Mr. BARASH. No.

Mr. STEARNS. Well, you just said that the Federal Trade Commission—

Mr. BARASH. If I could—if you could turn to this book to page 30—to the—

Mr. STEARNS. Well, I got tab 32 in front of me, and—

Mr. BARASH. How about 39?

Mr. STEARNS. [continuing] it talks about the product PediaLoss, and it talks about the ingredients in it. And the question I have for you is how did you come up with those ingredients for the tablets?

Mr. BARASH. I am the former President of DBS Laboratories, LLC. If you have the PediaLoss packaging, you will find that my company name and information is not on that product at all.

Mr. STEARNS. Well, who is David Wood?

Mr. BARASH. David Wood is a formulator or owns a manufacturing company in Ohio.

Mr. STEARNS. Did you have relationship with David Wood?

Mr. BARASH. I met him once.

Mr. STEARNS. And was he used as a credentialed person for the product?

Mr. BARASH. Him and Brian Newsome of Delta Body—

Mr. STEARNS. Okay. So David would be used—

Mr. BARASH. [continuing] are the ones who formulated the product.

Mr. STEARNS. Yes. Okay. So David Wood formulate the product?

Mr. BARASH. Yes. That was formulated before I became—got into the picture.

Mr. STEARNS. Yes. We cannot seem to get a hold of David Wood. We have been unable to find him anywhere. So we had this dubious distinction that David Wood who formulated your product, we cannot find him. We have no way to verify that the ingredients that are in the product have been researched and yet we have a list of products that the ingredients are being used in based upon someone that we cannot find and has not been credentialed. Is that accurate? Is that an accurate statement?

Mr. BARASH. I have no idea what—

Mr. STEARNS. Okay. When you met him, did you have the impression he was the authority for these ingredients?

Mr. BARASH. It was my understanding from Brian Newsome at Delta Body Systems that the two of them had discussions in formulating this product for Dynamic Health and for the purchase order that Dynamic Health placed with Delta Body Systems.

Mr. STEARNS. Okay.

Mr. Regalado, who wrote this ad that is here touting PediaLoss as this great all natural product for a child obesity?

Mr. REGALADO. Erin Fox, a legal firm here in Washington, D.C.

Mr. STEARNS. Did you have anything to do with it at all?

Mr. REGALADO. No. I asked them what I was allowed to say. They basically wrote the content.

Mr. STEARNS. Now you are part of Dynamic Health, are you?

Mr. REGALADO. Right. Was.

Mr. STEARNS. Was? And when you were with Dynamic Health, did you do the distribution of this product and marketing?

Mr. REGALADO. Did the marketing and distribution. I was the Vice President of Sales and Marketing, that is correct.

Mr. STEARNS. What do you think of the conversation I had relative to David Wood? Did you ever met David Wood?

Mr. REGALADO. No. I was not aware of the name or the person or his function until Jonathan and I completed the questionnaire requested from this Commission.

Mr. STEARNS. Did you ever question the ingredients or the credentials of David Wood who made up the formula for this?

Mr. REGALADO. No, I did not because rather than worrying about David Wood from my perspective, I wanted to know about the product for marketing purposes. And we had a technical data abstract and studies on the ingredients from a Dr. Guzman. And after reviewing that information, I felt that I had marketing materials to work with. That information assured us that it was safe, it was ef-

fective. And, in fact, one of the doctors that sat here did indicate that there were ingredients in there that had possible weight loss activities.

So based on reviewing that information, we felt that it was a viable product.

Mr. STEARNS. Do you have a medical degree?

Mr. REGALADO. No.

Mr. STEARNS. Mr. Barash, do you have a medical degree?

Mr. BARASH. No.

Mr. STEARNS. Are either one of you registered a dietician?

Mr. REGALADO. No.

Mr. STEARNS. Okay. Prior to arranging for this product to be advertized and sold on the market, did you give this formulation to any medical doctor or registered dietician to review?

Mr. REGALADO. Well, that was Dr. Guzman. He reviewed it. He gave us the technical abstracts, which was submitted to Kelli Andrews, a Ms. Kelli Andrews with the Commission.

Mr. STEARNS. Okay.

Mr. REGALADO. The technical data abstract and the studies were submitted to the Commission.

Mr. STEARNS. Now this Dr. Guzman you said, did you ever check Dr. Guzman's credentials?

Mr. REGALADO. Not myself personally, no.

Mr. STEARNS. Did you, Mr. Barash?

Mr. BARASH. No, I did not. He was recommended from the manufacturer that I had selected.

Mr. STEARNS. To your knowledge did Dr. Guzman ever do a study on this product?

Mr. BARASH. He did not do a study. He did the research reference on the ingredients.

Mr. STEARNS. And what does that mean?

Mr. BARASH. What he did was do detailed—he looked up detailed information on each one of the ingredients and wrote a technical abstract that was about 500 pages.

Mr. STEARNS. Were there any studies done on kids?

Mr. BARASH. For the formulation?

Mr. STEARNS. Yes.

Mr. BARASH. No.

Mr. STEARNS. Okay. So basically we really do not have, I think it has been brought out by this testimony, Mr. Chairman, for this particular product there is no credential to any information on PediaLoss and everything that they claim on this website cannot be corroborated.

And I yield back.

Mr. GREENWOOD. The Chair thanks the gentleman.

The gentleman from Oregon is recognized for 10 minutes.

Mr. WALDEN. Thank you, Mr. Chairman.

Mr. Rayman, Ms. Kaye had represented to the committee that there was never Skinny Pill for Kids, there never was one. Could you turn to tab 15 in the book? I will wait until you get there.

Mr. RAYMAN. That is the purchase order?

Mr. WALDEN. Yes. Does that evidence that a purchase order for 2,000 bottles of Skinny Pill for Kids was made?

Mr. RAYMAN. No. That is an order to make. We never made the product.

Mr. WALDEN. Okay. So Ms. Kaye never purchased these pills even though a check was written?

Mr. RAYMAN. That is correct.

Mr. WALDEN. What was the check for?

Mr. RAYMAN. The check was a down payment that—and the rest of the payment will be made once we delivered the pill. But we never manufactured the pill.

Mr. WALDEN. So did you refund the down payment then?

Mr. RAYMAN. I believe so, yes.

Mr. WALDEN. Were the pills ever in the process of being made?

Mr. RAYMAN. No, they never were.

Mr. WALDEN. Even when she was on national TV, they were not being made?

Mr. RAYMAN. That is correct.

Mr. WALDEN. Never at PAL Labs?

Mr. RAYMAN. No.

Mr. WALDEN. Okay. Did you feel—I am going back to the email that was sent by Ms. Kaye to PAL Labs saying, you know, time is kind of running out, I want a formula, I want it now, I want a pill targeted toward 6 year olds and up or I am going to go somewhere else. What kind of pressure did you feel? I mean, what was your response to that?

Mr. RAYMAN. As a sales person, you—you are exposed to threats, and this I felt was a threat. I wanted to make a sale, needless to say, but it was—I treated it as a threat that she might pull the business, and we had put a lot of effort in conversation wise with her.

Mr. WALDEN. And did you not end up, did your company not end up putting together a formula for the pill? You have a chemist here.

Mr. RAYMAN. We put together a formula, yes.

Mr. WALDEN. And did she sign off on the formula?

Mr. RAYMAN. I think that was signed off on the label, on I think right before she went on air.

Mr. WALDEN. In that purchase order in tab 15 the date indicates November 14, 2002 or 1 week after the email she sent. I thin that was November 7, if I recall. With a delivery date of December 19. What happened in the intervening time? When did you decide you are not going to make the pills and why?

Mr. RAYMAN. Okay. The process was once we get a formula that our customer approves and she signs off on it—

Mr. WALDEN. And that has happened in this case, right?

Mr. RAYMAN. Then we go ahead and we produce documents, supplemental facts box for the labeling which has to be signed off by the customer as well.

Mr. WALDEN. And did she do that?

Mr. RAYMAN. She did not do that until December 6.

Mr. WALDEN. Okay. But that was done.

Mr. RAYMAN. That was done on December 6.

Mr. WALDEN. All right.

Mr. RAYMAN. All right. And then we—we would then go ahead and start to order raw materials to manufacture the product.

Mr. WALDEN. What changed? What did you decide not to manufacture?

Mr. RAYMAN. Once we found out that there was a problem with the uva ursi in the product, over that weekend, that is when we decided as a company that we no longer wanted to manufacture that product.

Mr. WALDEN. And that was your decision or was that Ms. Kaye's decision.

Mr. RAYMAN. Actually, it was Jose de la Rocha's decision.

Mr. WALDEN. And when did that occur specifically, what day?

Mr. RAYMAN. That would probably—my best guess, somewhere like that Monday or Tuesday, maybe the 8th or the 9th, or I do not know the exact dates.

Mr. WALDEN. Was that before she went on national television?

Mr. RAYMAN. No, that was after she was on national TV.

Mr. WALDEN. Okay. So everybody's agreed to the formula, she goes on national television. You have got your order, which meant a lot to you. You were being threatened. It is a \$9,000 initial order, right?

Mr. RAYMAN. Correct.

Mr. WALDEN. Mr. de la Rocha, why the change of heart?

Mr. DE LA ROCHA. Could you rephrase your question?

Mr. WALDEN. Why did you decide not to go ahead with the manufacture?

Mr. DE LA ROCHA. Because the product is not safe for children.

Mr. WALDEN. How did you determine that?

Mr. DE LA ROCHA. We—I determined that I came back from vacations. I checked the PDR. I checked what, the doctor, he was saying. He was correct. And I say this formula is not going on.

Mr. WALDEN. But who came up with the formula that you all signed off on first?

Mr. DE LA ROCHA. Yes. I came on with the formula, but I was guided through the whole process.

Mr. WALDEN. You were guided through the process?

Mr. DE LA ROCHA. Yes.

Mr. WALDEN. By whom?

Mr. DE LA ROCHA. Mr. Rayman. I do not have any contact with Ms. Kaye.

Mr. WALDEN. And he is not a chemist?

Mr. DE LA ROCHA. No, but—

Mr. WALDEN. You are the chemist, but you do not usually do formulas?

Mr. DE LA ROCHA. Yes, I do not initially do formula—

Mr. WALDEN. Have you done any formulas since, are you currently doing any formulas like this? I mean—

Mr. DE LA ROCHA. No, not at all. I do not do formulas. Would you ever formulate a pill for children?

Mr. DE LA ROCHA. No.

Mr. WALDEN. Had you ever done it before?

Mr. DE LA ROCHA. No.

Mr. WALDEN. You will not ever do it again?

Mr. DE LA ROCHA. For sure.

Mr. WALDEN. For sure.

Mr. Rayman, how come you are guiding him on the formula?

Mr. RAYMAN. I was not guiding him on the formula.

Mr. WALDEN. He says you were.

Mr. RAYMAN. I was giving him the instruction, they were coming from my customer.

Mr. WALDEN. And your customer in this case was Ms. Ray—Ms. Kaye, I'm sorry.

Mr. RAYMAN. Edita Kaye, yes.

Mr. WALDEN. But I thought she turned to your company for the formula, is that not what you testified, Ms. Kaye, that you went to an FDA approved lab because they had people that had formulas?

Ms. KAYE. Yes.

Mr. WALDEN. Turn on your mike, please, if you would. Yes, thanks.

Ms. KAYE. They had formulators, that is what I believed, who understood how to develop formulas. I am not a chemist—

Mr. WALDEN. Well, were you guiding Mr. Rayman? He says you were. What did you tell him? Did you tell him what you wanted in the concoction?

Ms. KAYE. I told him that I wanted a safe and effective product for children.

Mr. WALDEN. Mr. Rayman, is that what you heard?

Mr. RAYMAN. That was part of what I heard.

Mr. WALDEN. What else did you hear?

Mr. RAYMAN. The first formula, which was all fiber, she rejected and wanted additional products added to it.

Mr. WALDEN. I'm sorry, could you say that again?

Mr. RAYMAN. The first product that we suggested that she use was a fiber product.

Mr. WALDEN. Okay. So she gave you specific instructions. How specific were they when you say "fiber product," did she get into naming a specific type of fiber product?

Mr. RAYMAN. She did not.

Mr. WALDEN. So she just said give me a fiber product in here?

Mr. RAYMAN. She said she did not want just a fiber product.

Mr. WALDEN. What did she want besides that?

Mr. RAYMAN. That's when she—in the email she said she wanted a thermogenic and also through conversation she also said she wanted an added diuretic.

Mr. WALDEN. So thermogenic and diuretic.

Is that true, Ms. Kaye? Is that what you told him?

Ms. KAYE. I told him about the thermogenic, which I believed would add energy so that children could be more active.

Mr. WALDEN. Opps, that clicked off again. Sorry.

Ms. KAYE. The rest of the ingredients including the diuretic—the fiber came because there was not in fact another product available for sale that contained—

Mr. WALDEN. That's the PediaLean, or whatever?

Ms. KAYE. Correct.

Mr. WALDEN. Okay.

Ms. KAYE. That contained fiber.

Mr. WALDEN. All right.

Ms. KAYE. And PAL Laboratories brought that product to my attention. I purchased that product. And in conversations it was de-

terminated that PAL Laboratories said it was a fiber formula and that they could improve on it. And I said fine.

Mr. WALDEN. Is that your recollection, Mr. Rayman?

Mr. RAYMAN. I know we talked about a fiber product. I do not have a recollection of improving upon it. I know as Edita was telling me that there were certain things that she wanted added to it.

Mr. WALDEN. But that is as specific as she got?

Mr. RAYMAN. The thermogenic and the diuretic.

Mr. WALDEN. Okay. And Mr. de la Rocha, is that what you heard then from Mr. Rayman?

Mr. DE LA ROCHA. Yes, sir.

Mr. WALDEN. So it was very generic sort of put a thermogenic in here and a diuretic, and some fiber?

Mr. DE LA ROCHA. Yes, sir.

Mr. WALDEN. Throw it together and give it to me for 6 year olds. Do any of you every worry about the impact of this stuff on kids?

Mr. RAYMAN. Yes, sir. Certainly.

Mr. WALDEN. Then why would you create these formulas and go along with it to the point of the client agreeing to the formula on any—do you believe in clinical trials that are real?

Mr. DE LA ROCHA. Yes, sir.

Mr. WALDEN. You are all shaking your heads.

Do any of you today manufacture products that have not been through clinical trials? Let us start right over here and work that way. Any of you in companies make things today that have not been through peer review clinical trials?

Mr. GAY. We do have food products that do not have trials.

Mr. WALDEN. You do?

Mr. GAY. Yes.

Mr. WALDEN. Okay. All right.

Mr. Gay, or Mr. Barash?

Mr. BARASH. I am not in the industry anymore.

Mr. WALDEN. You are not? Okay.

Mr. REGALADO. We do not manufacture any product. We are a marketing company and we rely on the information given to us from formulation companies.

Mr. WALDEN. All right.

Mr. REGALADO. And, in fact, the ingredients in most of what we use have had clinical trials, the ingredients.

Mr. WALDEN. But not in that combination?

Mr. REGALADO. Correct.

Mr. WALDEN. And you know that when you are doing the marketing, because you do not really care about what is it in? You take what they give you and you figure out how to spin it.

Mr. REGALADO. Well, it is not that we do not care. We trust the people that we work with and those are GNP certified laboratories with staff and so forth.

Mr. WALDEN. Right.

Let us go on down. Anybody else make dietary products that—

Mr. RAYMAN. Yes, we make dietary products.

Mr. WALDEN. [continuing] still that do not have real clinical trials?

Mr. RAYMAN. Yes, that is correct.

Mr. WALDEN. Okay. All right.

Thank you, Mr. Chairman.

Mr. GREENWOOD. The Chair thanks the gentleman, and recognizes himself for 10 minutes for a second round.

This is the assessment then, the conclusion that I am coming to from what I have heard so far. And that is that any scam artists or group of scam artists who wants to get rich quick, preying on the emotional pain of people suffering weight loss can go to a phony laboratory, give a screwball list of ingredients that are not proven to do a darn thing, put it in a pill, put the pill in a bottle, put the bottle in a box and make a mint. That is my conclusion from what I have heard today.

Now, I would like to know if anyone on the panel disagrees with that conclusion? Okay. Mr. Gay, why do you not tell me what is wrong with that conclusion?

Mr. GAY. I think that is, with all due respect, Congressman, I think that is a generalization. We build our company on a completely different basis. Dr. Mowrey, worked with him, he has been well published.

Mr. GREENWOOD. Okay. Well, let us talk about Dr. Mowrey, you can feel free to jump in here as you like. Because you just said—Mr. Gay, you said my conclusion is wrong because you rely on people like Mr. Mowrey.

Now, Mr. Mowrey is, as I understand it, has no—you have a degree in psychology, is that right, sir?

Dr. MOWREY. That is correct.

Mr. GREENWOOD. All right. So you have a degree in psychology. And I also understand that you have never studied botany, is that correct?

Dr. MOWREY. I have studied botany over the years. Yes, I have. I have a degree in experimental psychology, I would like to clarify that a little bit.

Mr. GREENWOOD. Okay. You have a degree in experimental—

Dr. MOWREY. So a scientific background then. Yes.

Mr. GREENWOOD. Okay. What is experimental psychology, Dr. Mowrey?

Dr. MOWREY. Experimental psychology, if we were to differentiate with, say, from clinical psychological which deals with treating problems such as one would come in for counseling, that sort of thing, experimental psychology deals more on a research basis—

Mr. GREENWOOD. Okay. Let me stop you there. Let me stop you.

Mr. Gay, you just said you—

Dr. MOWREY. I'm sorry.

Mr. GREENWOOD. My assessment of this industry is not a good one because you, for instance, rely on Dr. Mowrey to put together your formulations. And after all, he has a degree in experimental psychology.

Mr. GAY. He is well written.

Mr. GREENWOOD. And here is a quote from Mowrey from his book the Scientific Validation of Herbal Medicine, "The scientific method is a powerful tool, but it has its limits. Medical science in America is a unique combination of economic and political factors which fuse together almost religiously to promote synthesized, highly active chemicals." That is a quote from your expert.

Would you tell me how it is that you can rely on Dr. Mowrey who does not know the first thing about how to help people lose weight and yet you let him throw together your ingredients that you market, and what is his expertise to do that?

You know, there are lots of really qualified physicians in this country, there are lots of qualified dieticians in this country to whom you could turn to get some actual valid good information, but you turn to Dr. Mowrey who has a degree in experimental psychology. Could you explain that?

Mr. GAY. Congressman, with all due respect, Dr. Mowrey is well published in the herbal—

Mr. GREENWOOD. Anybody can be well published. All you have to do is write a book and promote it. That does not mean you know anything.

Your reliance on him is because he is well published, not because he is well educated, not because he is skilled, not because he knows anything?

Mr. GAY. He is a very well recognized in the dietary supplement industry as being knowledgeable.

Mr. GREENWOOD. But what does the fact that he is very well recognized have to do with his qualifications?

Mr. GAY. Mr. Chairman—

Mr. GREENWOOD. Yes.

Mr. GAY. [continuing] it is not just Dr. Mowrey that we rely on.

Mr. GREENWOOD. Okay. Tell me who else you rely on?

Mr. GAY. Okay. I'll finish talking about the company.

Mr. GREENWOOD. Okay.

Mr. GAY. We started off the company and decided that we were going to build a company. We used Dr. Mowrey to review research that has already been done by other people, other companies and then we—after we assess that research, then we take that research and turn it into a dietary supplement.

Mr. GREENWOOD. Like Zantrex-3?

Mr. GAY. Yes.

Mr. GREENWOOD. Zantrex-3. Okay. Main herbs in Zantrex-3 are guarana, yerba mate and damiana coupled with caffeine, ginseng and green tea. Right? Okay. Who is the expert that told you that is a good way—is that a correct description of the ingredients of Zantrex-3?

Mr. GAY. I believe it is.

Mr. GREENWOOD. Who is the expert that told you that is a good way for people to lose weight ingesting those?

Mr. GAY. Congressman, I thought we are here to talk about children, overweight children and products for—

Mr. GREENWOOD. No. Actually we are here to talk about the entire industry. But I would like you to just—before I leave this, can you tell me upon which expert you relied to determine that that is a good formula to help people lose weight?

Mr. GAY. Mr. Mowrey and Dr. Chevreau.

Mr. GREENWOOD. Okay.

And Dr. Chevreau, let me turn to you. How did you formulate these ingredients?

Ms. CHEVREAU. Based on my credential—

Mr. GREENWOOD. Which are?

Ms. CHEVREAU. My education. I am a Ph.D in chemistry, I have a master's in foods and nutrition and I am a registered dietician.

Mr. GREENWOOD. Okay.

Ms. CHEVREAU. So my qualification permits me to put products or give me the knowledge to put products together like that.

Mr. GREENWOOD. Okay. And how did you come up with those ingredients?

Ms. CHEVREAU. Based on the review of scientific literature, that is my job to look, review, study what has been published in the peer review scientific literature and make recommendation of—on ingredients.

Mr. GREENWOOD. And characterize that scientific literature, which is peer reviewed clinical studies?

Ms. CHEVREAU. Yes, correct.

Mr. GREENWOOD. Okay.

Ms. CHEVREAU. Yes, peer reviewed clinical studies.

Mr. GREENWOOD. Okay. And why do you not just cite for me on the ingredients in Zantrex and tell me about what you learned from your peer reviewed clinical studies?

Ms. CHEVREAU. In Zantrex there is a combination of three ingredients, Yerba mate, guarana and damlana, which have been studied in clinical study in Denmark.

Mr. GREENWOOD. In Denmark.

Ms. CHEVREAU. It was the combination of those three together. And our product exactly has the raw ingredients which were used in that clinical—

Mr. GREENWOOD. Do you know how many patients were involved in that clinical trial?

Ms. CHEVREAU. On top of my head, I do not remember.

Mr. GREENWOOD. Okay.

Dr. Ayoob, was I overly harsh in my characterization of this industry, particularly as it applies to children?

Mr. AYOOB. I'm sorry?

Mr. GREENWOOD. Was I overly harsh in my characterization of this industry?

Mr. AYOOB. I think you were right on the money.

Mr. GREENWOOD. Tell me why you say that?

Mr. AYOOB. These companies have made false claims. They have marketed what I have called junk science, which is making preposterous claims without enough evidence, and they do it to a very vulnerable population. Perfect for getting money. Perfect. Okay. If you want to get money out of people, you find what their weak spot is and where they are most vulnerable, and you go right for it.

And people who are either ill or have physical problems or have issues such as obesity or weight control or weight management issues are prime suspects. These are a known desperate population. They are ideally suited to giving up money to things that they think will help them, and because it is a difficult process, they think well I want a quick fix. And one of the tenants of junk science is when it—if it sounds too good to be true, it probably is or something that promises an incredible quick fix.

I certainly would never understand why a company would make a dietary supplement based on one very, very, very flawed study years ago that—I am talking about the one in PediaLean in par-

ticular. I would never even have reviewed this. It would have never—

Mr. GREENWOOD. They may not even have consulted an experimental psychologist to get information on the ingredients—

Mr. AYOOB. Very possibly.

Mr. GREENWOOD. [continuing] would be good for your health.

Mr. AYOOB. And the—and, you know, that study was so flawed. I can't even—and I tell you, it was translated from Italian. I am not sure that the study exists. There is no reference for it. It just says the Journal and it says the year, it does not give a reference. Highly unusual.

Mr. GREENWOOD. Mr. Gay, for how long have you sold PediaLean?

Mr. GAY. Since early 2002.

Mr. GREENWOOD. Okay. Do you know what quantities you have sold?

Mr. GAY. Off the top of my head, I do not.

Mr. GREENWOOD. Okay. Do you know what kind of profits you have reaped from the sale of PediaLean Mr. GAY. As I stated in my opening statement, PediaLean was part of an overall package which included the website, a support program and that for parents. It is actually at a giant loss today of several hundred thousand dollars.

Mr. GREENWOOD. It is a giant loss?

Mr. GAY. Yes, the program.

Mr. GREENWOOD. The program was a giant loss?

Mr. GAY. That is correct.

Mr. GREENWOOD. And how about the product itself?

Mr. GAY. The product—

Mr. GREENWOOD. Did you make \$580,270 in total net sales?

Mr. GAY. That is—that is gross income.

Mr. GREENWOOD. Okay. And you do not know what the profit margin on this was?

Mr. GAY. I do not.

Mr. GREENWOOD. Okay. Why did you continue to sell it for 2 years at such a loss?

Mr. GAY. Primarily because of a representation, the reason we are losing money on the product, in my opinion Congressman, is because of a representation on the website when this committee sent us a letter, they defined it as a designer steroid. And so we have not continued to advertise it there. We feel like it is a good product.

Congressman, I have nine children, me and my wife have nine children, 18 grandchildren. And I do not have any problem giving this product to my children. I love them dearly. So—

Mr. GREENWOOD. Do they take your products?

Mr. GAY. We had the—excuse me?

Mr. GREENWOOD. Do any of your nine children or 18 grandchildren ingest any of your products?

Mr. GAY. Absolutely. On a daily basis.

Mr. GREENWOOD. Okay. And including PediaLean, if that is not too personal a question?

Mr. GAY. In some cases, yes.

Mr. GREENWOOD. Okay. And with what results?

Mr. GAY. I have not monitored that. They continue to take it, so I assume they are seeing some benefit.

Mr. GREENWOOD. And do you believe—would you tell your children or grandchildren who are taking this that they could continue to enjoy their favorite foods as long as they were taking PediaLean?

Mr. GAY. With restricted—yes, because I do not think they're going to use very much when they take PediaLean.

Mr. GREENWOOD. Okay. And what studies have demonstrated that?

Mr. GAY. I will let Dr. Mowrey speak to that.

Mr. GREENWOOD. Okay. Dr. Mowrey, could you share with us what studies have demonstrated that PediaLean suppresses appetite?

Dr. MOWREY. The study that you are referring to undoubtedly, Mr. Congressman, is the Italian study that has been introduced here in conversation already. That study did not necessarily address appetite suppression. It is simply found that a group of children who were exposed to a normal caloric and exercise program, and also took the recommended amount of the PediaLean equivalent, the exact same material that is in PediaLean, we will call it Dicoman-5, they lost a greater percentage of their degree of overweight than did the children who were just doing the exercise and—

Mr. GREENWOOD. Okay. My time has expired. But, Dr. Mowrey, you have heard Dr. Ayoob and others in our first panel characterize that study as pathetic.

Dr. MOWREY. Yes. Yes, I have.

Mr. GREENWOOD. Okay. And when you take into consideration the smallness of the sample size, the fact that there were no controls, the fact that people dropped out of that study and that that was not calculated into the results, you must know that that study is laughable, is a laughable idea that you would base the sales of products to marketing products to millions of children based on an absurdly, grotesquely, inadequate, laughable—I cannot think of the next adjective to describe that study. How can you in good conscience do that?

Dr. MOWREY. Mr. Chairman?

Mr. GREENWOOD. Yes.

Dr. MOWREY. Part of the job that I do as a consultant for Basic Research is to review the world's literature on these kinds of problems, especially related to—

Mr. GREENWOOD. And the world's literature on this product consists of this one stupidly, ridiculously, inadequate study; that is the world's literature on this product? And on the basis of that you would market it?

Dr. MOWREY. That is—the world's literature on children's weight loss or children's obesity is not very extensive in terms of actual products that help out in this regard. This product—

Mr. GREENWOOD. Well, I am sure Dr. Ayoob will correct that very briefly, and then I will yield.

Dr. MOWREY. This product is—

Mr. GREENWOOD. Dr. Ayoob?

Dr. MOWREY. This product—I am sorry.

Mr. GREENWOOD. Wait a minute. Let me just turn to Dr. Ayooob—

Dr. MOWREY. Can I please answer your question, Mr. Congressman?

Mr. GREENWOOD. Well, you just made a statement and you said that the world's literature on—

Dr. MOWREY. I was answering your question. I am trying to answer your question. I am trying to answer your question on why—

Mr. GREENWOOD. Well, you did answer my question.

Dr. MOWREY. On why—

Mr. GREENWOOD. I asked you on what research you based your study, you told me it was the Italian research, which is laughable, and that there is not much else out there in the world of literature on childhood obesity. I am going to ask Dr. Ayooob is that a fair statement.

Mr. AYOOB. No, it is not.

Mr. BURBAGE. May the record show that Mr. Mowrey was not allowed to answer the question. There were three questions posed.

Mr. GREENWOOD. Well, we have time constraints here. I am already 5 minutes over my time. But we will come back to Dr. Mowrey.

The gentlelady from Colorado.

Ms. DEGETTE. Thank you, Mr. Chairman.

Mr. Gay, you said something that peaked my interest. You said that you have a number of relatives who are on PediaLean, is that right, or other supplements that your company makes?

Mr. GAY. Congresswoman, that implies to me that they're actively on it. I see them take them.

Ms. DEGETTE. Okay. PediaLean is not intended as a permanent dietary supplement, but rather a temporary weight loss tool, correct?

Mr. GAY. Along with diet and exercise.

Ms. DEGETTE. Along with diet and exercise.

Mr. GAY. Correct.

Ms. DEGETTE. So I guess I was interested when you said that your relatives on are on this. Have you seen them lose any weight from PediaLean?

Mr. GAY. Again, I have not monitored that.

Ms. DEGETTE. You do not know? You do not know if your own relatives, which take PediaLean, have lost weight?

Mr. GAY. Again, I have not monitored that.

Ms. DEGETTE. Okay.

Dr. Chevreau, I want to talk to you a little bit about the clinical basis for PediaLean, since you seem to be the only one with any kind of scientific background here that might lend itself to develop of dietary supplements.

As I understand it, PediaLean's formula is based on, you say it is based on clinical studies and so on. It is really based on the one Italian study from 1992, correct?

Ms. CHEVREAU. Incorrect, to a certain extent.

Ms. DEGETTE. Okay. What other studies did you rely on in the development of PediaLean?

Ms. CHEVREAU. I relied on—okay. Pedialean, let me back up for a second. PediaLean is up of a very specific type of glucomannan.

Ms. DEGETTE. Yes.

Ms. CHEVREAU. In that type of glucomannan called Dicoman-5, there are four adult study, four clinical study—

Ms. DEGETTE. And what are those four studies, please?

Ms. CHEVREAU. The name of them?

Ms. DEGETTE. Yes. Well, actually, Mr. Chairman, I would ask unanimous consent to have Dr. Chevreau supplement her testimony just by giving us the titles and names of those studies, and if possible copies of those studies. Would that be all right, Doctor?

Ms. CHEVREAU. Yes.

Ms. DEGETTE. Thank you.

Ms. CHEVREAU. Absolutely.

Ms. DEGETTE. Now let me say, though, PediaLean is specifically marketed to children, correct?

Ms. CHEVREAU. Yes. And four children study—I did not finish sentence.

Ms. DEGETTE. There are also four children studies?

Ms. CHEVREAU. That is correct.

Ms. DEGETTE. Ah. What are those studies, please?

Ms. CHEVREAU. You mean the name of them?

Ms. DEGETTE. Yes.

Ms. CHEVREAU. The author?

Ms. DEGETTE. Yes, where they were conducted and what journal they were published in?

Ms. CHEVREAU. The one we are referring to, the literary one—

Ms. DEGETTE. The Italian study from—

Ms. CHEVREAU. I would like to make the point—

Ms. DEGETTE. Well, we will talk about that in a minute. What are the other three studies?

Ms. CHEVREAU. The name of the author—study I know, I do not pronounce, it is an Italian author also. Another Italian—

Ms. DEGETTE. Okay. Where was that study published?

Ms. CHEVREAU. Oggi.

Ms. DEGETTE. And do we have a copy of that study? That is a second study?

Ms. CHEVREAU. I think so.

Ms. DEGETTE. On children?

Ms. CHEVREAU. Correct.

Ms. DEGETTE. And when was that study conducted?

Ms. CHEVREAU. 1991/92—

Ms. DEGETTE. The same time as the study that we have?

Ms. CHEVREAU. About.

Ms. DEGETTE. Okay. And the third study?

Ms. CHEVREAU. By Vito, V-I-T-O.

Ms. DEGETTE. Yes.

Ms. CHEVREAU. Italian study also.

Ms. DEGETTE. And where was that published?

Ms. CHEVREAU. Minerva—I will have to go back to the study.

Ms. DEGETTE. Okay. Doctor, would you please supplement if you have copies of those studies, that would be great.

Ms. CHEVREAU. I do. I do.

Ms. DEGETTE. Now, do you know the sample sizes of each of those studies?

Ms. CHEVREAU. Yes, I do.

Ms. DEGETTE. And how big are those sample sizes? So you relied on four Italian studies done at approximately the same time about 12 years ago, correct?

Ms. CHEVREAU. That is correct.

Ms. DEGETTE. All right. And what were the sample sizes?

Ms. CHEVREAU. In order to be exactly accurate, I will have to get my binder and look into it.

Ms. DEGETTE. Okay. Well, let us just talk about the main one that we are talking about today, the one Libieri.

Ms. CHEVREAU. Correct.

Ms. DEGETTE. Actually, was Libieri involved in all those four studies?

Ms. CHEVREAU. No.

Ms. DEGETTE. Okay. Now that study as 23 obese children, correct?

Ms. CHEVREAU. Complete the study, yes.

Ms. DEGETTE. Who completed the study? A number of children dropped out of the study, right?

Ms. CHEVREAU. That is correct.

Ms. DEGETTE. Now, those children were never followed to see why they dropped out, were they?

Ms. CHEVREAU. It is not indicated in the paper, correct.

Ms. DEGETTE. Okay. So you do not know? Now, that would be a standard technique in a clinical study, right?

Ms. CHEVREAU. It is.

Ms. DEGETTE. To follow those and see why they dropped out? For example, if you had 36 children who started in a study, 12 of them dropped out because they had abdominal pain and discomfort. You would want to know that, correct?

Ms. CHEVREAU. They indicated that a number of them who dropped out because of abdominal—

Ms. DEGETTE. Right. Did that concern you?

Ms. CHEVREAU. No.

Ms. DEGETTE. Well, why not? It seems like about a third of the children suffered some side effects from this root?

Ms. CHEVREAU. No, that is only five out of 30. That is not—

Ms. DEGETTE. Oh, I am sorry. Only five out of 30. Well, that is still one-sixth, right?

Ms. CHEVREAU. That is—this is not uncommon on clinical trials.

Ms. DEGETTE. Dr. Ayoob, I would ask you is this a common occurrence in clinical trials?

Mr. AYOOB. I would say if this is the study that they are advertising on their website as clinical proof, it leaves something to be desired. This is the study they are putting as their “best foot forward,” so to speak. I have a problem with a study that is so flawed. Congressman Greenwood put right in the money. It was laughable. And to say that—I think it was something like 14 percent of this very small population dropped out because of abdominal pains, and why the others dropped out we do not know.

Ms. DEGETTE. We do not know. It could have been—

Mr. AYOOB. It could have been the same thing. They just never bothered to come back and report.

Ms. DEGETTE. It could have been esophageal obstruction.

Mr. AYOOB. Exactly. I mean, it—

Ms. DEGETTE. Yes, we just do not know.

And Dr. Chevreau, I want to ask you about that because Dr. Hoppin talked a lot about this as well. One of the side effects, and this was in this Italian study, was esophageal obstruction.

Ms. CHEVREAU. No.

Ms. DEGETTE. Oh, I am sorry. No. I am sorry. This is a side effect of this root that has been demonstrated in adult women, correct?

Ms. CHEVREAU. No. Your comment is incorrect. Certain type of glucomannan has been associated with esophageal obstruction. The specific grade of glucomannan that we are using in PediaLean has not been associated with esophageal obstruction.

Ms. DEGETTE. The grade?

Ms. CHEVREAU. The grade.

Ms. DEGETTE. In other words, the amount to which it is ground?

Ms. CHEVREAU. Correct.

Ms. DEGETTE. Okay.

Ms. CHEVREAU. And purified.

Ms. DEGETTE. Now did you ever do any clinical trials? And I know you are not required to under the law, but all of you are holding yourselves up to a higher standard. So my question is did you ever do any clinical trials on this particular grade of the substance?

Ms. CHEVREAU. I submitted—I wrote a grant, proposal to the ASBIR program of NIH to request some money to do studies. Because as a small business and limited resources, we felt that we would like to do a study.

Ms. DEGETTE. And you did not do a study, though, did you?

Ms. CHEVREAU. We did not get funding from NIH—

Ms. DEGETTE. So you did not do the study, right? Yes, I mean, I did not ask you did you write a grant. I asked you did you do a study, and the answer is no correct?

Ms. CHEVREAU. It is no.

Ms. DEGETTE. Now, did you try to—do you know of studies that say this particular grade of the substance does not cause esophageal obstruction?

Ms. CHEVREAU. The four Italian study I am referring to use that particular grade and none indicated esophageal obstruction.

Ms. DEGETTE. Right. But as Dr. Ayoob is pointing out, we do not know why some of those kids left the study that you are putting out on your website, why they left. I mean, it could have been for this reason, we do not know one way the other, do we?

Ms. CHEVREAU. With due respect, we have talked to Dr. Libieri.

Ms. DEGETTE. Okay. But that is not a scientific technique. He would put it in his paper, right?

Ms. CHEVREAU. He is a woman.

Ms. DEGETTE. Her, sorry. She would put it in her paper then, right?

Ms. CHEVREAU. Excuse me?

Ms. DEGETTE. If she knew what happened to those people who left the study, she would follow up and put it in her paper. That is the science—I am not a scientist, but that would be part of the study.

Ms. CHEVREAU. That is correct, yes.

Ms. DEGETTE. Well let me ask you then, you did not ever do any tasks on this particular product, PediaLean, that was marketed to children, correct?

Ms. CHEVREAU. Correct.

Ms. DEGETTE. Now, one of the things I am concerned, because as described, I was a little bit relieved, frankly, to learn No. 1 your product unlike some of these other products just contains fiber, right?

Ms. CHEVREAU. Correct.

Ms. DEGETTE. And so it did not have the diuretics or stimulants that some of these other substances have. And it is in a capsule form, right?

Ms. CHEVREAU. Correct.

Ms. DEGETTE. so that made me feel like, well, you know maybe it is not that unsafe. But then when I looked on the box a few minutes ago, and I talked about this before, it says “Special note: If your child has difficulty swallowing capsules, do not worry. The PediaLean formula can be sprinkled between a small piece of bread, onto a spoonful of applesauce, peanut butter or yogurt, just about any food.” And that makes me concerned because what is it gets into the esophagus and expands? Have you ever done studies sprinkling PediaLean on these breaks or putting them in these foods?

Ms. CHEVREAU. Yes.

Ms. DEGETTE. You did?

Ms. CHEVREAU. Yes.

Ms. DEGETTE. Tell me about that study. How big was the sample?

Ms. CHEVREAU. It was not a clinical study, but we did do the best.

Ms. DEGETTE. How did you do the test?

Ms. CHEVREAU. When the investigator came to Salt Lake City back in March, I did to her a demonstration when I put PediaLean in a glass of water and show it to her how long it took to become a soft gelatinous mass.

Ms. DEGETTE. Right. That’s the capsule in the water, right?

Ms. CHEVREAU. No, no, no. The powder.

Ms. DEGETTE. The powder. Okay.

Ms. CHEVREAU. The actual powder. We put the powder, three capsules, the content of three capsules in water in a glass of water, a cup, and for 2 days she observed that. And at the end of 2 days she still had a very soft gelatinous mass which in no way or shape would cause obstruction?

Ms. DEGETTE. And that was the test you did? Now, the investigator—

Ms. CHEVREAU. No, that was the test I did in front of the investigator.

Ms. DEGETTE. Okay, that was the investigator from the FTC?

Ms. CHEVREAU. It was the lady—

Ms. DEGETTE. Investigator from the committee, this young woman sitting here?

Ms. CHEVREAU. Yes. Yes.

Ms. DEGETTE. And that was after you were already marketing PediaLean?

Ms. CHEVREAU. That is correct.

Ms. DEGETTE. Yes. Yes. Did you do any tests on bread or applesauce before?

Ms. CHEVREAU. Yes, I did.

Ms. DEGETTE. Tell me about that.

Ms. CHEVREAU. I am a bench chemist from training. I have tried all the different compilation of mixing, of different medium whether it was in vinegar to mimic the stomach acid or making more alkaline to observe—

Ms. DEGETTE. Was this documented? Did you write it down, the results? Did you measure how long it took to dissolve?

Ms. CHEVREAU. Or to gel, yes.

Ms. DEGETTE. Yes, you—with the vinegar and the break and the applesauce?

Ms. CHEVREAU. I do not recall on the top of my head but I would suspect it is my lab books.

Ms. DEGETTE. Did you mix this with applesauce? Now, I want to tell you, and I do not say this to be threatening in anyway. I do not want to make you go into a trap, okay.

Did you test this substance with applesauce?

Ms. CHEVREAU. Yes.

Ms. DEGETTE. And did you test it with peanut butter?

Ms. CHEVREAU. Yes.

Ms. DEGETTE. And did you sprinkle on a piece of bread?

Ms. CHEVREAU. Yes.

Ms. DEGETTE. And then what did you do?

Ms. CHEVREAU. I observed it over some period of time to see what was the reaction, whether it was going to become a hard gel.

Ms. DEGETTE. All right. Now, did you ever feed it to children?

Ms. CHEVREAU. Yes.

Ms. DEGETTE. Okay. How many children did you feed it to?

Ms. CHEVREAU. I used my neighbor's children.

Ms. DEGETTE. How many of them?

Ms. CHEVREAU. Three.

Ms. DEGETTE. And you fed it to them on bread, on peanut butter, okay?

Ms. CHEVREAU. Yes.

Ms. DEGETTE. And is this all documented in your lab books? I want you to really think hard about these answers. I am not trying to put you into a trap, okay.

Ms. CHEVREAU. I will have to go back to my lab book and—

Ms. DEGETTE. Would you be willing to give us that lab book?

Ms. CHEVREAU. Yes.

Ms. DEGETTE. Okay. Now, by the way, did your neighbor's children lose weight?

Ms. CHEVREAU. No. We did it a couple of times.

Ms. DEGETTE. Okay.

Ms. CHEVREAU. It was not intended for them to take that on a daily basis.

Ms. DEGETTE. It was not, as Mr. Greenwood fairly points out, it was not efficacy, it was for safety?

Ms. CHEVREAU. Correct.

Ms. DEGETTE. And was that all the children you tested it on, or did you test it on other children?

Ms. CHEVREAU. No. I did not test on other children.

Ms. DEGETTE. Thank you.

Mr. Chairman, thank for your comment.

Mr. GREENWOOD. Thank you.

The Chair recognizes himself for 10 minutes.

Mr. Gay, I may have cut you off a little short when you were talking about different experts on which you rely. You talked about Mowrey and Dr. Chevreau. My understanding is you rely on Dr. Friedlander as well, on his—Mr. Friedlander. I'm sorry. You rely on Friedlander?

Mr. GAY. Not for the science.

Mr. GREENWOOD. Pardon me?

Mr. GAY. Not for the science.

Mr. GREENWOOD. But then for what?

Mr. GAY. Primarily as a marketing consultant.

Mr. GREENWOOD. Okay. And describe what Mr. Friedlander does for your company as a marketing consultant.

Mr. GAY. Helps prepare, consults with Dr. Mowrey, Dr. Chevreau and other doctors that particular formulations and kinds of products and marketing strategies.

Ms. KAYE. Excuse me. May I be excused for about 2 minutes?

Mr. GREENWOOD. Yes, you may.

Ms. KAYE. Thank you.

Mr. GREENWOOD. Just bear with me, please.

Look at tab 87, Mr. Gay. Do you see that. It says at the top "Twenty-fourth story of level 2 printed in full format," do you see that?

Mr. GAY. Yes.

Mr. GREENWOOD. Okay. It says "A man accused of making millions by selling worthless mail order cures for ills from impotency to baldness to obesity has been banished from living and working in Florida. Mitchell Friedlander, the 38 year old owner of Robertson Taylor Company entered pleas of no contest Tuesday to 13 charges of operating a scheme to defraud." Is that the same Mr. Friedlander upon whom you rely for your marketing expertise?

Mr. GAY. I believe it is.

Mr. GREENWOOD. Okay. Again, Mr. Gay, I do not know if I was overly harsh about describing your industry as one in which scam artists can make a lot of money preying on the emotions of people. For instance, I guess is it Mr. Friedlander who put together this ad which ran in Redbook, "If your child is overweight and it is destroying both your lives, European breakthrough gives hope to you and your overweight child." Did Mr. Friedlander—I will ask you directly Mr. Friedlander, did you put together this advertisement?

Mr. FRIEDLANDER. I was involved with putting it together, yes. I was involved in putting it together. Yes, sir.

Mr. GREENWOOD. Okay. And so when you say "the European breakthrough," what did you mean when you wrote the words "European breakthrough"?

Mr. FRIEDLANDER. The studies were conducted in Italy and—
Mr. GREENWOOD. Oh, that study? That is the European breakthrough?

Mr. FRIEDLANDER. As far as that study. Dr. Ayoob suggested that the study might exist. It is available on the Pubmed, which is the national—the data base for the National Library of Medicine. Anybody who wanted to look for the study could find it.

Mr. GREENWOOD. Well, you have heard that story. You have heard the way people who know what they are talking about describe that, people who understand scientific studies have describe this study as laughable.

Mr. FRIEDLANDER. Well—

Mr. GREENWOOD. You disagree with that?

Mr. FRIEDLANDER. Yes, I do, sir. With all due respect the study was a published peer review clinical trial. It means that other experts in the area of pediatrics reviewed the study—

Mr. GREENWOOD. Who conducted the study?

Mr. FRIEDLANDER. Dr. Libieri.

Mr. GREENWOOD. Okay.

Mr. FRIEDLANDER. He conducted the study.

Mr. GREENWOOD. And what are his credentials?

Mr. FRIEDLANDER. Excuse me?

Mr. GREENWOOD. What are his credentials?

Mr. FRIEDLANDER. Doctor—it is a she, and she is an M.D., a pediatric doctor.

Mr. GREENWOOD. Okay. And the fact that the study had no control group—

Mr. FRIEDLANDER. No, it did have a control group, at least a control group as defined by the Food and Drug Administration. They list the number of controls and the type of controls that are used in clinical trials. This is a concurrent control. It was a substance that was tested up against diet and exercise alone. That is what was done. To say that it was not controlled is silly.

The other thing that you said—

Mr. GREENWOOD. Well, let us go back to Dr. Ayoob again. Mr. Friedlander is actually going to defend the value of this study, so would you respond to his defense?

Mr. AYOOB. Yes. In terms of the controls, those controls were not placebo controlled. That means that they are not particularly valid. What you are doing is you are testing, giving these pills to kids to or three times a day against not giving them. And you are attributing the results to the actual ingredient in the pill.

What a good placebo controlled trial would have done is given a placebo pill with the same amount of water to an equally matched group of children.

Also with that—as I said—

Mr. GREENWOOD. That is pretty much clinical control 101?

Mr. AYOOB. Oh, yes. Yes.

Mr. GREENWOOD. That is as fundamental as it gets?

Mr. AYOOB. Absolutely.

Mr. GREENWOOD. Is he wrong, Mr. Friedlander?

Mr. FRIEDLANDER. Well, he might not be wrong and you might not be wrong. But if I am wrong, so is the Food and Drug Adminis-

tration. And I refer to 21 CFR 314.126 which lists the type of controls that are available to use in clinical trials.

I know you are very emotional, but—

Mr. GREENWOOD. Address your questions to the committee please, Mr. Friedlander.

Mr. FRIEDLANDER. I'm sorry. But let's not blow this out proportion. There are other controls besides a double-blinded placebo controlled trial. As a matter of fact, Hoffman-LaRoche just released a study that was done all—on children that was—the study protocol was exactly the same as the Libieri study. It was just in the newspapers just the other day. And—

Ms. DEGETTE. Would the chairman yield?

Mr. GREENWOOD. I will yield to the gentlelady from Colorado.

Ms. DEGETTE. I have got to say, Mr. Friedlander—

Mr. FRIEDLANDER. Excuse me.

Ms. DEGETTE. [continuing] if a clinical trial using this methodology were submitted to the FDA for a drug, which is what they, you know, approve; they do not approve dietary supplements in the same way, this would have been laughed out of the FDA. And I think you now that as well as anybody.

This clinical trial was loose, at best. Thank you.

Mr. FRIEDLANDER. Again, Ms. DeGette, I am sorry that I have to disagree with you, but—and I will get you the statute. This was an awfully robust clinical trial. The p-value or the confidence value was .005. There is a statute—.0005. There is a statute in the FDA regulation—in the FDA Act which provides that studies with that robust of result only require one clinical trial, as long as there other supporting evidence that suggests that the trial was done correctly.

Mr. GREENWOOD. Well, reclaiming my time.

Mr. Gay, Mr. Friedlander seems like a nice guy, but he is also pled no contest to a long string of charges that had to do with selling worthless mail order cures for ills. Of all the experts in the world, why would you choose someone, how would you expect to build the credibility of your company by choosing someone with that background? I understand that he is—he had a suspended 1 year jail term, they put him on probation for 5 years and barred him from doing business or living in Florida. Why would this be—Dr. Mowrey is your expert on science, Dr. Friedlander is your expert on marketing.

Mr. FRIEDLANDER. I am not a doctor, sir.

Mr. GREENWOOD. I am sorry. Mr. Friedlander. This troubles us that these are the experts with whom you surrounded yourself and you are sitting here trying to convince us that you are legitimate business.

Mr. GAY. Actually, I am not trying to convince you of anything. You asked me here.

Mr. GREENWOOD. Right.

Mr. GAY. I am telling you the facts.

Mr. GREENWOOD. Right.

Mr. GAY. And the facts are this supplement that we are talking about in PediaLean, it is a food product. We eat it in ice cream. We eat it in cookies. We eat it imitation crab on a regular basis. And to say that it causes kinds of problems and they are outside,

it has not been studied for safety; it is something we ingest on a regular basis. It is a food product.

The thing that is revolutionary about this is the way it was applied.

Mr. GREENWOOD. Well, why did you not test it yourself? Why would you rely on—

Mr. GAY. I did test it myself.

Mr. GREENWOOD. No. In a clinical study?

Mr. GAY. No.

Mr. GREENWOOD. Well, what do you mean you tested it yourself?

Mr. GAY. Because that is not our business model. We think that the American public, that is our business model—

Mr. GREENWOOD. Which is what is your business model?

Mr. GAY. Deserves the right to food markets that are out there in the marketplace that can be used to benefit them and with basic research. And that is what this is, is basic research. It is not a drug.

Mr. GREENWOOD. And you do not have any qualms about using that same business plan to products that are marketed to 6 year old children?

Mr. GAY. The business plan had a study that was peer reviewed, published in a journal for studies. I used to Friedlander for marketing ideas. I used Dr. Chevreau primarily, Dr. Mowrey secondarily on this particular product to review the studies, are there to make sure we did not have—that we were within the guidelines that we needed to be—

Mr. GREENWOOD. I am a little confused about the four studies. Your advertisement only talks about one study. What are the other studies?

Mr. GAY. Those are the studies that Dr. Chevreau promised to offer to Congresswoman DeGette. She talked about them earlier.

Mr. GREENWOOD. Wait a minute. Which studies? Giving her next door neighbor's children your—

Mr. GAY. No.

Mr. GREENWOOD. Oh, these four—

Mr. GAY. Yes.

Mr. GREENWOOD. Okay. Well, why did you not say four studies in your ads? I am a little confused about that?

Mr. GAY. Did not need to. Felt like we had the substantiation.

Mr. GREENWOOD. Okay. At one point you had on your website BBB Online Reliability Program. BBB normally stands for Better Business Bureau. And then you took it off your website. Two different versions. Is there reason for that?

Mr. GAY. Yes.

Mr. GREENWOOD. What is the reason?

Mr. GAY. We are no longer a member of the BBB.

Mr. GREENWOOD. Why is that? I thought that would be helpful in gaining confidence in your consumers, would it not?

Mr. GAY. Maybe. But we restructured the company a couple of years ago. When we restructured the company we had to go back to the BBB and get reapproved for—

Mr. GREENWOOD. So this is the Better Business Bureau?

Mr. GAY. That is correct.

Mr. GREENWOOD. Okay. And you had to get approved and what?

Mr. GAY. We just have not done that. Did not see a need for it.

Mr. GREENWOOD. Did not see a need for it?

Mr. GAY. Correct.

Mr. GREENWOOD. Okay. Saw a need for it originally, but then did not see a need for it more recent.

Is there any reason to think that you might have difficulty getting the Better Business Bureau's approval?

Mr. GAY. No. Just I think the cost and expense of going through the process for the different entities for different product lines.

Mr. GREENWOOD. Okay.

My time has expired.

The gentlelady from Colorado?

Ms. DEGETTE. I do not have anymore questions, Mr. Chairman.

Mr. GREENWOOD. Okay. We thank the witnesses for your appearance today, and you are excused.

And the hearing is adjourned.

[Whereupon, at 1:54 p.m., the hearing was adjourned.]

[Additional material submitted for the record follows:]

Tab	Document Description	Date
Documents for Skinny Pill		
1	Skinny.com Detail Page	
2	Skinny.com - Skinny Store	
3	Skinny.com - Skinny Kids Detail Page	
4	Show: CNN - Connie Chung Tonight	12/9/2002
5	Show: NBC - Today Show	
6	Irish Examiner Article - 'Skinny Pills' for Obese Children Criticised as 'Junk Science' - by Tom Kelly	12/7/2002
7	Response to Committee Re: The Fountain of Youth Group, LLC from Stuart Lee Friedel - Davis & Gilbert LLP	3/3/2003
8	Response to Committee Re: The Fountain of Youth Group, LLC from Andrew Herman, Brand & Frulla - with a news release re: The Fountain of Youth Group's Self-Regulation	3/12/2003
9	Response to Committee Re: The Fountain of Youth Group, LLC and Ms. Kaye's unwillingness	6/10/2004
10	FTC Press Release - "The 'Skinny Pills' Do Not Make you Skinny"	2/4/2004
11	US District Court Middle District of Florida Complaint Filed Against Edita Kaye, FTC - Plaintiff - Complaint For Injunctive and Other Equitable Relief	
12	US District Court Middle District of Florida Complaint Filed Against Edita Kaye, FTC - Plaintiff - Stipulated Final Order For Permanent Injunction	
13	Email - To Jerry Rayman From Edita Re: Skinny Pill Salability	11/7/2002
14	PAL Laboratories Fact Sheet Re: Skinny Pill for Kids	
15	Skinny Pill for Kids Formula Purchase Order	11/14/2002
16	Copy of Check to PAL Labs from "The Skinny Pill"	11/14/2002
17	Quotation Re: Skinny Pill Order	11/25/2002
18	Purchase Order "On Hold" - Vendor John Henry Co.	12/20/2002
19	Email - From Silvana Coronado to Jackie Gutierrez - Subject: Skinny Pill for Kids Label	11/6/2002
20	PAL Laboratories Packaging Specifications - Customer: Fountain of Youth Group, Inc.	11/25/2002
21	PAL Laboratories Packaging Specifications	11/26/2002
22	Email - From Cara@skinny.com To Jackie Gutierrez - Subject: RE: Labels for Skinny Kids	12/13/2002
23	PAL Laboratories Fact Sheet Re: Skinny Pill for Kids	11/25/2002
24	PAL Laboratories Fax - To Edita Kaye From Jackie Gutierrez - Signed Label	12/6/2002
25	Subpoena Ducus Tecum to The Fountain of Youth Group and Edita Kaye	7/9/2003
Documents for Pedia Loss		
26	DBS Labs Response to Energy and Commerce Request	1/14/2004
27	DBS Labs Response to Energy and Commerce Request	1/28/2004
28	Energy and Commerce Information Request Letter to Dynamic Health Products	2/3/2004
29	Dynamic Health Responses to Energy and Commerce Request	2/17/2004
30	DBS Laboratories LLC Update Information on Pedia Loss	3/25/2004
31	DBS Labs Response to Energy and Commerce Request	3/30/2004
32	Pricing - David Wood - From DBS Labs Response	
33	Exhibit "D" - Research Agreement - University of Miami	
34	DBS Labs Libido Enhancers - Masculine Male - Advertisement	6/9/2004
35	DBS Labs Libido Enhancers - Arginine Plus - Advertisement	6/9/2004
36	DBS Labs Weight Loss - Apimin PM - Advertisement	6/9/2004
37	DBS Labs Weight Loss - Fat Fighter - Advertisement	6/9/2004
38	DBS Labs Weight Loss - Carb Control - Advertisement	6/9/2004
39	MedPharmacy.com Website	6/27/2003

Tab	Document Description	Date
	Documents for PediaLean	
40	"Usefulness of Highly Purified Extract of Proteinophallus Rivieri Fibers in Childhood Obesity	1992
41	"Miracle In A Bottle" - By Michael Specter - The New Yorker Magazine	2/2/2004
42	PediaLean Supplemental Facts Label	01/02/04
43	PediaLean Advertisement, Redbook Magazine	Feb-02
44	Klein-Becker USA – website www.kleinbecker.com advertisement with BBB logo	undate
45	Klein-Becker USA – website www.kleinbecker.com advertisement without BBB logo	6/14/2004
46	PediaLean advertisement, www.pedialean.com	2/20/2003
47	PediaLean Price information at www.pedialean.com	2/20/2003
48	PediaLean Advertisement re: price reduction on www.pedialean.com	6/7/2004
49	PediaLean Questions Re: Ingredients at www.pedialean.com	
50	PediaLean Directions for Use by children	6/7/2004
51	NIH Response to PediaLean Grant Proposal #1	10/31/2003
52	Revised Version of the PediaLean Proposal of December 1st, 2002 - Principal Investigator: Chevreau, Nathalie	
53	NIH Response to PediaLean Grant Proposal #2	3/28/2003
54	Email - PediaLean - From Jennifer Collard; To Kimm Humphreys RE: Pedialean question from Hong Kong	6/5/2003
55	Email - PediaLean - From Jennifer Collard; To Kimm Humphreys RE: asia 100	6/10/2003
56	Email - PediaLean - From Jennifer Collard; To Don Atkinson RE: FW: Safety Issue of PediaLean	6/13/2003
57	Email - Kristen Jones - From CstSrv - Subject RE: question about published study	11/22/2002
58	Email - Kristen Jones - From CstSrv - Subject RE: PediaLean Studies	8/15/2002
59	Email - PediaLean - from Caria Fobbs To Stephen Nagin; Subject RE: removal of bbb logo on pedialean website	3/7/2003
60	Email - Kristen Jones - From CstSrv - Subject RE: Question	9/24/2002
61	Email - Kristen Jones - From CstSrv - Subject RE: Taking Med. In School	9/9/2002
62	Email - Kristen Jones - From Daniel Mowrey - Subject RE: PediaLean study ref on website	2/13/2002
63	Email - Caria Fobbs - From MK555; Subject: Fw: Kidde Instructions	6/16/2003
64	Email - Caria Fobbs - From MK555; Subject: Fw: Contact Us Email message from: Mary Varrone	6/16/2003
65	Email - From MK555; Subject: Fw: It made it to Yahoo: Article on AP re: Skinny Pill for Kids	12/7/2002
66	Email - Kristen Jones - From Nathalie Chevreau; To Mitch Friedlander; Subject RE: invitation to become part of the advisory committee to the www.weightlossforchildren.com site	2/6/2002
67	Email - Kristen Jones – Customer question re: Pedialean side effects	5/13/2002
68	Email –Nathalie Chevreau response to customer re: complaint no efficacy of PediaLean	5/6/2002
69	Email - PediaLean – Mowrey paragraph on PediaLean to Carla Fobbs	2/18/2002
70	Email - PediaLean – From Cst Service re: question about what p. rivieri is	7/2/2002
71	Email - From Nathalie Chevreau To Robert Mendoza re inquiry about study of PediaLean	12/20/2002
72	Basic Research Response to Energy and Commerce Request	4/1/2004
73	PediaLean Data Chart: Direct Sales Breakdown and Total Sales Breakdown	4/1/2004
74	PediaLean Project Costs/Program Costs Per Unit	4/1/2004
75	Email - PediaLean - From Michael Meade To Kristen Jones; Subject RE: PediaLean request - product price	6/12/2003
76	Klein-Becker - PediaLean Sales Review Chart	2002-200
77	New Product Update - "Testosterone: Not just for the hardcore" - Androgen-Saturated Transepidermal Gel	6/7/2004

Tab	Document Description	Date
78	New Product Update by Klein-Becker USA - Weight Loss for Children	
79	Website: KleinBecker.com - "Testosterone - Are you man Enough?"	6/13/2004
80	Website: KleinBecker.com - Testogel Purchase Page	6/13/2004
81	Website: KleinBecker.com - "Mamralin-ARa: The first and only formulation designed to protect a woman's breast from sag and shrinkage caused by weigh loss"	6/13/2004
82	Website: KleinBecker.com - Mamralin-Ara - Purchase Page	6/13/2004
83	Website: GetSupps.com - "Anorex: Tired of Diet Failure?"	
84	Oxydrene: Deep Tissue Oxygenator and Viagra	6/14/2004
85	Klein-Becker USA - Oxydrene - Purchase Page	6/7/2004
86	Mitchell Friedlander's Background - Memo by Paul Hatch	
87	Associated Press Article: Owner of Mail-Order Company Banned from Living, Working in Florida - Regarding Mitchell Friedlander	3/23/1988
88	United States Postal Service Complaint Filed Against Mitchell Friedlander - Docket Number 19/182	9/10/1985
89	United States Postal Service Complaint Filed Against Mitchell Friedlander - Docket Number 19/105	9/30/1985
90	United States Postal Service Complaint Filed Against Mitchell Friedlander - Docket Number 19/104	9/10/1985
91	Article: "Court Issues Temporary Restraining Order Against Mail-Order Companies For Misrepresenting Diet Products and Baldness "Cures"	8/14/1985
FTC Complaints		
92	FTC Complaint Filed Against Mitchell K. Friedlander - United States District Court, Southern District of Florida	3/3/1986
93	FTC Complaint Filed Against Chhabra and Barash	
94	FTC Complaint Filed Against Chhabra and Barash - Decision and Order Against Jonathan Barash	
95	FTC Complaint Filed Against Chhabra and Barash - Agreement Containing Consent Order Against Jonathan Barash - File No. 042-3002	
96	Analysis of Proposed Consent Order to Aid Public Comment	
97	FTC Complaint Against: Basic Research, L.L.C, Klein-Becker USA L.L.C., Dennis Gay, Daniel Mowrey, and Mitchell Friedlander. - Docket Number 9318	



Detail Page

Skinny Pages

- Home Page
- Skinny Store
- Free Skinny Club
- Get Skinny Now!
- Skinny Testimonials
- Meet Edita
- Skinny News
- Skinny E.A.C.A.
- Skinny Distributor
- Contact Us

Skinny Products

- Skinny Makeover
- Skinny Starter Basic
- The Buddy Pack
- 3-Product Skinny Pak
- Skinny Pill AM
- Skinny Sleep PM
- Skinny Carbs 30-Day
- Skinny AM Special

Skinny Tools

- New Skinny Recipes
- Skinny Calculator
- BMI Calculator

Skinny Resources

Tab 1

3-Product Skinny Pak

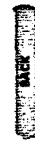
Special! Try all 3 of my fantastic skinny supplements at a very special price. That's my Skinny AM Pill, my Skinny PM Pill and my Skinny Carbs. Buy now, and you'll save \$20 and lose up to 30-pounds in your first 30 days. But hurry. This special offer ends soon.

The Skinny Pill formula is safe, Non-prescription. All natural. Effective. It includes the top 5 skinny supplements that help turn off your body's fat switch and break your food-to-fat cycle starting in just 24 hours.



3-Product Skinny Pak

Retail Price: \$149.97
Our Skinny Price: \$79.99



Here's what the Skinny AM Pill formula contains:

Carnitine 250 mg

Carnitine is a supernutrient... it helps to burn off stored fat, increases your energy levels, suppresses your appetite and reduces cravings.

Chromium 400 mcg

Chromium is an essential trace element. It acts as a thermogenic (fat burning) agent, reducing body fat without dieting or exercise. It has also been shown to be an insulin cofactor, helping this hormone regulate sugar and blood fat more efficiently.

Citrimax 300 mg

Decreases fat gain by inhibiting lipogenesis, the metabolic process by which our bodies turn food into fat. It also lowers blood fat levels and is an appetite control center. Studies show it may also stimulate fat loss by boosting body heat (thermogenesis).

Chitosan 250 mg

Chitosan is derived from shellfish and packs a double fat fighting whammy. It's a fat magnet, attracting fat before it gets digested and it's also a fat sponge, absorbing over four times its own weight in dietary fat.

Citrus Aurantium 300 mg

Unlocks fat cells. Speeds up the rate at which fat is released from fat storage (lipolysis). Increases resting metabolism (thermogenesis) accelerating the rate at which your body burns fat. Stimulates the growth of fat burning muscle cells.

Guarana seed extract 250 mg (providing 50 mg caffeine)

Guarana is an herbal tonic with numerous health benefits. You too can tap the energy source of guarana to "rev up" your average day.

Green Tea Leaf Extract 30 mg

As the research on green tea progresses, many studies have attributed the various traditionally acclaimed effects of green tea to its active constituents, the polyphenols. These active components possess potent antioxidant properties and may help maintain healthy cholesterol levels.

The Skinny Pill contains shellfish-derived fiber. Do not take if you are allergic. Do not take if you are pregnant or under 14 years of age. As with any diet or exercise program, you should consult with a physician before you start. Individual results may vary. The Skinny Pill is a unique combination of ingredients, that when used as part of the diet and exercise program can help you get a head start on your own fat reduction campaign.

About Editla's Skinny PM Pill

A nighttime thermogenic formula

<file:///E:/www-skinnypill-com/www-skinnypill-com/Content/products/p3pro.htm>

Here is everything you need to know about Edita's Skinny PM

This is a wonderful new formula that can help you with the two most frequent medical problems and frustrations American's suffer from today...fatigue & fat. And now, in a study, reported by USA Today, it appears that the two are linked.

The more fatigued, the more fat!

Makes sense. When you are fatigued, exhausted, stressed, the natural tendency is to give your "wiped out" body some energy. The faster the better. And that energy is usually in the form of fast fat...so, you may actually be fat because you're tired.

So I developed this exciting new formula of supplements that can help you reverse fatigue AND fat, overnight, while you sleep!

Here's how it works. My special blend contains sleepy time herbs and supplements that soothe and quiet your body and your mind so that you can enjoy a restful and refreshing sleep. In the meantime, my special blend also contains skinny supplements that help your own natural fat fighting systems start to empty out those fat cells, overnight.

The result? You should wake up rested, refreshed, and SKINNIER!

Here's my blend:

The Skinny Part Vitamin B6

One of the most powerful metabolism boosting vitamins

Chromium

A thermogenic agent and insulin cofactor, helping your body regulate sugar and blood fat more efficiently.

Citrus Aurantium

Researchers believe that citrus aurantium zeros in on special Beta-3 receptors only, turning on their powerful fat fighting signal, without stimulating the receptors that change heart rate or blood pressure, for a safer fat burn.

Citrimax

This is also called garcinia cambogia, which contains HCA, a compound similar to citric acid. Preliminary research shows that HCA decreases fat gain by inhibiting lipogenesis, the metabolic process by which our bodies turn food into fat.

file:///E:/www-skinnypill-com/www.skinnypill.com/Content/products/p3pro.htm

L-Carnitine
Helps burn off stored fat, and increases your energy.

The "Get a good night's sleep" part

Chamomile

This wonderful natural plant has been used for centuries to soothe away tension and anxiety and to ease pain and discomfort especially of indigestion and other disruptions to a good night's sleep

Kava Kava

A gentle supplement that helps reduce stress and anxiety and promotes restful sleep

Medium Chain Fatty Acids

Help your body absorb the good nutrients and fat fighting supplements more efficiently

Melatonin

Increases your ability to sleep fully and deeply and wake up alert and rested.

Here are the dosages in Skinny PM Pill

Vitamin B6	12 mg
Chromium	200 mcg
Chitos Aurantium	500 mg
Chimax	200 mg
L-Carnitine	150 mg
Chamomile	50 mg
Kava Kava	50 mg
Medium Chain Fatty Acids	50 mg
Melatonin	2 mg

Skippy Sleep is contained in capsules. You would take 2 capsules about an hour before bedtime.

Skippy Carbs is the miracle that lets you occasionally "cheat" without guilt or added fat pounds. Skippy Carbs begin to work within minutes to help keep you skinny even when you can't eat skinny. When you eat a carb, Skippy Carbs blocks the starch from being broken down into sugar. Our bodies use sugar for energy. That's good. But if there's too much sugar our bodies store it as fat. That's bad. Skippy carbs cuts into that cycle and prevents starch

from turning into sugar and then into fat. Instead, it just passes right through our system. The result? We can enjoy our carbs without having them turn into body fat.

Skinny Carbs contain the following ingredients:

- Chromium: 200 mcg
- Vanadium: 250 mcg
- PhaeoLamin: 60 mg
- Glucosol™: 16 mg
- Skinny Blend: 250 mg
- Bitter melon fruit, gymnema sylvestre leaf, lycium berry

Editas
SKINNY.com
 America's Favorite Nutritionist

Tab 2

Thursday, J
 Skinny St

Skinny Pages

- Home Pages
- Skinny Store
- Skinny Club
- Get Skinny Now
- Skinny Testimonials
- Meet Editas
- Skinny News
- Skinny F.A.Q's
- Skinny Distributor
- Contact Us

Catalog View



Skinny Makeover

Retail Price:
 \$194.95
 Skinny Web Price:
 \$99.99

[Buy Now!](#)

[More Info](#)



3-Product Skinny Pak

Retail Price: \$149.95
 Skinny Web Price:
 \$79.99

[Buy Now!](#)

[More Info](#)

Skinny Products

- Skinny Makeover
- Skinny Starter Basic
- The Buddy Pak
- 3-Product Skinny Pak
- Skinny Pill AM
- Skinny Sleep PM
- Skinny Carbs 30-Day
- Skinny AM Special

One of my very best values. Just \$99.99 for a limited time. You'll get every single one of my products for a full month and lose up to a pound a day and save almost \$100!!! That's 30-days of Skinny AM Pills, 30-days of Skinny PM Pills, 30-days of Skinny Carbs, my Skinny Pill Book, my Skinny Fridge Guide and my newest Skinny Rules Book, too!

Try all 3 of my fantastic skinny supplies at a very special price. That's my Skin AM Pill, my Skinny PM Pill and my Sk Carbs. Buy now, and you'll save \$20 & lose up to 30-pounds in your first 30 d But hurry. This special offer ends soon!

Skinny Tools

- New Skinny Recipes
- Skinny Calculator
- BMI Calculator

Skinny Resources

- Terms of Use



Skinny Starter Basic

Retail Price:
 \$119.93
 Skinny Web Price:
 \$59.99

[Buy Now!](#)

[More Info](#)



The Buddy Pak

Retail Price \$219
 Skinny Web Price
 \$99.99

[Buy Now!](#)

[More Info](#)

Not sure you'll like the program? Try my Skinny Starter Basic. You'll get my new Skinny Rules book PLUS your first 30-days of my Skinny Pill PLUS your first 30-nights of my Skinny Sleep Pill. I know if you follow the program you'll lose up to 30 pounds and save 50%.

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The Best Selling Skinny Books!



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Edita's best selling diet books have helped thousands of people get healthy, skinny, happy. There have been so many articles, newspaper stories and television shows about amazing skinny pills that some people find Edita's best selling diet books have helped thousands find the path to wellness.

You will always find links to Edita's newest right here at skinny.com

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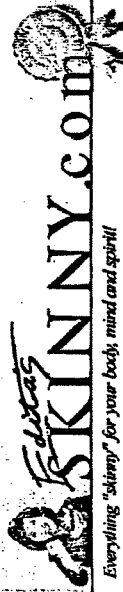
NEW!

Now Kids have their very own SKINNY PILL!

Coming Soon

Edita's newest book and the first skin cookbook that will let you eat yourself AND lose one pound a day and another pound overnight! Over 200 Recipes 130 Food Tips Easy, Economical. F Includes Edita's newest 2- Day Wee Fast Fat Loss Menu & 5-Day Fat De

Skinnypill.com - Skinny Kids Detail Page



Skinny Kids

Skinny Pages

- Home Page
- Skinny Store
- Fires Skinny Club
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- Skinny Testimonials
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- Skinny Makeover
- Skinny Starter Bundle
- The Buddy Pack
- 2-Product Skinny Pak
- Skinny Pill AM
- Skinny Sleep PM
- Skinny Carbs 30-Day
- Skinny AM Special

Skinny Tools

- Personalized Receipts
- Online Calculator
- BMI Calculator
- Skinny Resources
- Terms of Use



Retail Price: \$49.99
Web Price: \$39.99

Tab 3

Skinny Pill For Kids

Edie is proud to offer you and your children the first SKINNY PILL just for kids! And because it's from Edie, America's Favorite Nutritionist, you know you and your kids can trust the Skinny Pill for Kids™.

This is the FIRST thermic and herbal formula ever developed for weight loss for children 6 to 12 and has been created to help our children win their battle with fat.

ORDER IT TODAY AT THE INTRODUCTORY PRICE OF ONLY \$39.99 FOR A 30-DAY SUPPLY! PRODUCT WILL SHIP IN LATE DECEMBER.

ADD TO CART

BACK



Skinny Pill For Kids

file:///E:/www-skinnypill-com/www-skinnypill-com/content/products/skinnykids.htm

3. It is formulated with the finest ingredients, to help children reduce their risk of obesity-related diseases such as heart disease, high blood pressure and diabetes.
4. It offers very real weight-loss help through supplements that metabolically assist children to burn more fat pounds and inches, block new fat deposits and help regulate insulin levels to help mitigate fat factors.
5. When used as part of Edita's Skinny AM-PM System of foods, meals and menu plans the Skinny Pill for Kids offers children the first real help in fighting fat.

The media has focused attention on the very real health problems faced by our children because of obesity. They are the onset of diabetes growing at alarming rates in children as young as 6! There is high blood pressure! Heart disease! Vascular disease! An increase in breathing-related disorders such as asthma! Our children, the media tells us every day, are unhealthy. Fat. Obese. They don't exercise. They sit in front of TV sets or computers for hours. They are out of shape. That's on the physical side.

Emotionally and psychologically our children are suffering also. Over fat, chubby, obese children are teased and tormented at school. They are excluded from sports and social activities. They are unable to enjoy the clothes, the friendship, the sheer joy of being a carefree child. They are alone. They are trapped in their

120 meg, which equals 100% of the daily value.

Chromium is sometimes called the glucose tolerance factor or GTF, because it is involved in the metabolism of glucose. Chromium is needed for energy, fat burning, vital in the synthesis of cholesterol, fat and protein. This essential mineral also maintains stable blood sugar levels through the proper utilization of insulin and can be a helpful nutrient in people with diabetes and those with hypoglycemia. Low levels of chromium can also be an indicator of coronary artery disease.

Pectins

Pectins slow the absorption of food after meals and also help lower cholesterol levels. These fruit fibers, or pectins, have been found to be very effective in offering nutritional support to people at risk for diabetes, or who already have the disease.

Bioflavonoids

Bioflavonoids are sometimes referred to as vitamins and they enhance the absorption of vitamin C and stimulate bile production and lower cholesterol.

Chitosan

This substance actually picks up and removes fat from the colon wall. It is good for diabetes and obesity, because one of its primary functions is the removal of fat. It has also been recognized for normalizing blood sugar. It is an doing help maintain a healthy weight, and in so doing helps minimize feelings of fullness and curb appetite. It is important to drink a large glass of water with this ingredient, as it can lodge in the throat and expand there and may cause breathing problems.

Uva Uva!

Lunch
 1 slice pizza, or 1 cup of macaroni and cheese with fresh veggies with reduced fat
 1 sliced dressing for dunking.
Editor's Skinny AM-PM System 3-Day Afternoon Snack
 1 ice cream cone made with your favorite ice cream or frozen yogurt. (1 scoop)
Dinner
 4 to 6 ounces lean steak, broiled, or 2 hamburger patties, a large green salad with reduced fat salad dressing, and steamed broccoli.
Bedtime Snack
 2 large stalks of celery stuffed with 2 tablespoons peanut butter

Day 3
Pre-breakfast
 Apple, orange, or pear
Breakfast
 Breakfast bananas split made with 1 banana, 2 scoops of ice cream or frozen yogurt and fresh chopped fruit and berries.
Morning Snack
 1 muffin or 2 slices of bread or rice cakes with jam or jelly
Lunch
 1 pita or wrap stuffed with lettuce, re-fried beans, fresh tomatoes, and salsa, or 1 cup canned pork and beans with 2 slices of bread.
Afternoon Snack
 3 ounces of cheese or 1 small container nonfat yogurt
Dinner
 2 pieces chicken, 4 ribs, 2 slices turkey, or 1 large pork chop, a large green salad with reduced fat salad dressing, and steamed spinach or 1 cup mixed vegetables.
Bedtime Snack
 2 large stalks of celery stuffed with 2 tablespoons peanut butter or 2 scrambled eggs with 2 slices bacon.

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Tab 4

CNN

SHOW: CNN CONNIE CHUNG TONIGHT 20:00

December 9, 2002 Monday

Transcript # 120900CN.V92

SECTION: News; International

LENGTH: 8436 words

HEADLINE: Is United States Closer to War With Iraq?; Is Skinny Pill Dangerous for Children?

GUESTS: Federico Castelluccio, Edita Kave, Michael Hudson, Patrick Williams, Charles Sheehan-Miles, Richard Holbrooke

BYLINE: Keith Ayoob, Art Harris, Wolf Blitzer, Bill Hemmer

HIGHLIGHT: American officials have obtained a copy of Iraq's 12,000-page weapons report to the U.N. and are racing to find any falsehoods before another country declares the report acceptable. Skinny pills being peddled on the Internet are targeting kids as young as 6 years old, but are they safe? "Sopranos" actor Federico Castelluccio discusses the show's season finale.

BODY:

BILL HEMMER, GUEST HOST: And good evening. Good to have you with us this evening.

Tonight: several new developments in America's ongoing showdown with Baghdad. American officials have obtained a copy of Iraq's 12,000-page report to the U.N. on the state of its weapons program and are racing right now to find any lies or falsehoods before another country declares the report acceptable.

Also today, U.N. Secretary-General Kofi Annan called on nations to share their intelligence on Iraq's programs, something the U.S. is still weighing right now.

And in Baghdad, meanwhile, weapons inspectors continued their work, checking out a former nuclear facility and a military chemical plant. Now, because the White House considers Iraq's report essentially a lie, the report's release is being seen by some as a step closer to war tonight.

And one of the people making that assessment is former U.S. ambassador to the U.N. Richard Holbrooke. He is our guest tonight.

Good to see you again, Mr. Ambassador.

CNN CONNIE CHUNG TONIGHT 20:00 December 9, 2002 Monday

HEMMER: Michael Hudson from Georgetown University with us tonight, again, in Washington.

Still ahead in a moment: Did he get whacked? Will he be back? Hell hath no Furio, but we do. We'll chat with him after the break here.

ANNOUNCER: Next: Skinny pills being peddled on the Internet targeting kids as young as 6 years old, are they safe? And how young is too young?

CONNIE CHUNG TONIGHT will be right back.

(COMMERCIAL BREAK)

HEMMER: Has America's obsession with weight gone too far? And are kids as young as 6 years old paying the price for that?

Fifteen percent of kids 6 to 11 years old are said to be overweight in the U.S. And now a new product targeting those kids, or at least the parents anyway. It's called the Skinny Pill. It's a mixture of minerals, vitamins and herbs. And it's marketed as part of an overall weight loss plan. And it's causing a lot of controversy, too.

Pediatric experts told CNN that diuretics in the pill could damage your child's kidneys and liver and possibly lead to electrolyte imbalance.

Earlier today, I talked with the creator the Skinny Pills, Edita Kaye.

(BEGIN VIDEOTAPE)

HEMMER: Good evening.

EDITA KAYE, CREATOR OF SKINNY PILLS: Good evening.

HEMMER: Thanks for joining us tonight.

KAYE: Thank you very much for inviting me.

HEMMER: Well, you are welcome.

Why do you believe that young kids in America need this pill?

KAYE: Well, the pill is really getting a lot of controversial coverage today.

The pill is part of a complete program that I have developed for children as a result of requests from parents, from mothers and fathers, and from teachers and from children themselves. I have been doing weight loss for women for about three years now with a product I call the Skinny Pill. And it's been very successful. And women have been calling me and e-mailing me, as have their kids, and saying: "You know what? I'm doing great. What can I do for my children?"

HEMMER: And this is how you respond.

KAYE: And this is how it evolved.

HEMMER: What's in it?

KAYE: Well, I think I have my science team on after this. And they will explain.

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But, basically, what's in it are wonderful vitamins. The B vitamins are there. We have -- fruit fibers are in it. We have got things that you could really go and get in any good health food store or any drugstore for children. And the product comes with what I'm very excited about. It comes with a wonderful food plan that's quite unique for kids.

It's a series of flash cards for children. And it talks about -- it takes a positive approach. Our kids are getting fatter and fatter, as are grownups, actually. We Americans are the fattest people on Earth. Here's what I always say. Look, the traditional things that we've tried are not working. We have very frightened and frustrated parents out there with obese children, who, some of them, the tragedy, they get stuffed into garbage cans and so on.

HEMMER: Let me stop you on that.

(CROSSTALK)

KAYE: I'm sorry. Go ahead.

HEMMER: Why did you need medication for that? What ever happened to exercise?

KAYE: Well, it's not medication. These are vitamin supplements.

What ever happened to exercise? OK, see, this is great. You're taking the traditional route.

HEMMER: It's fine. Not a problem at all.

KAYE: And I will tell you.

First of all, let's go out and exercise. This is the traditional wisdom. Go out and exercise. Stop eating fast food and turn off the TV. America, let's get real.

HEMMER: It sounds logical, though, right?

KAYE: This is not going to happen.

HEMMER: Why not?

KAYE: Well, because, first of all, parents lose control of their children from the minute they put them on a school bus to the minute they get them back.

I think many families are overworked, overstressed. We have a lot of single parents raising children. And we also have problems now. Where are our children going to actually play? It's not safe for us. When I was a kid, I rode my bike on the street, played in a park. I think there is a huge concern. We live in a different world than I grew up in -- certainly not you, because you're much younger than me.

So, what I'm doing is, I'm saying to kids: Look, getting skinny and getting healthy can be fun. The same foods that made you fat are going to make you skinny. All you need is to have a watch to be able to tell time. In the morning, have an orange. At night, have some peanut butter. Take some of these supplements. The supplements are a motivator as well. They're an important motivator. I'm just ringing a bell here.

HEMMER: Yes, I got you and I want you to stop for a second.

KAYE: You want me to inhale?

(LAUGHTER)

HEMMER: No, we are going to have some people come on here.

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Frankly, we've heard from a lot of experts today who say it is junk science. They say it doesn't work, it's not plausible, and you shouldn't be teaching kids this way. You should revert back to more traditional ways, which is something you referred to a minute ago.

KAYE: The traditional ways aren't working, then.

HEMMER: How do you defend the claim that it's junk science?

KAYE: Well, I do defend it.

First of all, it's put together by scientists. I didn't cook this stuff up in my kitchen on the sink. This was put together by scientists. I have a list of physicians, if anybody needs a doctor who would like to talk -- they would like to talk to, they can simply call me or go to Skinny.com and we are happy to help them find an American doctor who would be happy to tell them the positive things.

I think it's been exciting. There's been a debate focused. The debate really should be -- here's what I say. And this is my challenge today. And thank you for saying it. Everybody, doctors, nurses, teachers, big brothers, moms and dads, help me. If you may not agree with what I'm doing, I'm trying to get American kids healthy. There's room for all of us. Help me out, guys.

HEMMER: We are going to continue the debate here.

But, first, thanks to you, Edita Kaye.

KAYE: Thank you very much for inviting me.

HEMMER: Nice to see you. You got it.

KAYE: It was a pleasure. Thanks.

HEMMER: And joining me now: Jose Diaz De La Rocha director of quality control and formulation at Powell Laboratories, which produces those pills. And we have Albert Einstein College of Medicine associate professor of pediatrics Keith Ayoob, who is also a spokesperson for the American Dietetics Association and opposes the release of the Skinny Pills.

Good evening to you as well.

Let's start here in New York.

You are the one who coined this phrase, junk science, earlier today. Why is it junk? Why is this stuff not good?

KEITH AYOOB, AMERICAN DIETETIC ASSOCIATION: Actually, it's a term that's been around a long time.

And, first of all, one of the red flags of junk science, Bill, is, you never get nutrition information from somebody who is trying to sell you a product. Now, the ingredients here have never been tested on kids. And there are herbs in here that are not indicated for kids.

HEMMER: First of all, are there people taking this?

AYOOB: I believe the release date is this weekend.

HEMMER: If that's the case, what kind of reaction have they gotten from it?

(CROSSTALK)

AYOOB: It's a new product that hasn't come out until I think today.

HEMMER: OK. And given that, though, has there been anything done in terms of laboratory testing? Have there been any clinical trials? Has there been anything that has gone on record and said, yes, this in fact does work?

AYOOB: To my knowledge -- and I've read a lot of the research -- the research on the ingredients in this pill are not associated with weight loss.

There's no magic pill, Bill. The only way to lose weight is to reduce your calorie intake and to increase your activity. And this just kind of goes to show you how dangerous it is sometimes to get your nutrition information from somebody who is not credentialed.

HEMMER: Why is this dangerous? What's harmful?

AYOOB: Because you are getting inaccurate information. This is a bogus product. It is not going to help anybody lose weight. The only weight you are going to lose is from your pocketbook.

HEMMER: I want to go to Mr. De La Rocha in Florida with us.

Sir, tell us about this, this claim that, essentially, Dr. Ayoob and others expressed a concern about this being, essentially, dangerous for young people. That claim is backed up by you how?

JOSE DIAZ DE LA ROCHA, PAL LABORATORIES: OK. First, good evening for you and for all your TV.

This product is a fiber product. Mainly, it's fiber. And fiber is proven that the children and all the people that eat fiber will feel full and they're going to eat less. This product has also some vitamin B, but the mainly ingredients are fiber. If you look at the fiber, you will see they are very good to lose weight.

HEMMER: What is uva ursi, which is one of the components. What is that ingredient?

DE LA ROCHA: Yes, that is a diuretic. But they are in the very, very small amount, far away, very far away from the therapeutic dosage.

HEMMER: So you're saying, essentially, that all this does is fill up a person's stomach and prevents them from eating more, right?

DE LA ROCHA: That's correct. And that's correct.

And, of course, I agree with -- if you take this pill and, of course, if you do exercise, it will be better. But with this pill, the children will feel full. That's the purpose of the pill.

HEMMER: Got it.

Doctor?

AYOOB: OK, first of all, if the uva ursi is in such small quantities, keep it out of there, because the "Physician's Desk Reference" on uva ursi, the gold standard, has indicated -- I've got the printout right here -- it says it is contraindicated for children under the age of 12. Anybody who had done their homework would realize that is not an herb to be giving to kids. A diuretic for kids, it doesn't work.

HEMMER: So, again, your claim is that this is dangerous for some people.

AYOOB: It could potentially be.

(CROSSTALK)

AYOOB: It hasn't been tested on kids. It hasn't been tested on kids. It shouldn't be in this product.

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DE LA ROCHA: He said potentially. I agree.

The amount, again, of the diuretics are in very small amount, very small amount, because the children have to take a lot of water with this pill. This is not a problem at all.

(CROSSTALK)

DE LA ROCHA: Excuse me.

The therapeutic dosage for uva ursi is 10 grams per day. And this is far, far, far away from that kind of amount. It's only a few milligrams.

AYOQB: First of all, it doesn't belong in a product. The product will not help anybody lose weight. My God, that's why we want kids to eat more fruits, eat more vegetables, eat more whole grains.

And that's what a qualified nutrition professional, like myself and other registered dietitians work every day with families, because they're important to me and their kids are important to me.

HEMMER: Doctor, hold that thought. You raised an interesting point before.

Mr. De La Rocha, why has this not been tested with children?

DE LA ROCHA: First of all, this product is a fiber product. And we are only the manufacturers. We at Pal Labs in Miami, Florida, we manufacture the products for clients in all the world at the request of a client. What the client do --- the marketing of the product, we are not involved in the marketing of the product.

HEMMER: Mr. De La Rocha, do you have children?

DE LA ROCHA: No, sir.

HEMMER: You don't.

DE LA ROCHA: Yes. But I have almost children that are mine.

HEMMER: If that's the case, then, would you give them this pill?

DE LA ROCHA: Of course.

First of all, I believe any people, any father or mother, that have kids, if you give someone to your child, you have to consult with your doctor. You have to be careful. We agree with that. We are an FDA facility. We don't do nothing that is against the law.

But for all the fathers and mothers that are seeing this, if you give someone this pill or whatever pill you're giving to your child, you have to see a doctor, if something goes wrong. I agree with that. I agree with the doctor. But this is

(CROSSTALK)

DE LA ROCHA: Excuse me.

This is fiber. And the fiber -- the kids, you know, Doctor, they don't want to eat fiber. That's the problem.

HEMMER: I understand your point.

Doctor, a quick final thought here.

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A YOOb: I absolutely disagree. I disagree. I work with kids every day who eat higher-fiber diets. And we gradually change their diets.

You want to get your nutrition information. I agree. Ask your doctor. If you ask your doctor, a medical doctor would never want a child to be harmed by the nutritional ingredients in this product. There are herbs that should not be given to children. And it's in the "Physician's Desk Reference" that it should not be given to children under 12, the very children it's marketed to.

HEMMER: That is going to be the last word.

Dr. Ayoob...

(CROSSTALK)

HEMMER: Sorry, Mr. De La Rocha, we're out of time.

Jose Diaz De La Rocha in Florida, thank you both gentlemen tonight.

I should add, the "Physician's Desk Reference" states that uva ursi, the ingredient in the pill we just mentioned, should never be given to children, because they say it can cause liver damage.

And the controversy does not stop there. Later this week, on Wednesday, we'll have a teenager and her mother. Both had gastric bypass surgery in order to lose weight.

In a moment tonight: HBO's shattering "Sopranos" season finale and the man behind this secret finally revealed. Furio is here -- back after this.

(COMMERCIAL BREAK)

HEMMER: Well, last evening, if you saw it on HBO, "The Sopranos" season finale went down during a scene far more intense and suspenseful than any mob whacking. Edie Falco turned in a stunning performance -- in fact, she did it twice within the hour -- telling her husband, Tony, she's been fantasizing about another man.

(BEGIN VIDEO CLIP, "THE SOPRANOS")

JAMES GANDOLFINI, ACTOR: He talked to you. Oh, poor you.

EDIE FALCO, ACTRESS: He made me feel like I mattered!

GANDOLFINI: You asked me the other day what Irene's cousin has that you don't have. And I thought about, because it's a pretty good (EXPLETIVE DELETED) question. And, yes, she's sexy enough, even with the one pin gone. But that's not it. I could converse with her because she had something to say!

FALCO: I am here! I have things to say!

(END VIDEO CLIP)

HEMMER: So, then, who was the other man who triggered such rage? How about Furio, played by actor Federico Castelluccio? And he's our guest tonight.

Good to see you.

FEDERICO CASTELLUCCIO, ACTOR: All right, good to see you.

HEMMER: So, you're trouble, huh, with a capital T.

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NBC News Transcripts

SHOW: Today (7:00 AM ET) - NBC

Tab 5

December 9, 2002 Monday

LENGTH: 1375 words

HEADLINE: Edita Kave, inventor of the "Skinny Pill" for kids, and Dr. Keith Ayoob of Albert Einstein College of Medicine, debate of the effectiveness of the pill

ANCHORS: KATIE COURIC

BODY:

KATIE COURIC, co-host:

Obesity in children have reached epidemic proportions. According to the Centers for Disease Control, more than six million kids in the United States are severely overweight. That's 15 percent of all children and adolescents. But is a diet pill for children the answer? Edita Kave is the creator of skinny.com and the new skinny pill for kids. And Dr. Keith Ayoob is an associate professor of pediatrics at Albert Einstein College of Medicine.

Good morning to both of you.

Dr. KEITH AYOOB (Albert Einstein College of Medicine): Good morning.

COURIC: Let me start with you, if I could, Edita Kave.

Ms. EDITA KAYE (Created "Skinny Pill" For Kids): Good morning, Katie.

COURIC: Good morning. Nice to see you.

Ms. KAYE: Thank you.

COURIC: You have been marketing a skinny pill for adults on--on a Web site. And now, you have a skinny pill for kids.

Ms. KAYE: Yes.

COURIC: Why? Obviously, for the reasons I just outlined?

Ms. KAYE: I will tell you why. Because in the past 36 months that I've been selling the skinny pill, which is a dietary nutritional supplement for women and men, I have had requests. We have almost 500,000 people who have used our product and it's safe and successful, and there's a wonderful food plan that goes with it. And moms have been writing to me, e-mailing me, calling me saying, 'Edita, what can I do for my kids?' And children have called me. And it breaks your heart, Katie, the letters and e-mails that I get. Kids get thrown into garbage cans, they have no self-esteem. They're afraid to go to school. They can't play with their friends. They can't eat in the restaurants that their friends eat

in. So I thought, 'OK, I'll come up with something that I'm going to call the skinny pill for kids and to me. I'm ringing a great big bell out there across America.'

COURIC: What's in this pill?

Ms. KAYE: In this pill, we have vitamin--B vitamins, which are wonderful, and they help with energy, all right? We have dietary fibers, which are wonderful, because what they do is they give you the feeling of fullness...

COURIC: Right.

Ms. KAYE: ...so you don't eat as much or as often.

COURIC: In other words, it's all natural ingredients, right?

Ms. KAYE: Absolutely. These are--no one has questioned the contents of the skinny pill.

COURIC: There's no ephedrine in it.

Dr. AYOOB: Excuse me.

Ms. KAYE: There is--oh, no, no, no.

Dr. AYOOB: Excuse me.

COURIC: OK, wait--wait a second, Doctor. You're going to get--I'm going to get to you in a second, because I'm sure you have some serious issues with the whole notion of marketing a--a skinny pill for children. What are they?

Dr. AYOOB: Yes, I do. Big-time issues. First of all, I work with this issue every single day, and kids are the most important people in the world to me. I have a real issue when somebody is marketing--marketing a bogus product that has no scientific evidence behind it. And when it includes herbs that are essentially diuretics and have never been tested on kids, I would never recommend this product for anybody.

COURIC: And in fact, it contains niacin, folate, vitamin B12, chromium...

Dr. AYOOB: And Katie...

COURIC: ...wait a second-- pectin, bioflavonoids, glucomannan, uni ursi****(as spoken)****whatever that is, am I pron--buchu leaf and juniper berry. And you say it's based on scientific research done in Australia and the UK?

Ms. KAYE: Yes. It comes to--together with a food plan. We know that pectins, such as the fibers that are in this product, are, you know, are ways of helping sa--satisfy children's fullness. The B vitamins, you know, there's nothing in this product that you can't get in other vitamins. But what I'm saying here is you've got to--you know, I'll tell what you the experts are saying to our kids. They're saying, 'Look, you're fat, here's what you have to do. Turn off the TV and stop eating fa--fast-foods. How real is it? It's not going to happen. So what I'm saying is...

Dr. AYOOB: Excuse me. Excuse me. I have a real issue with that, I'm sorry. The ingredients in this product have never been tested on kids. Edita, you don't have any evidence, and until you do have evidence, you shouldn't be making bogus claims. This pill is not going to help anybody lose weight. A balanced eating plan and lifestyle change that parents can gradually work on is what's going to help kids lose weight.

COURIC: Has this been tested on children?

Ms. KAYE: I--I produced this in a--in a lab. It has formulators, a chemist...

COURIC: Has--has it been test on children?

Ms. KAYE: This particular products, some of the ingredients have, and I don't know about the others.

COURIC: But this particular product hasn't been tested on children.

Ms. KAYE: My--no. The various ingredients are being taken.

Dr. AYOOB: Well, if you don't know about the other ingredients...

COURIC: Excuse me, Dr. Ayoob. Doesn't that make you--give you real cause for concern?

Ms. KAYE: No, because what happens, Katie, is what I'm saying is you need to take some supplements and you need to eat skinny foods. And no one is saying that I'm not doing that. In fact, I welcome the Dr. Ayoobs of the world, come and help me, help me do something about this problem. Let's get doctors working on this with me, dieticians, nutritionists, parents...

Dr. AYOOB: Katie, the only way...

Ms. KAYE: ...grownups...

Dr. AYOOB: Katie, the only way this product...

Ms. KAYE: ...children.

COURIC: Go head, Doctor.

Dr. AYOOB: The only--the only way you're going to lose from this product is from your pocketbook, not from your body.

Ms. KAYE: That--oh!

Dr. AYOOB: And I take kids much more seriously than this. And Edita, if you want me to help you, I will. I'll help you take it off the market.

Ms. KAYE: Oh, thank you, thank you.

Dr. AYOOB: I will help you take it off the market.

COURIC: He wants you to take it off the market, though. That's his way of helping you.

Dr. AYOOB: And Katie, I'm not even sure this is legal--these are legal herbs to put--and to give to kids.

Ms. KAYE: No, I don't...

COURIC: Let me ask you both...

Dr. AYOOB: The FTC recently had a press conference...

COURIC: Go ahead, I'm sorry.

Dr. AYOOB: ...last week...

Ms. KAYE: You know, the...

Dr. AYOOB: ...about making bogus claims for health products, and I think this has never been tested on kids, I would not give these herbs--these are contro--these are diuretic herbs. You don't give those to six-year-old children.

COURIC: Let me just ask you about the psychological impact of this. To tell children that frankly, there is a magic bullet.

Ms. KAYE: But that's not what I'm saying.

COURIC: Yes, you say, there's exercise and an eating plan.

Ms. KAYE: That's not what I'm saying.

COURIC: But--but in the adult Web site, you do say, quote, "magic will happen." And...

Ms. KAYE: Well...

COURIC: ...and frankly...

Ms. KAYE: Magic happens when you take...

COURIC: ...isn't this misleading and psychologically difficult for children?

Ms. KAYE: No, no, because Katie, I'll tell you what happens, OK? Chil--here's what happens. I say to kids, 'look, let's--let's use this time that you have blessed me with.' Let's say to kids, 'Look, this morning, when you're having that glass of orange juice, have an orange. An orange has fiber in it. I'm saying tonight at bedtime, have some peanut butter.

Dr. AYOOB: Katie...

Ms. KAYE: That's wonderful. That's where the magic happens.'

Dr. AYOOB: Katie, a sensible eating plan is what's going to...

Ms. KAYE: The supplements and there are foods.

COURIC: Dr. Ayoob...

Dr. AYOOB: A--excuse me...

COURIC: ...we're almost out of time. You get the last word, Dr. Ayoob.

Dr. AYOOB: Thank you very much, Katie. Katie, this is a bogus product. There are eight ingredients that I would never give to kids. I'm not even sure it's legal to have this in--give this to kids, and a sensible eating plan with a lifestyle, a healthy eating style, is the way to get kids to lose weight. Pills aren't the answer.

COURIC: All right. That'll be the last word. Thank you both so much.

Ms. KAYE: Thank you, Katie.

COURIC: We'll be back after this.

LOAD-DATE: March 18, 2003

Archives Irish Examiner

Tab 6

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TCM Archives > Irish Examiner > 2002/12/07 > 'Skinny Pills' for obese children criticised as 'junk science'

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'Skinny Pills' for obese children criticised as 'junk science'

By Tom Kelly, New York

DOCTORS yesterday criticised a new "Skinny Pill" for children which claims to help obese American youngsters "win their battle with fat."

The diet supplement, a mix of minerals, vitamins and herbs, is targeted at overweight six to 12-year-olds.

Creator Edita Kaye claimed it was "a safe solution to the very real risk ... created by juvenile obesity."

"It helps their metabolism and gives kids hope and motivation," Ms Kaye, who describes herself as America's favourite nutritionist, told the New York Post.

"The reality is, mommy is taking pills to lose weight and daddy's taking stuff to help him, so why not make something safe for kids?"

But Dr Keith Ayoob, professor of paediatrics at New York's Albert Einstein College of Medicine, called the supplements "junk science." "The vitamins she puts in there aren't anything you can't get from a balanced diet or a regular multivitamin," he said.

Dr Kerry Sulkowicz, from the American Psychoanalytic Association, said it set a dangerous precedent that pills could provide a solution to every problem. "Clearly there are risks, psychologically and physically, to obesity at any age, but obesity is not a simply physical matter.

A 30-day supply of Skinny Pills is sold for \$40 on Ms Kaye's website, which she runs from Jacksonville, Florida.

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212-468-4888

Tab 7

March 3, 2003

BY FAX: 202-225-1919

Kellie Andrews
Majority Counsel
U. S. House of Representatives
Committee on Energy and Commission
Washington, D. C. 20515

Re: The Fountain of Youth Group, LLC

Dear Ms. Andrews:

We are counsel to Edita Kaye, President of The Fountain of Youth Group, LLC and am responding on her behalf to the letter from the Committee dated February 25, 2003 vis-à-vis "Skinny Pills for Kids" and "Skinny Pills for Teens".

AS WE HAVE MENTIONED IN THE PAST THERE HAS NEVER BEEN A SKINNY PILL FOR KIDS OR SKINNY PILL FOR TEENS EVER PRODUCED.

The Fountain of Youth Group, LLC is a small company with less than five employees. Edita Kaye is a noted nutritionist who has been giving advice on nutrition and weight loss to adults for many years. About two years ago she became very interested in the health and weight management of children, particularly because of the rise in obesity in children. She began a study of this issue by reading books available on the subject written by health care professionals and others. She has also interviewed children about their weight and weight loss problems.

As you also know, obesity in children is a concern of national importance. Ms. Kaye decided that a positive approach based upon her program for adults could be helpful in this area. Her goal was to create a nutritional food program based on the concept of high fiber foods and high protein foods and which could be made appealing to children through flash cards, posters, refrigerator magnets and even a kids cookbook which would allow them to prepare fast nutritious meals by themselves. The idea of coupling this food plan with a dietary

DAVIS & GILBERT LLP

Kellie Andrews
March 3, 2003
Page 2

supplement stem from Ms. Kaye becoming aware of the product, PediaLean, a product of the Klein-Becker Company (see www.pedialean.com).

Ms. Kaye contacted PAL Laboratory, a Florida company and had discussion with that company's formulator concerning the appropriate formula for a dietary supplement. PAL is owned by Farned, a multi-million dollar U. S. pharmaceutical company. The formula for the dietary supplement to which you have referred is one designed by PAL Laboratory.

After reviewing information from PAL Laboratory, Ms. Kaye sat down with a web designer to create a page which would appear on her website discussing the concept of a food plan accompanied with a nutritional supplement for children. The page was developed and was to be placed on a test server to allow Ms. Kaye to examine it and make necessary revisions. Unfortunately, the page was placed onto Ms. Kaye's active website on November 29, 2002. When Ms. Kaye became aware of this fact she ordered the page removed and that took place on December 15, 2002. Ms. Kaye has no plans of marketing a dietary supplement designed specifically for kids or teens.

We hope the above explains the confusion that has arisen from Ms. Kaye's appearance on television. If you believe you need any further information, please contact me.

Very truly yours,



Stuart Lee Friedel

SLF/nro
copy: Edita Kaye

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Tab 8

March 12, 2003

VIA FACSIMILE AND FIRST CLASS MAIL

Kellie Andrews, Esquire
Majority Counsel
U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515-6115

Re: The Fountain of Youth Group, LLC

Dear Ms. Andrews:

My firm has been retained by Edita Kaye, President of The Fountain of Youth Group, LLC, to serve as Washington counsel.

Although Ms. Kaye's counsel has already corresponded with you regarding this matter, I would like to re-emphasize that the dietary supplement which you referenced in your February 25, 2003, letter is not being sold, marketed or advocated by my client or her company. As such, there is no "Skinny Pill for Kids" or "Skinny Pill for Teens," a fact that has been distorted by the national media. Enclosed please find a news release from the National Advertising Division addressing Ms. Kaye's efforts to clarify this matter.

Hopefully this information is sufficient to satisfy your concerns regarding this matter and resolves the confusion which may have inadvertently been created by the media. If you would like to discuss this further please do not hesitate to contact me.

Sincerely,



Andrew D. Herman

Enclosure

2003-03-11 03:26pm From:

DATE

PAGE 81

03/11/2003 13:52 NFD + 12124594888

T-535 P.002/103 F-473

NO.866 2882

NATIONAL ADVERTISING DIVISION

70 West 36th Street, New York, NY 10018

NEWS RELEASEFor Immediate Release
Contact: 212.705.0120**THE FOUNTAIN OF YOUTH GROUP SUCCESSFULLY PARTICIPATES
IN NAD SELF-REGULATORY PROCESS***NAD pleased that Edin's Skinny.com has discontinued advertising claims for The Skinny Pill For Kids*

New York, NY - March 13, 2003 - The National Advertising Division (NAD) of the Council of Better Business Bureaus, Inc., the advertising industry's self-regulatory forum, announced that it was pleased to learn that The Fountain of Youth Group, producer of Edin Kaye's Skinny.com website had discontinued publication of its advertising claims for the product The Skinny Pill For Kids. The truth and accuracy of the advertiser's claim was brought to the attention of NAD through its routine and on-going monitoring program.

NAD was concerned about the accuracy of the claims and representations that The Skinny Pill For Kids is, "the first real help in fighting fat" and that it is "formulated with the finest ingredients to help children reduce their risk of obesity-related diseases...." NAD also expressed concern about other claims that The Skinny Pill For Kids "offer[s] very real weight loss help through supplements that metabolically assist children to burn more fat pounds and inches, block new fat deposits and help regulate insulin levels to help mitigate fat factors," and that it is "an exciting proprietary blend of safe, natural vitamins, minerals, and fat fighting nutrients in a special blend just for children's unique needs." In light of its concerns as to the safety and efficacy of this product, NAD was pleased that the advertising was no longer being published and all references to The Skinny Pill For Kids had been discontinued.

In a statement to NAD, the advertiser thanked NAD for the way in which the matter was handled and stated that the claims were unintentionally published on the website. The advertiser further noted that, "While meetings had been held with professionals regarding development of the product, no product had been formulated."

For a complete case report of the NAD decision, please contact Sheryl Harris at 212.705.0120.

NAD's inquiry was conducted under NAD/CARUNARB Procedures for the Voluntary Self-Regulation of National Advertising. Details of the initial inquiry, NAD's decision, and the advertiser's response will be included in the next NAD Case Report.

phone: 866.334.6272 • fax: 212.705-0134 • www.nadreview.org

Administered for the National Advertising Review Council (NARC) by the Council of Better Business Bureaus (CBBB)

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 2009-03-11 06:27pm From-

PAGE 02

T-395 P.003/003 F-473

03/11/2003 13:52 NAD + 12124684988

NO.865 0083

The National Advertising Review Council (NARC) was formed in 1971 by the Association of National Advertisers, Inc. (ANA), the American Association of Advertising Agencies, Inc. (AAAA), the American Advertising Federation, Inc. (AAF), and the Council of Better Business Bureaus, Inc. (CBBB). Its purpose is to foster truth and accuracy in national advertising through voluntary self-regulation. NARC is the body that establishes the policies and procedures for the CBBB's National Advertising Division (NAD), the Children's Advertising Review Unit (CARU), and the National Advertising Review Board (NARB).

NAD and CARU are the investigative arms of the advertising industry's voluntary self-regulation program. Their casework results from competitive challenges from other advertisers, and also from self-monitoring traditional and new media, including the internet. The National Advertising Review Board (NARB), the appeals body, is a peer group from which ad-hoc panels are selected to adjudicate those cases that are not resolved at the NAD/CARU level. This unique, self-regulatory system is funded entirely by the business community; CARU is financed by the children's advertising industry, while NAD/NARB's sole source of funding is derived from membership fees paid to the Council of Better Business Bureaus.

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Tab 9

June 10, 2004

VIA FACSIMILE AND FIRST CLASS MAIL

Kelli Andrews, Esquire
Majority Counsel
U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515-6115

Re: **The Fountain of Youth Group, LLC**

Dear Ms. Andrews:

My firm represents Edita Kaye and I am responding to the June 8, 2004, facsimile inviting Ms. Kaye to testify voluntarily before the Energy and Commerce Committee's Subcommittee on Oversight & Investigations on Wednesday, June 16, 2004. As requested by the Subcommittee, I am providing this response prior to the deadline of 5 p.m. on Thursday, June 10, 2004.

Ms. Kaye has elected to decline respectfully your invitation to testify before the Subcommittee on the subject of "Parents Be Aware: Health Concerns about Dietary Supplements for Overweight Children." As I noted to you in my March 12, 2003, letter regarding your initial inquiry, no dietary supplement for children or teens is being "sold, marketed or advocated by my client or her company." Accordingly, Ms. Kaye will not accept your invitation to testify.

Sincerely,



Andrew D. Herman

BRAND & FRULLA, P.C.

923 Fifteenth Street, N.W.
Washington, D.C. 20005
(202) 662-9700 (telephone)
(202) 737-7565 (facsimile)

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Date: June 10, 2004

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Time:

TOTAL NUMBER OF PAGES, INCLUDING COVER SHEET: 2

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Tab 10

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For Release: February 4, 2004

Related Documents:

The "Skinny Pills" Do Not Make You Skinny, Says the FTC

Marketers of the Skinny Pill Settle FTC Charges That They Made False and Unsubstantiated Weight-Loss Claims

The Fountain of Youth Group, LLC, and its principal, Edita Kaye, have settled Federal Trade Commission charges that they made false and unsubstantiated weight-loss and health claims for their dietary supplement products – Skinny Pill AM, Skinny Sleep PM, Skinny Carbs, and Skinny Pill for Kids (collectively "Skinny Pills"). The proposed settlement, which requires the court's approval, prohibits the defendants from making any weight-loss or health benefit claims for the Skinny Pills and similar products, unless they have competent and reliable scientific evidence to support such claims. The proposed settlement also contains a judgment of \$6 million, which has been suspended due to the defendants' inability to pay.

The Fountain of Youth LLC, a Limited Liability Company, and Edita Kaye, individually and as Founder and Manager of Fountain of Youth Group, LLC, are named as defendants in *United States District Court Middle District of Florida, Jacksonville Division*, FTC File No. 032-3041, Action No. 3:04-CV-47-

Consumer Information

The FTC filed its complaint in federal district court alleging that the Florida-based defendants advertise their products on the Internet at www.skinnypill.com and through other multimedia advertisements, making claims such as:

- Amazing Weight Loss Web site

"My PM Skinny Sleep works overnight with a thermic formula to burn fat while you sleep . . . to make sure you wake up . . . skinnier than when you went to bed."

"Skinny Carbs is the miracle that lets you occasionally 'cheat' without guilt or added fat pounds. . . . When you eat a carb, Skinny Carbs blocks the starch from being broken down into sugar. . . . Skinny carbs cuts [sic] right into that cycle . . . and prevents starch from turning into sugar and then into fat. Instead, it passes right through our system. The result? We can enjoy our carbs without having them turn into body fat."

The Skinny Pill for Kids

"This is the FIRST thermic and herbal formula ever developed for weight loss for children 6 to 12 and has been created to help our children win their battle with fat."

The FTC complaint alleges that the defendants did not have a reasonable basis to substantiate the claims that use of the Skinny Pill AM and the Skinny Sleep PM causes weight loss, increases fat burning, normalizes insulin and blood sugar levels, and causes dietary fat to be passed out of the body before it can be digested; that use of Skinny Carbs blocks the absorption of carbohydrates, preventing them from being converted into fat, and thereby causing weight loss; and that use of Skinny Carbs normalizes insulin and blood sugar levels. The FTC's complaint also alleges as false the claim that use of the Skinny Pill AM and Skinny Sleep PM causes dietary fat to be passed out of the body before it can be digested, thereby causing substantial weight loss. In addition, the FTC alleges that the defendants' claims that scientific research establishes the use of the Skinny Pill AM and the Skinny Sleep PM causes weight loss and that use of Skinny Carbs blocks new fat from forming when one eats a starchy meal are false.

The FTC further alleges that the defendants did not have reasonable basis to substantiate the

claims that use of the Skinny Pill for Kids for children 6 to 12 years old causes weight loss; causes children to burn increased fat; blocks new fat deposits; normalizes insulin and blood sugar levels; reduces the risk of obesity-related disease, including heart disease, high blood pressure, and diabetes; helps control diabetes and digestive disorders in children; or is safe. Finally, the FTC alleges that the defendants' claims that scientific research establishes that use of the Skinny Pill for Kids causes weight loss in, or is safe for, children 6 to 12 years old is false.

The proposed stipulated final order prohibits The Fountain of Youth and Kaye from representing, including through the use of names "Skinny Pill" or "Skinny Sleep," that use of Skinny Pill AM, Skinny Sleep PM, or any substantially similar product causes weight loss, increases fat burning, or normalizes insulin and blood sugar levels, unless these claims are substantiated by competent and reliable scientific evidence. Moreover, the defendants are prohibited from representing that use of the Skinny Pill AM, Skinny Sleep PM, or any substantially similar product will cause dietary fat to be passed out of the body before it can be digested, thereby causing substantial weight loss.

With respect to Skinny Carbs or any substantially similar product, the settlement prohibits the defendants from representing, including through the use of the name "Skinny Carbs," that use of the product blocks the absorption of carbohydrates, preventing them from being converted into fat and thereby causing weight loss, or that use of such product normalizes insulin or blood sugar levels, unless these claims are substantiated by competent and reliable scientific evidence.

The settlement also prohibits the defendants from representing, including through the use of the name "Skinny Pill," that use of Skinny Pill For Kids for children 6 to 12 years old or any substantially similar product causes weight loss; increases fat burning; blocks new fat deposits; normalizes insulin and blood sugar levels; reduces the risk of obesity-related disease; controls diabetes and digestive disorders; or is safe, unless these claims are substantiated by competent and reliable scientific evidence.

The proposed stipulated order further requires The Fountain of Youth LLC and Kaye to possess competent and reliable scientific evidence to substantiate any future representations, including through the use of trade names or endorsements, concerning the absolute or comparative weight loss or other health benefit, performance, safety, or efficacy of any dietary supplement, food, drug, or device; or any program that purports to promote weight loss and that involves the offering for sale or sale of any product or service of the defendants. The order prohibits the defendants from misrepresenting the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

Finally, the settlement contains various recordkeeping requirements to assist the FTC in monitoring the defendants' compliance.

The Commission vote to authorize staff to file the complaint and proposed stipulated final order for permanent injunction was 5-0. The complaint and stipulated final order were filed in the U.S. District Court, Middle District of Florida, Jacksonville Division, on January 28, 2004. The stipulated final order requires the court's approval.

NOTE: The Commission files a complaint when it has "reason to believe" that the law has been or is being violated, and it appears to the Commission that a proceeding is in the public interest. The complaint is not a finding or ruling that the defendant has actually violated the law. The case will be decided by the court.

NOTE: This proposed stipulated final order for permanent injunction is for settlement purposes only and does not constitute an admission by the defendants of a law violation. Stipulated final order for permanent injunctions have the force of law when signed by the judge.

Copies of the complaint and stipulated final order for permanent injunction are available from the FTC's Web site at <http://www.ftc.gov> and also from the FTC's Consumer Response Center, Room 130, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580. The FTC works for the consumer to prevent fraudulent, deceptive, and unfair business practices in the marketplace and to provide information to help consumers spot, stop, and avoid them. To file a complaint, or to get free information on any of 150 consumer topics, call toll-free, 1-877-FTC-HELP (1-877-382-4357), or use the complaint form at <http://www.ftc.gov>. The FTC enters internet, telemarketing, identity theft, and other fraud-related complaints into Consumer Sentinel, a secure, online database available to hundreds of civil and criminal law enforcement agencies in the U.S. and abroad.

MEDIA CONTACT:

Brenda Mack
Office of Public Affairs
202-326-2182

STAFF CONTACT:

Barbara Anthony, Donald D'Amato, or Michael Bloom
FTC NERO - New York
212-607-2829

(FTC File No. 032-3041)
(Civil Action No. 3:04-CV-47-J-99HTS)

(<http://www.ftc.gov/opa/2004/01/funeral.htm>)

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UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
JACKSONVILLE DIVISION

FEDERAL TRADE COMMISSION,

Plaintiff,

v.

THE FOUNTAIN OF YOUTH GROUP,
LLC,
a limited liability company, and

EDITA KAYE,
individually and as founding member and
manager of The Fountain of Youth Group,
LLC.

Defendants.

Tab 11

Civ. No.

**STIPULATED FINAL ORDER
FOR PERMANENT INJUNCTION**

Plaintiff, the Federal Trade Commission ("FTC" or "Commission"), commenced this action by filing its Complaint for a permanent injunction and other relief against The Fountain of Youth Group, LLC, a limited liability company, and Edita Kaye, individually and as founding member and manager of The Fountain of Youth Group, LLC, pursuant to Section 13(b) of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 53(b), alleging violations of Sections 5 and 12 of the FTC Act, 15 U.S.C. §§ 45 and 52.

The Commission, by and through its counsel, and defendants, by and through their counsel, have agreed to the entry of this Stipulated Final Order For Permanent Injunction ("Order") and have requested that the Court enter the same to resolve all matters of dispute

between them in this action without trial and adjudication of any issue of law or fact herein.

NOW, THEREFORE, the Commission and defendants having requested this Court to enter this Order, **IT IS HEREBY ORDERED, ADJUDGED, AND DECREED** as follows:

FINDINGS

1. This Court has jurisdiction of the subject matter of this case and of the parties consenting hereto. Venue in the Middle District of Florida is proper.

2. The Complaint states a claim upon which relief can be granted, and the Commission has authority to seek the relief it has requested under Sections 5, 12, and 13(b) of the FTC Act, 15 U.S.C. §§ 45, 52, and 53(b).

3. The acts and practices of the defendants were or are in or affecting commerce, as "commerce" is defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

4. Defendants waive all rights to seek judicial review, or otherwise challenge or contest the validity, of this Order. Defendants also waive any claim that they may have held under the Equal Access to Justice Act, 28 U.S.C. § 2412, concerning the prosecution of this action to the date of this Order.

5. This action and the relief awarded herein are in addition to, and not in lieu of, other remedies as may be provided by law.

6. Each party shall bear its own costs and attorneys' fees.

7. Defendants, without admitting or denying the allegations of wrongdoing set forth in the Commission's Complaint, stipulate and agree to entry of this Order under Section 13(b) of the FTC Act, 15 U.S.C. § 53(b). This Order does not constitute and shall not be interpreted to constitute either an admission by defendants, or a finding by the Court, of any liability or wrongdoing by any of the defendants or any violation of any law, rule, or

regulation.

8. Entry of this Order is in the public interest.

DEFINITIONS

1. "Defendants" shall mean The Fountain of Youth Group, LLC and Edita Kaye.
2. "Competent and reliable scientific evidence" shall mean tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.

3. "Food," "drug," and "device" shall have the same meaning as "food," "drug," and "device" as defined in Section 15 of the Federal Trade Commission Act, 15 U.S.C. § 55.

4. "Covered product or service" shall mean: (a) any dietary supplement, food, drug, or device; or (b) any program that involves the offering for sale or sale of any product or service in which defendants have, directly or indirectly, a financial interest, that purports to promote weight loss, the reduction or elimination of fat, slimming, or caloric deficit; or that purports to prevent weight gain, in a user of such product or service.

5. "Person" shall mean a natural person, organization, or other legal entity, including a partnership, corporation, limited liability company, proprietorship, association, cooperative, or any other group acting together as an entity.

CONDUCT PROHIBITIONS

I.

IT IS HEREBY ORDERED that defendants, and their agents, servants, employees, attorneys, corporations, subsidiaries, successors, assigns, and all other persons or entities in

active concert or participation with any of the defendants who receive actual notice of this Order by personal service, facsimile, or otherwise, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of Skinny Pill AM, Skinny Sleep PM, or any substantially similar product in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, including through the use of the names "Skinny Pill" or "Skinny Sleep," that:

- A. use of such product causes weight loss;
- B. use of such product causes increased fat burning;
- C. use of such product normalizes insulin and blood sugar levels; or
- D. use of such product causes dietary fat to be passed out of the body before it can be digested;

unless, at the time the representation is made, defendants possess and rely upon competent and reliable scientific evidence that substantiates the representation.

II.

IT IS FURTHER ORDERED that defendants, and their agents, servants, employees, attorneys, corporations, subsidiaries, successors, assigns, and all other persons or entities in active concert or participation with any of the defendants who receive actual notice of this Order by personal service, facsimile, or otherwise, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of Skinny Pill AM, Skinny Sleep PM, or any substantially similar product in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, that use of such product causes dietary fat to be passed out of the body before it can be digested, thereby causing substantial weight loss.

III.

IT IS FURTHER ORDERED that defendants, and their agents, servants, employees, attorneys, corporations, subsidiaries, successors, assigns, and all other persons or entities in active concert or participation with any of the defendants who receive actual notice of this Order by personal service, facsimile, or otherwise, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of Skinny Carbs or any substantially similar product in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, including through the use of the name "Skinny Carbs," that:

- A. use of such product blocks the absorption of carbohydrates, preventing them from being converted into fat and thereby causing weight loss; or
- B. use of such product normalizes insulin and blood sugar levels;

unless, at the time the representation is made, defendants possess and rely upon competent and reliable scientific evidence that substantiates the representation.

IV.

IT IS FURTHER ORDERED that defendants, and their agents, servants, employees, attorneys, corporations, subsidiaries, successors, assigns, and all other persons or entities in active concert or participation with any of the defendants who receive actual notice of this Order by personal service, facsimile, or otherwise, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of Skinny Pill for Kids or any substantially similar product in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, including through the use of the name "Skinny Pill," that:

- A. use of such product causes weight loss in children 6 to 12 years old;

- B. use of such product causes children 6 to 12 years old to burn increased fat;
- C. use of such product blocks new fat deposits in children 6 to 12 years old;
- D. use of such product normalizes insulin and blood sugar levels in children 6 to 12 years old;
- E. use of such product reduces the risk of obesity related disease, including heart disease, high blood pressure, and diabetes, in children 6 to 12 years old;
- F. use of such product helps control diabetes and digestive disorders in children 6 to 12 years old; or
- G. use of such product is safe for children 6 to 12 years old;

unless, at the time the representation is made, defendants possess and rely upon competent and reliable scientific evidence that substantiates the representation.

V.

IT IS FURTHER ORDERED that defendants, and their agents, servants, employees, attorneys, corporations, subsidiaries, successors, assigns, and all other persons or entities in active concert or participation with any of them, directly or through any corporation, subsidiary, division, or other device, and all other persons or entities in active concert or participation with any of them who receive notice of this Order by personal service or otherwise, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any covered product or service in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, including through the use of trade names or endorsements, about the absolute or comparative weight loss or other health benefits, performance, efficacy, safety, or side effects, of any covered product or service, including, but not limited to the following:

- A. use of such product causes weight loss;

- B. use of such product increases fat burning;
- C. use of such product causes dietary fat or starch to be passed out of the body before it can be digested;
- D. use of such product enables users to lose weight at any specified rate or to lose any specified amount of weight in total;
- E. use of such product enables users to lose weight or fat without dieting or exercising;
- F. use of such product enables users to maintain permanent or persistent weight loss;
- G. use of such product normalizes insulin or blood sugar levels;
- H. use of such product reduces the risk of obesity related disease, including heart disease, high blood pressure, and diabetes, or otherwise improves health;
- I. use of such product is safe or has no side effects; or
- J. scientific research establishes any of the claims in Subparagraphs A through I hereof;

unless, at the time the representation is made, defendants possess and rely upon competent and reliable scientific evidence that substantiates the representation.

VI.

IT IS FURTHER ORDERED that defendants, and their agents, servants, employees, attorneys, corporations, subsidiaries, successors, assigns, and all other persons or entities in active concert or participation with any of them, directly or through any corporation, subsidiary, division, or other device, and all other persons or entities in active concert or participation with any of them who receive notice of this Order by personal service or otherwise, in connection with the manufacturing, labeling, advertising, promotion, offering

for sale, sale, or distribution of any covered product or service in or affecting commerce, shall not misrepresent, in any manner, expressly or by implication, the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

FOOD AND DRUG REGULATIONS

VII.

Nothing in this Order shall prohibit defendants from making any representation for any drug that is permitted in labeling for such drug under any tentative final or final standard promulgated by the Food and Drug Administration, or under any drug application approved by the Food and Drug Administration. Nor shall it prohibit defendants from making any representation for any product that is specifically permitted in labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990.

SUSPENDED JUDGMENT

VIII.

IT IS FURTHER ORDERED that judgment is entered against defendants, jointly and severally, in the amount of six million dollars (\$6,000,000), *provided, however*, that this judgment shall be suspended subject to the conditions set forth in Section IX of this Order.

RIGHT TO REOPEN

IX.

IT IS FURTHER ORDERED that the Commission's agreement to this Order is expressly premised upon the truthfulness, accuracy, and completeness of defendants' financial conditions as represented in the Financial Statements and information provided to the Commission, including the financial records provided to the Commission on June 9, 2003, July 22, 2003, July 23, 2003, and August 26, 2003 and defendants' financial

statements executed on May 29, 2003 and revised and re-executed on August 22, 2003, which contain material information and documents upon which the Commission relied in negotiating and agreeing to the terms of this Order.

- A. If, upon motion by the Commission, this Court finds that defendants' financial statements failed to disclose any material asset, or materially misrepresented the value of any asset, or made any other material misrepresentation in or omission from any financial statement, the Court shall enter judgment against defendants, jointly and severally, and in favor of the Commission, in the amount of six million dollars (\$6,000,000), which will become immediately due and payable less any amounts previously paid. For purposes of this Section and any subsequent proceedings to enforce payment, including but not limited to a non-dischargeability complaint filed in a bankruptcy case, defendants waive any right to contest any of the allegations in the Commission's complaint.
- B. All funds paid pursuant to this Section shall be deposited into a fund administered by the Commission or its agent to be used for equitable relief, including but not limited to, consumer redress and any attendant expenses for the administration of any redress fund. In the event that direct redress to consumers is wholly or partially impracticable or funds remain after redress is completed, the Commission may apply any remaining funds for such other equitable relief (including consumer information remedies) as it determines to be reasonably related to the defendants' practices alleged in the complaint. Any funds not used for such equitable relief shall be deposited to the Treasury as disgorgement. Defendants shall have no right to challenge the Commission's choice of

remedies under this Section. No portion of this Judgment for equitable monetary relief shall be deemed a fine, penalty or punitive assessment, or forfeiture. The Commission shall have full and sole discretion to:

1. Determine the criteria for participation by individual claimants in any consumer redress program implemented pursuant to this Order;
 2. Determine the manner and timing of any notices to be given to consumers regarding the existence and terms of such programs; and
 3. Delegate any and all tasks connected with such redress program to any individuals, partnerships, or corporations; and pay reasonable fees, salaries, and expenses incurred thereby from the payments made pursuant to this Order;
- C. Defendants expressly waive their rights to litigate the issue of disgorgement. Defendants acknowledge and agree that all money paid pursuant to this Order is irrevocably paid to the Commission for purposes of settlement between plaintiff and defendants;
- D. Defendants shall also furnish to the Commission, in accordance with 31 U.S.C. § 7701, their taxpayer identification numbers (social security number, social insurance number, or employer identification number), which shall be used for purposes of collecting and reporting on any delinquent amount arising out of defendants' relationship with the government.

COMPLIANCE MONITORING

X.

IT IS FURTHER ORDERED that, for the purpose of monitoring and investigating compliance with any provision of this Order,

- A. Within ten (10) days of receipt of written notice from a representative of the Commission, any defendant receiving such notice shall submit additional written reports, sworn to under penalty of perjury; produce documents for inspection and copying; appear for deposition; and/or provide entry during normal business hours to any business location in such defendant's possession or direct or indirect control to inspect the business operation;
- B. In addition, the Commission is authorized to monitor compliance with this Order by all other lawful means, including but not limited to the following:
1. obtaining discovery from any person, without further leave of court, using the procedures prescribed by Fed. R. Civ. P. 30, 31, 33, 34, 36, and 45;
 2. posing as consumers and suppliers to: defendants or employees of The Fountain of Youth Group, LLC or Edita Kaye, or any other entity managed or controlled in whole or in part by defendants The Fountain of Youth Group, LLC or Edita Kaye, without the necessity of identification or prior notice;
- Provided that*** nothing in this Order shall limit the Commission's lawful use of compulsory process pursuant to Sections 9 and 20 of the FTC Act, 15 U.S.C. §§ 49, 57b-1, to obtain any documentary material, tangible things, testimony, or information relevant to unfair or deceptive acts or practices in or affecting commerce (within the meaning of 15 U.S.C. § 45(a)(1)).
- C. Defendants The Fountain of Youth Group, LLC and Edita Kaye shall permit representatives of the Commission to interview any employer, consultant, independent contractor, representative, agent, or employee who has agreed to such an interview, relating in any way to any conduct subject to

this Order. The person interviewed may have counsel present.

COMPLIANCE REPORTING BY DEFENDANT

XI.

IT IS FURTHER ORDERED that, in order that compliance with the provisions of this Order may be monitored:

- A. For a period of five (5) years from the date of entry of this Order,
 - 1. Defendant Edita Kaye shall notify the Commission of the following:
 - a. Any changes in her own residence, mailing addresses, and telephone numbers, within ten (10) days of the date of such change;
 - b. Any changes in her employment status (including self-employment) within ten (10) days of the date of such change. Such notice shall include the name and address of each business that she is affiliated with, employed by, or performs services for; a statement of the nature of the business; and a statement of her duties and responsibilities in connection with the business;
 - c. Any changes in her name or use of any aliases or fictitious names; and
 - 2. Defendants The Fountain of Youth Group, LLC and Edita Kaye shall notify the Commission of any changes in corporate structure that may affect compliance obligations arising under this Order, including but not limited to a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor corporation; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this Order; the filing of a bankruptcy petition; or a change in the corporate name or address, at least thirty (30) days prior to such change, *provided*

that, with respect to any proposed change in the corporation about which the defendants learn less than thirty (30) days prior to the date such action is to take place, defendants shall notify the Commission as soon as is practicable after obtaining such knowledge.

B. One hundred eighty (180) days after the date of entry of this Order, defendants

The Fountain of Youth Group, LLC and Edita Kaye each shall provide a written report to the FTC, sworn to under penalty of perjury, setting forth in detail the manner and form in which they have complied and are complying with this Order. This report shall include, but not be limited to:

1. Any changes required to be reported pursuant to Subparagraph A above;
2. A copy of each acknowledgment of receipt of this Order obtained by defendant pursuant to Section XIII;

C. For the purposes of this Order, defendant shall, unless otherwise directed by the Commission's authorized representatives, mail all written notifications to

the

Commission to:
Regional Director for Northeast Region
Federal Trade Commission
One Bowling Green, Suite 318
New York, NY 10004

Re: FTC v. The Fountain of Youth Group, LLC et al.,

Civil Action No. _____.

D. For purposes of the compliance reporting required by this Section, the

Commission is authorized to communicate directly with defendants
The Fountain of Youth Group, LLC and Edita Kaye

RECORD KEEPING PROVISIONS**XII.**

IT IS FURTHER ORDERED that, for a period of eight (8) years from the date of entry of this Order, defendants The Fountain of Youth Group, LLC and Edita Kaye, and their agents, employees, officers, corporations, successors, and assigns, and those persons in active concert or participation with them who receive actual notice of this Order by personal service or otherwise, are hereby restrained and enjoined from failing to create and retain the following records applicable to defendant The Fountain of Youth Group, LLC and any business where: (1) defendant Edita Kaye is the majority owner of the business or directly or indirectly manages or controls the business; and (2) the business is engaged in the manufacturing, labeling, advertising, promotion, offering for sale, or distribution, in or affecting commerce, of any covered product:

- A. all advertisements and promotional materials containing representation(s) relating to a covered product;
- B. all materials that were relied upon in disseminating representation(s) relating to a covered product;
- C. all tests, reports, studies, surveys, demonstrations, and other evidence in their possession, custody, or control that contradict, qualify, or call into question the representation(s) relating to a covered product, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental entities or consumer protection organizations;
- D. accounting records that reflect the cost of goods or services sold, revenues generated, and the disbursement of such revenues;
- E. personnel records accurately reflecting: the name, address, and telephone

number of each person employed in any capacity by such business, including as an independent contractor; that person's job title or position; the date upon which the person commenced work; and the date and reason for the person's termination, if applicable;

F. customer files containing the names, addresses, phone numbers, dollar amounts paid, quantity of items or services purchased, and description of items or services purchased, to the extent such information is obtained in the ordinary course of business;

G. complaint and refund requests (whether received directly, indirectly, or through any third party) and any responses to those complaints or requests; and

H. copies of all sales scripts, training materials, advertisements, and other marketing materials.

DISTRIBUTION OF ORDER BY DEFENDANTS

XIII.

IT IS FURTHER ORDERED that, for a period of five (5) years from the date of entry of this Order,

A. Defendant The Fountain of Youth Group, LLC shall deliver a copy of this Order to all principals, officers, directors, managers, employees, agents, and representatives having responsibilities with respect to the subject matter of this Order, and shall secure from each such person a signed and dated statement acknowledging receipt of the Order. The Fountain of Youth Group, LLC shall deliver this Order to current personnel within thirty (30) days after the date of service of this Order, and to new personnel within thirty (30) days after the person assumes such position or responsibilities.

B. Defendant Edita Kaye shall deliver a copy of this Order to the principals, officers, directors, managers and employees under Edita Kaye's control, of Fountain of Youth Group, LLC and any business that (1) employs or contracts for personal services from Edita Kaye and (2) has responsibilities with respect to the subject matter of this Order. Edita Kaye shall secure from each such person a signed and dated statement acknowledging receipt of the Order within thirty (30) days after the date of service of the Order or the commencement of the employment relationship.

ACKNOWLEDGMENT OF RECEIPT OF ORDER BY DEFENDANTS

XIV.

IT IS FURTHER ORDERED that each defendant, within five (5) business days of receipt of this Order as entered by the Court, must submit to the Commission a truthful sworn statement acknowledging receipt of this Order.

RETENTION OF JURISDICTION

XV.

IT IS FURTHER ORDERED that this Court shall retain jurisdiction of this matter for purposes of construction, modification, and enforcement of this Order.

SO STIPULATED:

PLAINTIFF:

BARBARA ANTHONY (BA 02000)
Regional Director, Northeast Region
Federal Trade Commission

MICHAEL BLOOM (MB 7732)
Senior Counsel to the Northeast Region
Federal Trade Commission

DONALD D'AMATO (DD 3008)
Assistant Regional Director, Northeast Region
Federal Trade Commission
One Bowling Green, Suite 318
New York, NY 10004
(212) 607-2829
(212) 607-2822 (facsimile)

DEFENDANTS:

THE FOUNTAIN OF

YOUTH GROUP, LLC
Edita Kaye, as Founding Member and Manager

EDITA KAYE, Individually and
as Founding Member and Manager of
The Fountain of Youth Group, LLC

STUART FRIEDEL
Attorney for Defendants
Davis & Gilbert LLP

ADAM SOLOMON
Attorney for Defendants
Davis & Gilbert LLP
1740 Broadway
New York, NY 10019
(212) 468-4800
(212) 468-4888 (facsimile)

JOHN BALL
(Fl. Bar No.)
Attorney for Defendants

SO ORDERED, this _____ day of _____, 2004, at _____.

UNITED STATES DISTRICT JUDGE

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
JACKSONVILLE DIVISION

FEDERAL TRADE COMMISSION,

Plaintiff,

v.

THE FOUNTAIN OF YOUTH GROUP,
LLC,
a limited liability company, and

EDITA KAYE,
individually and as founding member and
manager of The Fountain of Youth Group,
LLC.

Defendants.

Tab 12

Civ. No.

**COMPLAINT FOR INJUNCTIVE
AND OTHER EQUITABLE
RELIEF**

Plaintiff, the Federal Trade Commission ("FTC" or "Commission"), by its undersigned attorneys, alleges as follows:

1. This is an action under Section 13(b) of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 53(b), to secure a permanent injunction and other equitable relief against defendants for engaging in deceptive acts or practices and the making of false advertisements in connection with the advertising, offering for sale, selling, and/or distribution of alleged weight loss products, Skinny Pill AM, Skinny Sleep PM, Skinny Carbs, and Skinny Pill for Kids, in violation of Sections 5 and 12 of the FTC Act, 15 U.S.C. §§ 45 and 52.

JURISDICTION AND VENUE

2. This Court has jurisdiction over Plaintiff's claim pursuant to 28 U.S.C. §§ 1331, 1337(a) and 1345, and 15 U.S.C. §§ 45(a), 52 and 53(b).
3. Venue in this District is proper under 28 U.S.C. §§ 1391(b) and (c) and 15 U.S.C. § 53(b).

PLAINTIFF

4. Plaintiff FTC is an independent agency of the United States Government created by statute. 15 U.S.C. §§ 41-58. The FTC enforces Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52, which prohibit, respectively, deceptive acts and practices, and false advertisements for food, drugs, devices or cosmetics in or affecting commerce. The FTC may initiate federal district court proceedings to enjoin violations of the FTC Act and to secure such equitable relief as may be appropriate in each case. 15 U.S.C. § 53(b).

DEFENDANTS

5. Defendant The Fountain of Youth Group, LLC ("Fountain of Youth") is a Delaware limited liability company with its principal office or place of business at 830-13 A1A North, Ponte Vedra Beach, Florida 32082. It markets various dietary supplements that purportedly cause substantial weight loss. Fountain of Youth transacts business in the Middle District of Florida.
6. Defendant Edita Kaye is founding member and manager of Fountain of Youth. Her principal office or place of business is the same as that of Fountain of Youth. In connection with the matters alleged herein, Edita Kaye transacts business in the Middle District of Florida. At all times material to this complaint, Edita Kaye, individually or in concert with others, formulated, directed, controlled, or participated in the policies, acts, or practices of Fountain of Youth, including the acts and practices alleged in this complaint.

COMMERCE

7. The acts and practices of defendants as alleged herein are in or affecting commerce, as "commerce" is defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

DEFENDANTS' COURSE OF CONDUCT

8. Beginning in 2000, defendants have marketed a variety of dietary supplements that purportedly cause substantial weight loss. These products have included Skinny Pill AM, Skinny Sleep PM capsules, Skinny Carbs capsules, and the Skinny Pill For Kids. These dietary supplements, which contain ingredients such as chromium, citrus aurantium, chitosan, green tea leaf extract, and herbal blends and diuretics, are purported to cause substantial weight loss through, among other means, speeding up thermogenesis (the production of heat through burning of calories) and blocking starch absorption.

9. Defendants have advertised, offered for sale, sold, and/or distributed Skinny Pill AM, Skinny Sleep PM, Skinny Carbs, and the Skinny Pill For Kids to consumers throughout the United States by means of personal promotions by Defendant Edita Kaye, radio commercials, a test infomercial, and Internet website(s).

Skinny Pill AM and Skinny Sleep PM

10. Defendants have disseminated or have caused to be disseminated advertisements for Skinny Pill AM and Skinny Sleep PM, including, but not limited to, the attached Exhibits A and B (excerpts from defendants' Internet website, www.skinnypill.com, on December 11, 2002), which include, among other things, the following statements and depictions:

[Edita's] **AM Skinny Pill** . . . works all day with a combination of the top five

fat fighters. (Ex. A-1)

Everything about Edita's Skinny Pill

The Skinny Pill formula is safe. . . . Effective. It includes the top 5 skinny supplements that help turn off your body's fat switch and break your food-to-fat cycle starting in just 24 hours.

Here's what this winning skinny formula contains:

Carnitine 250 mg

It helps to burn off stored fat . . . , suppresses your appetite and reduces cravings.

Chromium 400 mcg

. . . It acts as a thermogenic (fat burning) agent, reducing body fat without dieting or exercise.

Citrimax 300 mg

Decreases fat gain by inhibiting lipogenesis, the metabolic process by which our bodies turn food into fat.

Chitosan 250 mg

[P]lucks a double fat fighting whammy. It's a fat magnet, attracting fat before it gets digested and it's also a fat sponge, absorbing over four times its weight in dietary fat.

Citrus Aurantium 300 mg

Unlocks fat cells. Speeds up the rate at which fat is released from fat storage (lipolysis). Increases resting metabolism (thermogenesis) accelerating the rate at which your body burns fat. (Ex. A-5, A-6)

I [Edita Kaye] lost 67 pounds on the Skinny Pill! ["Before" and "after"

photographs shown.] (Ex. A-9)

Tracy

lost 26 pounds and ten inches on the Skinny Pill! ["Before" and "after" photographs shown.]

Priscilla

lost 30 pounds and 4 dress sizes on the Skinny Pill! ["Before" and "after" photographs shown.] (Ex. A-10, A-11)

Rebecca

lost 75 pounds and hubby lost 55 on the Skinny Pill! ["Before" and "after" photographs shown.] (Ex. A-13)

Lorraine

I have been taking the Skinny Pill for two months and have lost 32 pounds. (Ex. A-14)

Edita's Skinny products are the BEST! They are safe. Effective. Researched. Tested. Proven. (Ex. A-15)

Here is everything you need to know about Edita's Skinny PM.

[M]y special blend also contains skinny supplements that help your own natural fat fighting systems start to empty out those fat cells, overnight.

The Result? You should wake up rested, refreshed and SKINNER!

Here's my blend:

The Skinny Part Vitamin B6 [sic]

One of the most powerful metabolism boosting vitamins[.]

Chromium

A thermogenic agent and insulin cofactor, helping your body regulate sugar

and blood fat more efficiently.

Citrus Aurantium

Researchers believe that citrus aurantium zeros in on special Beta-3 receptors only, turning on their powerful fat fighting signal

Citrimax

Preliminary research shows that HCA [which is contained in Citrimax] decreases fat gain by inhibiting lipogenesis, the metabolic process by which our bodies turn food into fat.

L Carnitine

Helps burn off stored fat (Ex. B-3, B-4)

My **PM Skinny Sleep** works overnight with a thermic formula to burn fat while you sleep . . . to make sure you wake up . . . skinnier than when you went to bed. (Ex. B-6)

What is Skinny Sleep™?

[B]ased on the latest scientific research into both sleep supplements and thermogenics to help you . . . burn fat all night long. The result? You'll wake up rested . . . and skinnier than when you went to bed! (Ex. B-8)

Edita's Skinny products are the BEST! They are safe. Effective. Researched. Tested. Proven. (Ex. B-11)

Skinny Carbs

11. Defendants have disseminated or have caused to be disseminated advertisements for Skinny Carbs, including, but not limited to, the attached Exhibit C (excerpts from defendants' Internet website, www.skinnypill.com, on December 11, 2002), which include,

among other things, the following statements:

What is Skinny Carbs™?

Skinny Carbs is the miracle that lets you occasionally "cheat" without guilt or added fat pounds. . . . When you eat a carb, Skinny Carbs blocks the starch from being broken down into sugar. . . . Skinny carbs cuts [sic] right into that cycle [of conversion of excess sugar into fat stores] and prevents starch from turning into sugar and then into fat. Instead, it passes right through our system. The result? We can enjoy our carbs without having them turn into body fat.

What does it contain?

Skinny Carbs contain [sic] the following ingredients to help you get skinny, even if you have to cheat, occasionally.

Chromium: 500 mcg

Chromium plays an important role in the regulation of insulin and glucose levels, controlling hunger, and in regulating the metabolic rate. It promotes loss of body fat

Vanadium: 200 mcg

Most research has focused on its role in improving insulin action and reducing sugar cravings.

Glucosol™: 16 mg

Shown to reduce blood sugar levels [which otherwise usually would be converted into blood sugar].

D-Carb Energy Blend 450 mg

Green tea leaf extract, . . . fights fatigue, and helps diminish appetite. It's

also a thermogenic that can promote the burning of fat and regulate blood sugar.

D-Carb Support Blend 250 mg

Gymnema sylvestre leaf, . . . inhibits the digestive process causing the elimination of excess calories before they can be absorbed

How fast does it work?

Skinny Carbs begin to work within minutes to help keep you skinny even when you can't eat skinny. (Ex. C-1, C-2)

Edita's Skinny products are the BEST! They are safe. Effective. Researched. Tested. Proven. (Ex. C-4)

Skinny Pill For Kids

12. Defendants have disseminated or have caused to be disseminated advertisements for Skinny Pill for Kids, including, but not limited to, the attached Exhibit D (excerpts from defendants' Internet website, www.skinnypill.com, on December 11, 2002), which include, among other things, the following statements:

Edita is proud to offer you and your children the first SKINNY PILL just for kids! And because it's from Edita, America's Favorite Nutritionist, you know you and your kids can trust the Skinny Pill for Kids™.

This is the FIRST thermic and herbal formula ever developed for weight loss for children 6 to 12 and has been created to help our children win their battle with fat.

...

Here is a real solution for overweight kids and the adults that care about them. I give

you with great pride, America's first SKINNY PILL for Kids! [followed by
Edita' Kaye's signature]

**Here's how very special and exciting this new Skinny Pill for Kids really
is!**

1. It is the very first product that brings together fat fighting ingredients in one formula.
2. It contains an exciting, proprietary blend of safe . . . fat fighting nutrients . . . just for children's unique needs.
3. It is formulated . . . to help children reduce their risk of obesity-related diseases such as heart disease, high blood pressure and diabetes.
4. It offers very real weight-loss help through supplements that metabolically assist children to burn more fat pounds and inches, block new fat deposits, and help regulate insulin levels to mitigate fat factors.

. . .

Edita's Skinny Pill for Kids proprietary blend contains:

Niacin

[A]ids in the metabolism of carbohydrates, fat, and proteins.

. . .

Chromium

[I]s involved in the metabolism of glucose. . . . This essential mineral also maintains stable blood sugar levels

Pectins

[S]low the absorption of food after meals and also helps to lower cholesterol levels.

...

Glucommanan

This substance actually picks up and removes fat from the colon wall. It is good for diabetes and obesity, because one of its primary functions is the removal of fat. . . . It expands up to sixty times its own weight, and in so doing, helps maintain a feeling of fullness and curbs appetite.

...

Buchu Leaf

Aids in controlling diabetes, digestive disorders, and fluid retention. (Ex. D-1 thru D-4)

Edita's Skinny products are the BEST! They are safe. Effective. Researched. Tested. Proven. (Ex. D-6)

DEFENDANTS' VIOLATIONS OF THE FTC ACT

13. Section 5(a) of the FTC Act, 15 U.S.C. § 45(a), prohibits unfair or deceptive acts or practices in or affecting commerce. Section 12(a) of the FTC Act, 15 U.S.C. § 52(a), prohibits the dissemination of any false advertisement in or affecting commerce for the purpose of inducing, or which is likely to induce, the purchase of food, drugs, devices, services, or cosmetics. For the purposes of Section 12 of the FTC Act, Skinny Pill AM, Skinny Sleep PM, Skinny Carbs, and the Skinny Pill For Kids are either a "food" or "drug" as

defined in Section 15(b) and (c) of the FTC Act, 15 U.S.C. § 55(b) and (c).

14. As set forth below, the defendants have engaged in unlawful practices in violation of Sections 5(a) and 12(b) of the FTC Act in connection with the marketing and/or sale of Skinny Pill AM, Skinny Sleep PM, Skinny Carbs, and the Skinny Pill For Kids .

COUNT ONE

Unsubstantiated Efficacy Claims For Skinny Pill AM and Skinny Sleep PM

15. Through the means described in Paragraph 10, defendants have represented, expressly or by implication, that:

- A. Use of Skinny Pill AM and Skinny Sleep PM causes weight loss;
- B. Use of Skinny Pill AM and Skinny Sleep PM causes increased fat burning;
- C. Use of Skinny Pill AM and Skinny Sleep PM normalizes insulin and blood sugar levels; and
- D. Use of Skinny Pill AM and Skinny Sleep PM causes dietary fat to be passed out of the body before it can be digested.

16. Through the means described in Paragraph 10, defendants have represented, expressly or by implication, that they possessed and relied upon a reasonable basis that substantiated the representations set forth in Paragraph 15 at the time the representations were made.

17. In fact, defendants did not possess and rely upon a reasonable basis that substantiated the representations set forth in Paragraph 15 at the time the representations were made. Therefore, the making of the representation set forth in Paragraph 16 constitutes a deceptive practice, and the making of a false advertisement, in or affecting commerce, in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52.

COUNT TWO

False Claim For Skinny Pill AM and Skinny Sleep PM

18. Through the means described in Paragraph 10, defendants have represented, expressly or by implication, that use of Skinny Pill AM and Skinny Sleep PM causes dietary fat to be passed out of the body before it can be digested, thereby causing substantial weight loss.

19. In fact, use of Skinny Pill AM and Skinny Sleep PM does not cause dietary fat to be passed out of the body before it can be digested, thereby causing substantial weight loss. Therefore, the making of the representation set forth in Paragraph 18 constitutes a deceptive practice and the making of a false advertisement, in or affecting commerce, in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52.

COUNT THREE

False Establishment Claims For Skinny Pill AM and Skinny Sleep PM

20. Through the means described in Paragraph 10, defendants have represented, expressly or by implication, that scientific research establishes that use of Skinny Pill AM and Skinny Sleep PM causes weight loss.

21. In fact, scientific research does not establish that use of Skinny Pill AM and Skinny Sleep PM causes weight loss. Therefore, the making of the representation set forth in Paragraph 20 constitutes a deceptive practice and the making of a false advertisement, in or affecting commerce, in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52.

COUNT FOUR

Unsubstantiated Efficacy Claims For Skinny Carbs

22. Through the means described in Paragraph 11, defendants have represented,

expressly or by implication, that:

- A. Use of Skinny Carbs blocks the absorption of carbohydrates, preventing them from being converted into fat and thereby causing weight loss; and
- B. Use of Skinny Carbs normalizes insulin and blood sugar levels.

23. Through the means described in Paragraph 11, defendants have represented, expressly or by implication, that they possessed and relied upon a reasonable basis that substantiated the representations set forth in Paragraph 22 at the time the representations were made.

24. In fact, defendants did not possess and rely upon a reasonable basis that substantiated the representations set forth in Paragraph 22 at the time the representations were made. Therefore, the making of the representation set forth in Paragraph 23 constitutes a deceptive practice and the making of a false advertisement, in or affecting commerce, in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52.

COUNT FIVE

False Establishment Claim For Skinny Carbs

25. Through the means described in Paragraph 11, defendants have represented, expressly or by implication, that scientific research establishes that use of Skinny Carbs blocks new fat from forming when the user eats a starchy meal.

26. In fact, scientific research does not establish that use of Skinny Carbs blocks new fat from forming when one eats a starchy meal. Therefore, the making of the representation set forth in Paragraph 25 constitutes a deceptive practice and the making of a false advertisement, in or affecting commerce, in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52.

COUNT SIX

Unsubstantiated Efficacy and Safety Claims For The Skinny Pill For Kids

27. Through the means described in Paragraph 12, defendants have represented, expressly or by implication, that:
- A. Use of Skinny Pill for Kids causes weight loss in children 6 to 12 years old;
 - B. Use of Skinny Pill for Kids causes children 6 to 12 years old to burn increased fat;
 - C. Use of Skinny Pill for Kids blocks new fat deposits in children 6 to 12 years old;
 - D. Use of Skinny Pill for Kids normalizes insulin and blood sugar levels in children 6 to 12 years old;
 - E. Use of Skinny Pill for Kids reduces the risk of obesity related disease, including heart disease, high blood pressure, and diabetes, in children 6 to 12 years old;
 - F. Use of Skinny Pill for Kids helps control diabetes and digestive disorders in children 6 to 12 years old; and
 - G. Use of Skinny Pill for Kids is safe for children 6 to 12 years old.

28. Through the means described in Paragraph 12, defendants have represented, expressly or by implication, that they possessed and relied upon a reasonable basis that substantiated the representations set forth in Paragraph 27 at the time the representations were made.

29. In fact, defendants did not possess and rely upon a reasonable basis that substantiated the representations set forth in Paragraph 27 at the time the representations were made. Therefore, the making of the representation set forth in Paragraph 28 constitutes a deceptive practice and the making of a false advertisement, in or affecting commerce, in

violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52.

COUNT SEVEN

False Establishment Claim For Skinny Pill For Kids

30. Through the means described in Paragraph 12, defendants have represented, expressly or by implication, that scientific research establishes that use of Skinny Pill for Kids causes weight loss in, and is safe for, children 6 to 12 years old.

31. In fact, scientific research does not establish that use of Skinny Pill for Kids causes weight loss in, or is safe for, children 6 to 12 years old. Therefore, the making of the representation set forth in Paragraph 30 constitutes a deceptive practice and the making of a false advertisement, in or affecting commerce, in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52.

CONSUMER INJURY

32. Defendants' law violations have injured consumers throughout the United States. In addition, defendants have been unjustly enriched as a result of their unlawful practices. Absent injunctive relief by this Court, defendants are likely to continue to injure consumers, reap unjust enrichment, and harm the public interest.

33. Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), empowers this Court to grant injunctive and other relief as the Court may deem appropriate to prevent and remedy any violations of the FTC Act. The Court, in the exercise of its equitable jurisdiction, may award other ancillary relief, including consumer redress, disgorgement, and restitution, to prevent and remedy injury caused by defendants' law violations.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff FTC requests that this Court, as authorized by Section 13(b)

of the FTC Act, 15 U.S.C. § 53(b), and pursuant to its own equitable powers:

1. Enjoin defendants permanently from violating Sections 5(a) and 12 of the FTC Act, as alleged herein, in connection with the offer, sale, advertising, or other promotion or distribution of any dietary supplement, food, drug, or device; and the offer, sale, advertising, or other promotion or distribution of any service or program that promotes weight loss.

2. Award such equitable relief as the Court finds necessary to redress injury to consumers resulting from defendants' violations of Sections 5(a) and 12 of the FTC Act, including but not limited to, rescission of contracts and restitution, and the disgorgement of ill-gotten gains by the defendants; and

3. Award the plaintiff the costs of bringing this action, as well as such additional equitable relief as the court may determine just and proper.

Dated: _____, 2004

Respectfully submitted,

170

WILLIAM E. KOVACIC
General Counsel

BARBARA ANTHONY
Regional Director

MICHAEL J. BLOOM (MB 7732)
Senior Counsel to the Northeast Region
DONALD G. D'AMATO (DD 3008)
Assistant Regional Director
FEDERAL TRADE COMMISSION
1 Bowling Green, Suite 318
New York, NY 10004
(212) 607-2829 (voice)
(212) 607-2822 (facsimile)

Attorneys for Plaintiff

Rayman, Jerry

From: edita [edita@skinny.com]
 Sent: Thursday, November 07, 2002 6:47 AM
 To: 05-Jerry Rayman
 Cc: 01-Cara Sowerby
 Subject: Skinny Kids

Importance: High

Tab 13

Dear Jerry,

I received your fax and I have some pretty serious issues with what your company is proposing--it is not at all what we agreed or what we talked about, or what I need.

1. I do not want tablets. I want capsules. I simply don't like the tablet for children. I don't even like it for adults.
2. The serving size is now 2 per meal. And there are 30 servings per container. If someone is to take this product for 30 days, they would, according to my math, need $2 \times 3 \times 30 = 180$ tablets per month. What they are actually getting is 60 tablets, or 90 tablets (its not clear to me) but in any case less than HALF a month's worth. I can't possibly present this to customers. They will immediately think I'm shorting them. In fact, and my hard won credibility is gone.
3. This is a formula which was clearly stated to be for CHILDREN. What you have here in all your disclaimers, is 12 years PLUS. I might just as well put a different label on my far superior existing Skinny Pill formula and sell it to 12 years PLUS. I NEED A FORMULA FOR CHILDREN 6 YEARS OLD AND UP! That's what we have been talking about for months!

Well, I've now run out of time. I need this formula with price quote by the end of business today. So please provide the following:

1. A skinny capusule
2. For children 6 years of age and older.
3. To be taken 3 times a day (two is better, but I can live with 3)
4. That is also a thermic formula.
5. And I need to be able to say ON THE LABEL that this is for children 6 years old and up.

Jerry, if I can't get this, I'm going to have to go to another formulator. I have an entire campaign built around the belief, that you could deliver this type of product for me. I don't want a "me too" fiber formula like Pedialean. I want something that noone else out there has. And I need it by today.

I don't mean to sound difficult, but I'm very disappointed.

Edita



100 capsules 500 mg / capsule



PAL Laboratories, Inc.

10655 NW 29th Terrace • Miami, FL 33172
Tel: (305) 463-2270 • Fax: (305) 576-5795

Tab 14

Description: Skinny Pill for kids		BK# N/A
Coating:	Size tab / cap	Weight
Shape:		

Supplement Facts		
Serving size: <i>2 capsules</i>		
Servings per container: 30		
	Amount per serving	% Daily Value
Calcium (as dicalcium phosphate)	150 mg	15%
Chromium (as chromium chelate)	120 mcg	100%
L-Carnitine	100 mg	
Herbal blend	600 mg	
Apple pectin		*
Grapefruit pectin		*
Citrus Bioflavonoids		*
Glucosamin		*
Chitosan (marine fiber concentrate)	250 mg	*
Herbal diuretic complex	200 mg	*
Uva ursi		*
Buchu leaf		*
Juniper berry		*

30 capsules

Other ingredients: Microcrystalline cellulose, croscarmellose sodium, stearic acid, magnesium stearate, silicon dioxide.

Directions: Adults and children more than 12 years old, take two tablets half hour before each meal with a 12 oz glass of water. Taking this product without enough liquid may cause choking.

**KEEP OUT OF THE REACH OF CHILDREN
DO NOT USE IF SAFETY SEAL IS BROKEN OR MISSING.
STORE IN A COOL, DRY PLACE**

CAUTION

Do not take this product if you are allergic to shellfish.
Not for use by persons under the age of 12. If pregnant, nursing or taking a prescription drug, consult health care practitioner prior to use. Do not exceed recommended dose.
It's important to drink at least 6-8 cups of water daily when increasing your fiber intake.

Written by: _____ Date: _____

Approved by: _____ Date: _____



Tab 15

The Fountain of Youth Group, LLC
 dba The Skinny Pill
 830-13 A1A North
 Ponte Vedra Bch., FL 32082
 904-273-3981 fax (904)280-9253

Purchase Order No. 011142002B

PURCHASE ORDER

Vendor		Ship To	
Name	PAL Laboratories	Name	Southland Logistics
Address	10655 NW 29th Terrace	Address	7803 Southland Blvd. Suite 204
City	Miami St FL ZIP 33172	City	Orlando St FL ZIP 32809
Phone	305-463-2269	Phone	407-859-7701

Qty	Units	Description	Unit Price	TOTAL
2,000	bottles	Skinny Pill For Kids formula (180 capsules per bottle) FY002.	\$4.95	\$9,900.00

Payment Details <input checked="" type="radio"/> Check Pre-paid 50% check # 1744 <input type="radio"/> Cash <input type="radio"/> Account No. <input type="radio"/> Credit Card Name _____ CC # _____ Exp Date _____		SubTotal \$9,900.00 Shipping & Handling _____ Taxes State _____ TOTAL \$9,900.00
--	--	---

Shipping Date
 Delivered by: Dec. 19, 2002

Approval _____ _____	Date <u>11/14/2002</u> Order No _____ Sales Rep _____ Ship Via _____
-----------------------------------	---

Notes/Remarks
 * Ship 500 bottles to billing address, 1500 to shipping address



6/12/03 THU 14:44 FAX 305 3589617

MRAM & Z PA

004

11/25/02
06:30 PM

1

Tab 17

* QUOTATION *

301637
FOUNTAIN OF YOUTH GROUP, INC.
830-13 A1A NORTH
PONTE VEDRA BEACH FL 32082

888-775-4669
FOUNTAIN OF YOUTH GROUP, I
830-13 A1A NORTH
PONTE VEDRA BEACH FL 32082

Re: Tax ID: Ordered by C

03690600 11/25/02 JRR 011142002B EDITA KAY

PREPAID

2000.000 2000.000 .000 FY002 SKINNY PILL FOR KIDS 180C 4.95 US\$9,900.00

order cancelled

***** THANK YOU FOR YOUR BUSINESS *****
CUSTOMERS PLACING ORDERS FOR CUSTOM FORMULAS, ARE
RESPONSIBLE FOR THE PURCHASE OF OVERRUNS UP TO 10%
OF THE ORIGINAL ORDER.

US\$9,900.00
.00
.00
.00



L. LABORATORIES
N.W. 19TH TERRACE
MIAMI, FL 33134
PHONE (305) 468-1122

* PURCHASE ORDER *
* NEW ORDER *
* P.O. #: 00014-00 *
* PAGE : 1 *

Tab 18

JOHN HENRY CO
5600 W GRAND RIVER AVE
LANSING MI 48901

SHIP TO -----
PAL LABS
10855 NW 29 TERR
MIAMI, FL 33170

DATE: 12/06/02 VENDOR: JOHN DUE: 12/20/02 ORDERED BY: KG

NOTE: NEW LABEL

QTY	ITEM NO./DESCRIPTION	BIN	UNIT COST	EXT COST
2.2000 M	L-FN002 LED SHENNY PILL HIDS 150		30.250	66.55
1.0000 M	*** 4 3/4" X 5" NO REV * FILE PREP		30.500	30.50
SUBTOTAL:				97.05
TOTAL:				97.05

On Hold
1/6/03



Coronado, Silvana

From: Coronado, Silvana
Sent: Monday, November 18, 2002 11:39 AM
To: Gutierrez, Jackie
Cc: Rayman, Jerry
Subject: FW: Skinny Pill for Kids Label

Tab 19

Follow Up Flag: Follow up
Due By: Friday, November 22, 2002 5:00 PM
Flag Status: Flagged

Jackie:

Do you have any idea of what is she talking about?

Please supply me with the packaging specs of these products to provide her with the information she requested.

Thanks,

Silvana

-----Original Message-----

From: Clair Hartmann [mailto:clair@hartmannndesign.net]
Sent: Monday, November 18, 2002 10:07 AM
To: Coronado, Silvana
Subject: Skinny Pill for Kids Label

Hi, Edita put in an order for the Kids supplement & a teen supplement.
Could you send me the info for the label?
Thanks.

--
Clair Hartmann / Clair Hartmann Design / Art Director
office: 904.387.6892 mobile: 904.307.6642 (call to fax)
website: hartmannndesign.net



8010070896 103100 8042802200 HAVE
 FROM : PDL REPT 497224384-1210X 11/14/00 11/14/00 11/14/00 11/14/00
 TO : PDL REPT 497224384-1210X 11/14/00 11/14/00 11/14/00 11/14/00

Tab 20 **PAL Laboratories Inc.**
Packaging Specifications

Product Number: **FY082**
 Product Name: **Bonny Pk for Kids Formula**
 Quantity: **180 Capsules**

- I. Customer: **Fountain of Youth Group, Inc**
- II. Approvals
 Sales/Marketing: [Signature] Date: 11/29/00
 Customer: [Signature] Date: 11/29/00
 Copy Verification: _____ Date: _____
 Quality Assurance: _____
 Warehouse Manager: _____

III. Packaging Specifications/Description

Part	Part Number	Description	Quantity	Material	Color
Box	8K1300	Bonny Pk for Kids Case	100	Red/White	Capsules
Bottle Label	L-FY082 Customer BUBBY	Bonny Pk for Kids Formula 180 Capsules			
Bottle	8080Y	3 oz HDPE Cylinder 38-400	8 oz		White
Cap	8080	Bonny Pk for Smooth Cap	38 mm		White
Content	8K2300	100% White Cotton	12 grams		100% White
Blair	808FS	Neck Band Full Blanca	80 x 160		Clear
Blower					24x case
Content Labels		No special instructions	4 x 3		White
Other					

Comments: **PLEASE REMEMBER TO
 PUT THE UPC BAR
 CODE 712170 03005** Rev. Date: 11/9/02
 Thank You [Signature]



PAL Laboratories Inc.

Tab 21 *Packaging Specifications*

Product Number: FY002
 Product Name: Skinny Pill for Kids Formula
 Description: 180 Capsules

I. Customer: Fountain of Youth Group, Inc.

II. Approvals

	Signature	Date
Sales/Marketing	_____	_____
Customer	_____	_____

III. Copy Verification

	Signature	Date
Quality Assurance	_____	_____
Warehouse Manager	_____	_____

IV. Packaging Specifications/Description

	Item #	Item Description	Size	Additional Description (Ex: color, resin, style)
Bulk	BK1303	Skinny Pill Kids Caps	"00"	Red/White Capsules
Bottle Label	L-FY002 Customer Supply	Skinny Pills for Kids Formula 180 Capsules		
Bottle	8OZCY	8 oz. HDPE Cylinder 38/400	8 oz.	White
Cap	C38S	38mm White Smooth Cap	38mm	White
Cotton	BK3300	100% White Cotton	12 grams	100% White
Seal	S88FS	Neck Band Full Sleeve	88 x 160	Clear
Cartons				48 per case
Carton Labels		No special instructions	4 x 3	White
Other				

Comments: _____

Gutierrez, Jackie

From: cara@skinny.com
Sent: Friday, December 13, 2002 8:29 AM
To: Gutierrez, Jackie
Cc: Edita Kaye; Jerry Rayman
Subject: RE: labels for Skinny for Kids

Tab 22

Dear Jackie,

Actually, Edita and I both spoke to Jerry and this project is on hold for now. I'm sure you are aware of the publicity on this and we are currently working on solving the problems that have come about. We will be in touch soon.

Thanks,
Cara

-----Original Message-----

From: Gutierrez, Jackie [mailto:jgutierrez@pbarx.com]
Sent: Thursday, December 12, 2002 10:38 AM
To: 'cara@skinny.com'
Subject: labels for Skinny for Kids

Hi Cara,

Hope all is well. Do you know when the labels for Skinny Pill for Kids will arrive at Pal? Please let me know ASAP so we can schedule the product.

Thanks,

Jackie Gutierrez

Pal Laboratories, Inc.

A Pharmed Group Company



PAL Laboratories, Inc.

10656 NW 29th Terrace • Miami, FL 33172
Tel: (305) 450-0270 • Fax: (305) 574-8795

Tab 23

Description: Skinny Pill for kids	BK# 1303
Coating:	Size-tab/-cap
Shape:	Weight

Supplement Facts		
Serving size: 2 capsules		
Servings per container: 30 30		
	Amount per serving	% Daily Value
Niacin (as niacinamide)	25 mg	100%
Folate (as folic acid)	400 mcg	100%
Vitamin B12 (as cyanocobalamin)	6 mcg	100%
Chromium (as chromium chelate)	120 mcg	100%
Herbal blend	600 mg	
Apple pectin		*
Grapefruit pectin		*
Citrus Bioflavonoids		*
Glucosaminan		*
Herbal diuretic complex	200 mg	
Uva ursi		*
Buena leaf		*
Juniper berry		*
Metabromin-3™	50 mg	*

* Daily value not established
Other ingredients: Gelatin, stearic acid, magnesium stearate, silicon dioxide.


Directions: Children more than 6 years old, take two capsules half hour before each meal with a 12 oz glass of water. Taking this product without enough liquid may cause choking.

KEEP OUT OF THE REACH OF CHILDREN
DO NOT USE IF SAFETY SEAL IS BROKEN OR MISSING.
STORE IN A COOL, DRY PLACE

CAUTION

Not for use by children under the age of 6.
Do not exceed recommended dose.
It's important to drink at least 6-8 cups of water daily when increasing fiber intake.

Written by: _____ Date: _____

Approved by:  _____ Date: 11/25/2002

Customer Approval: _____ Date: _____



03/07/1994 20:25 9042839253 KAYE PAGE 01
FROM : PBA MGMT FAX NO. : 305 463 2258 OK 03 2000 04:55PM PJ



PAL Laboratories, Inc.
A Pharmed Group Company
10655 N.W. 29th Terrace
Miami, FL 33172

Telephone: (305) 463-2270/(888) 707-2279
Facsimile: (305) 463-2258

Tab 24

FACSIMILE COVER SHEET

TO:- Edita Kay @ Skinny
Fax Number: (904) 280-9253
FROM:- Jackie Gutierrez
DATE:- 12/09/02
RE:- Supplemental Facts
NO. OF PAGES (including cover sheet):- 2

MESSAGE:

Dear Edita,

Attached is the Supplemental Facts for Skinny Pill Kids Capsules. Please review and if approved sign and fax back to me at (305) 463-2258. If you have any questions of there is anything else i can help you with, please feel free to give me a call at (305) 463-2253.

Thank you,

Jackie Gutierrez
Administrative Assistant
Pal Laboratories, Inc.
A Pharmed Group Company

The information contained in this transmission is privileged and confidential information intended only for use of the individual or entity named above. If the reader of this message is not the intended recipient, you are hereby notified that any dissemination, distribution or copy of this communication is strictly prohibited. If you have received this communication in error please immediately notify us by telephone and return the original message to us at the above address to the attention of the sender via the U.S. postal service or as otherwise directed by telephone. Thank you.



03/07/1994 20:25 9042809253 KAYE PAGE 02
 FROM : PBR MGMT FAX NO. : 305 483 2256 Jc 26 2002 05:00PM 52



PAL Laboratories, Inc.

10686 NW 29th Terrace - Miami, FL 33172
 Tel: (305) 483-2270 - Fax: (305) 676-6796

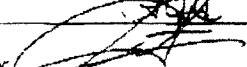
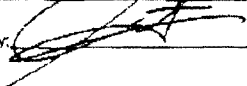
Description: Skinny Pfl Kids Caps		BK# 1303
Coating:	Size tab / cap	Weight
Shape: red/white	'00'	
Supplement Facts		
Serving size: 2 capsules		
Servings per container: 33		
	Amount per serving	% Daily Value
Niacin (as niacinamide)	20 mg	100%
Folate (as folic acid)	400 mcg	100%
Vitamin B12 (as cyanocobalamin)	6 mcg	100%
Chromium (as chromium chelate)	120 mcg	100%
Apple Pectin	100 mg	*
Grapefruit extract 4:1	100 mg	*
Citrus Bioflavonoids	100 mg	*
Glucomannan	300 mg	*
Uva ursi (<i>Aroctostaphylos pinnatifida</i>) (leaf)	100 mg	*
Buchu (<i>Barosma betulina</i>) (leaf)	50 mg	*
Juniper berry (<i>Juniperus communis</i>)	50 mg	*
Metabromine-G™	100 mg	*
* Daily Value not established		

Other ingredients: Gelatin, magnesium stearate and silicon dioxide.

Directions:

DO NOT USE IF SAFETY SEAL IS BROKEN OR MISSING.
 STORE IN A COOL, DRY PLACE

CAUTION: FOLLOW LABEL DIRECTIONS. Do not take more than 500 mg of niacin per day except under supervision of a physician.
 POSSIBLE SIDE EFFECTS: Temporary flushing, itching, rash or gastric disturbances may occur. If these symptoms persist, discontinue use and consult a physician.

Written by:  Date: 12/5/02
 Approved by:  Date: 12/6/02

12/5/2002

By Authority of the House of Representatives of the Congress of the United States of America

Tab 25

To The Fountain of Youth Group

You are hereby commanded to produce the things identified on the attached schedule before the Committee on Energy and Commerce of the House of Representatives of the United States, of which the Hon. W.J. "Billy" Tauzin is chairman, by producing such things in Room 2125 of the Rayburn Building in the city of Washington, on July 21, 2003 at the hour of 12:00 p.m. (noon)

To the U.S. Marshal or any staff member of the Committee on Energy and Commerce to serve and make return.

Witness my hand and the seal of the House of Representatives of the United States, at the city of Washington, this 9th day of July, 2003

Billy Tauzin Chairman

Attest:

[Signature] Clerk

Subpoena for The Fountain of Youth Group

.....

.....

.....

before the Committee on the

Energy and Commerce

.....

.....

Served

.....

.....

.....

.....

.....

..... House of Representatives

.....

SCHEDULE

A. To The Fountain of Youth Group. For the following records:

1. All records relating to the ingredients and the amount of each ingredient contained in the Skinny Pill for Kids, and all records that relate to any research and/or testing of any and all ingredients in such product, whether conducted by your company or any other person or entity.
2. All records relating to the development and marketing of the Skinny Pill for Kids.
3. All records of communications between or among Edita Kaye. The Fountain of Youth Group, The Skinny Pill company, any corporate entity with which Edita Kaye is affiliated, and PAL Laboratories relating to the Skinny Pill for Kids product or any product contemplated for ingestion by children 18 years of age and under.
4. All records relating to the "scientific research done in Australia and the U.K.," as referenced by Ms. Edita Kaye on a December 9, 2002 segment of "The Today Show," with respect to the Skinny Pill for Kids.
5. All records relating to any testing of the Skinny Pill for Kids (or any of its active or inactive ingredients) for either safety or efficacy on children ages 6-12 years old.
6. All records relating to the scientists who "put together" the Skinny Pill for Kids, and their efforts to develop such product, as referenced by Ms. Edita Kaye on a December 9, 2002 segment of "Connie Chung Tonight."
7. The list of physicians referenced by Ms. Edita Kaye on the December 9, 2002 segment of "Connie Chung Tonight," as supportive of the Skinny Pill for Kids and, for each such physician, all records relating to --
 - a. The name of the physician;
 - b. The address and telephone number for the physician;
 - c. The identification of States in which the physician is licensed to practice medicine;
 - d. Whether the physician received any compensation or benefit, monetary or otherwise, for agreeing to speak on behalf of the Skinny Pill for Kids, and if so, all records that relate to such compensation or benefit, including, but not limited to, any written contracts between the physician and Ms. Edita Kaye. The Skinny Pill company, The Fountain of Youth Group or any corporate entity with which she is affiliated; and

1. The term “records” is to be construed in the broadest sense and shall mean any written or graphic material, however produced or reproduced, of any kind or description, consisting of the original and any non-identical copy (whether different from the original because of notes made on or attached to such copy or otherwise) and drafts and both sides thereof, whether printed or recorded electronically or magnetically or stored in any type of data bank, including, but not limited to, the following: correspondence, memoranda, records, summaries of personal conversations or interviews, minutes or records of meetings or conferences, opinions or reports of consultants, projections, statistical statements, drafts, contracts, agreements, purchase orders, invoices, confirmations, telegraphs, telexes, agendas, books, notes, pamphlets, periodicals, reports, studies, evaluations, opinions, logs, diaries, desk calendars, appointment books, tape recordings, video recordings, e-mails, voice mails, computer tapes, or other computer stored matter, magnetic tapes, microfilm, microfiche, punch cards, all other records kept by electronic, photographic, or mechanical means, charts, photographs, notebooks, drawings, plans, inter-office communications, intra-office and intra-departmental communications, transcripts, checks and canceled checks, bank statements, ledgers, books, records or statements of accounts, and papers and things similar to any of the foregoing, however denominated.
2. The terms “relating,” “relate,” or “regarding” as to any given subject means anything that constitutes, contains, embodies, identifies, deals with, or is in any manner whatsoever pertinent to that subject, including but not limited to records concerning the preparation of other records.
3. The term “The Skinny Pill company” means the company, its officers or employees, members of its Board of Directors, or one or more of its divisions, subsidiaries or affiliates, or related entities.
4. The term “Edita Kaye” means Edita Kaye, individually, and any agent, servant, representative, or other individual acting on behalf of Edita Kaye.
5. The term “Fountain of Youth Group” means the corporate entity, its officers or employees, members of its Board of Directors, or one or more of its divisions, subsidiaries or affiliates, or related entities.



1485 North Park Dr.
Weston, FL 33326

US House of Representatives
Committee on Energy and Commerce
Attn. Kelli Andrews
Washington D.C. 20515

Tab 26

RE: Pedia Loss DBSlabs.com website
Sent Via Fax to: 202-226-2447

Dear Mrs. Kelli Andrews

DBS Labs seeks to cooperate fully with the Committee on Energy and Commerce to resolve any concerns regarding the Company's products. Enclosed please find a voluntary submission of information made on behalf of DBS Laboratories, LLC ("DBS Labs" or "the Company"), a formulary company of certain dietary supplement products for Dynamic Health of Florida.

It is important to note that while DBS Labs was incorporated in March 2003, the Company only began selling products in August 2003, with total sales to date of less than \$9,000. Further, the Company voluntarily has decided to discontinue its Pedia Loss product.

In Reference to your opening statement on the letter sent to DBS dated 12/19/03, I personally, must state that www.dbslabs.com and our company's website; DOES NOT SELL or MARKET our formulated products. www.dbslabs.com is an information website only, carefully reviewed by the best FTC, FDA law firms and does not sell directly to any consumers.

We have retained Dynamic Health of Florida a sales and marketing company, for our products. DBS is not responsible for distributor statements, copy, marketing materials, PR and websites; for any claims. As per our phone conversation; I had stated that Pedia has been completely moved out of the marketplace and has not available for sale to distributors since 12/1/03. We have no control of the removal of this product information from other sites or distributors. DBS Labs has sold only four units to distributors to date.

The following copy is the only one that DBS is responsible for providing, as per our website and any other info we have represented for the product to our distributors.

PEDIA LOSS



1485 North Park Dr.
Weston, FL 33326

Child obesity is a growing problem in North America. Pedia Loss is an appetite suppressant for children 6 years and older. Allow children to enjoy their favorite foods without gaining weight. This revolutionary new formula slows the absorption of carbohydrates, allowing more to be burned for energy and less to be stored as fat. This highly effective and natural dietary supplement comes in berry-flavored chewable tablets for easy consumption. In conjunction with a proper diet and exercise program, Pedia Loss can keep your child from becoming a statistic.

Please consult your healthcare provider before giving Pedia Loss to your child.

As per your NNFA statement, DBS labs contract manufacturers with Nutrition Formulators to make our nutraceutical products. It was important to me to use a GMP certified lab, so in my research in identify labs I had spoken to NNFA about GMP Labs and the use of the logo. NNFA stated to me that if we have our products manufactured at a certified NNFA GMP facility, we may use their logo on our products, just like other companies have for both USP, GMP and NNFA. Our NNFA GMP facility is Nutrition Formulators in Miami.

Question 1

Inulin – 500mg, Glutamine 400mg, FOS – 100mg, Lecithin – 100mg, HCA - 25mg

Question 2

There are no responsive documents

Question 3

No, we are not a member of NNFA, our contract manufacturer Nutrition Formulators is GMP certified with NNFA, located at 11005 NW 33rd Street Miami, Florida 33172, (305) 592-2111 Adolfo Graubard, President.

Question 4

No, we are not a member of NNFA, our contract manufacturer Nutrition Formulators is GMP certified with NNFA, located at 11005 NW 33rd Street Miami, Florida 33172, (305) 592-2111 Adolfo Graubard, President.

Question 5

Sending in the FedEx package

Question 6

No other brand names.



1485 North Park Dr.
Weston, FL 33326

Question 7

Sending in the FedEx package

Question 8

Dr Guzman is our scientist for reviewing our formulations; DBS received the original formulation for Pedia Loss from a David Woods in 2002, he represented that he contract manufactured for Pfizer Pharmaceutical and this was a nutraceutical formula he discovered for them that they passed on; we don't have updated information on him.

- a. ALBERTO C. GUZMAN ROJAS, MD
- b. There are no responsive documents
- c. There are no responsive documents
- d. Dr. Guzman has not received compensation
- e. Reference the CV (included in fax)
- f. Include in fax
- g. Sending in the FedEx package

Question 9

DBS has received no consumer complaints regarding the subject products.

Question 10

There are no responsive documents

Question 11

Chhabra International Ltd

Question 12

Dynamic Health of Florida was our sales and marketing company until December 1, 2003, they have been released of their contract.

Question 13

Dynamic Health of Florida was our sales and marketing company until December 1, 2003, they have been released of their contract

Question 14

DBS Labs, President, Jonathan Barash
Dynamic Health, VP Sales & Marketing, Guy Regalado

Question 15

DBS began selling products in August 2003, with total sales to date of less than \$9,000



1485 North Park Dr.
Weston, FL 33326

Pedia Loss sales - 4 units (\$16.00)

Question 16

- a. Nutrition Formulators = contract manufacturer for Pedia Loss.
- b. Dynamic Health - sales and marketing company for Pedia Loss

Question 17

DBS Labs was incorporated in March 2003, but has only sold products since August 2003

- a. December 2003 Federal Trade Commission - weight loss products investigation.

We are hopeful that you find this information useful in resolving any concerns you may have. To the extent that additional relevant information becomes available to the Company, we voluntarily will supplement this submission. DBS Labs requests that all documents and information submitted pursuant to this voluntary submission remain confidential pursuant to 15 U.S.C. §§ 46(f) and 57b-2(f) and 16 C.F.R. §§ 4.10-4.11.

As submitted by;

Jonathan Barash
President
DBSLabs



1485 North Park Dr.
Weston, FL 33326

US House of Representatives
Committee on Energy and Commerce
Attn. Kelli Andrews
Washington D.C. 20515

Tab 27

RE: Pedia Loss DBSlabs.com website
Sent Via Fax to: 202-226-2447

Dear Mrs. Kelli Andrews

DBS Labs seeks to cooperate fully with the Committee on Energy and Commerce to resolve any concerns regarding the Company's products. Enclosed please find a voluntary submission of information made on behalf of DBS Laboratories, LLC ("DBS Labs" or "the Company"), a formulary company of certain dietary supplement products for Dynamic Health of Florida.

It is important to note that while DBS Labs was incorporated in March 2003, the Company only began selling products in August 2003, with total sales to date of less than \$9,000. Further, the Company voluntarily has decided to discontinue its Pedia Loss product.

In Reference to your opening statement on the letter sent to DBS dated 12/19/03, I personally, must state that www.dbslabs.com and our company's website; DOES NOT SELL or MARKET our formulated products. www.dbslabs.com is an information website only, carefully reviewed by the best FTC, FDA law firms and does not sell directly to any consumers.

We have retained Dynamic Health of Florida a sales and marketing company, for our products. DBS is not responsible for distributor statements, copy, marketing materials, PR and websites; for any claims. As per our phone conversation, I had stated that Pedia has been completely moved out of the marketplace and has been available for sale to distributors since 12/1/03. We have no control of the removal of this product information from other sites or distributors. DBS Labs has sold only four units to distributors to date.

The following copy is the only one that DBS is responsible for providing, as per our website and any other info we have represented for the product to our distributors.

PEDIA LOSS



1485 North Park Dr.
Weston, FL 33326

Child obesity is a growing problem in North America. Pedia Loss is an appetite suppressant for children 6 years and older. Allow children to enjoy their favorite foods without gaining weight. This revolutionary new formula slows the absorption of carbohydrates, allowing more to be burned for energy and less to be stored as fat. This highly effective and natural dietary supplement comes in berry-flavored chewable tablets for easy consumption. In conjunction with a proper diet and exercise program, Pedia Loss can keep your child from becoming a statistic.

Please consult your healthcare provider before giving Pedia Loss to your child.

As per your NNFA statement, DBS labs contract manufacturers with Nutrition Formulators to make our nutraceutical products. It was important to me to use a GMP certified lab, so in my research in identify labs I had spoken to NNFA about GMP Labs and the use of the logo. NNFA stated to me that if we have our products manufactured at a certified NNFA GMP facility, we may use their logo on our products, just like other companies have for both USP, GMP and NNFA. Our NNFA GMP facility is Nutrition Formulators in Miami.

Question 1

Inulin – 500mg, Glutamine 400mg, FOS – 100mg, Lecithin – 100mg, HCA – 25mg

Question 2

Dr. Guzman, David Wood

Question 3

No, we are not a member of NNFA, our contract manufacturer Nutrition Formulators is GMP certified with NNFA, located at 11005 NW 33rd Street Miami, Florida 33172, (305) 592-2111 Adolfo Graubard, President.

Question 4

No, we are not a member of NNFA, our contract manufacturer Nutrition Formulators is GMP certified with NNFA, located at 11005 NW 33rd Street Miami, Florida 33172, (305) 592-2111 Adolfo Graubard, President.

Question 5

e-mails and records from David Woods and new formulation from Dr Guzman.

Question 6

No other brand names.



1485 North Park Dr.
Weston, FL 33326

Question 7

There are no responsive documents

Question 8

Dr Guzman is our scientist for reviewing our formulations; DBS received the original formulation for Pedia Loss from a David Woods in 2002, he represented that he contract manufactured for Pfizer Pharmaceutical and this was a nutraceutical formula he discovered for them that they passed on; we don't have updated information on him.

- a. ALBERTO C. GUZMAN ROJAS, MD
- b. There are no responsive documents
- c. There are no responsive documents
- d. Dr. Guzman has not received compensation
- e. Reference the CV (included in fax)
- f. Reference fax
- g. Reference fax

Question 9

DBS has received no consumer complaints regarding the subject products.

Question 10

DBS is just a formulation Company (Middle Man) We do not need that documentation.

Question 11

No lawsuits

Question 12

- Chhabra International Ltd
- Dynamic Health of Florida was our sales and marketing company until December 1, 2003, they have been released of their contract.

Question 13

Dynamic Health of Florida was our sales and marketing company until December 1, 2003, they have been released of their contract.

Question 14

DBS Labs, President, Jonathan Barash
Dynamic Health, VP Sales & Marketing, Guy Regalado

Question 15



1485 North Park Dr.
Weston, FL 33326

DBS began selling products in August 2003, with total sales to date of less than \$9,000

Pedia Loss sales = 4 units (\$16.00)

Question 16

- a. Nutrition Formulators = contract manufacturer for Pedia Loss.
- b. Dynamic Health = sales and marketing company for Pedia Loss

Question 17

DBS Labs was incorporated in March 2003, but has only sold products since August 2003

- a. December 2003 Federal Trade Commission – weight loss products investigation.

We are hopeful that you find this information useful in resolving any concerns you may have. To the extent that additional relevant information becomes available to the Company, we voluntarily will supplement this submission. DBS Labs requests that all documents and information submitted pursuant to this voluntary submission remain confidential pursuant to 15 U.S.C. §§ 46(f) and 57b-2(f) and 16 C.F.R. §§ 4.10-4.11.

As submitted by;

Jonathan Barash
President
DBS Labs

Received Fax : Feb 03 2004 2:55PM Fax Station : CHHABRA GROUP p 2

Feb-03-04 01:48pm From-

T-364 P 002/006 F-721

MICHAEL BLUMBERG, FLORIDA
JOE BARTON, TEXAS
FRED LUTTMAN, MICHIGAN
CLIFF STEARNS, ILLINOIS
PAUL E. GILLMOYER, OHIO
JAMES P. GREENWOOD, PENNSYLVANIA
DIPLOMATA, CALIFORNIA
NINA ANDERSON, GEORGIA
RICHARD BLUMENTHAL, CONNECTICUT
L. PATRICK BROWN, OHIO
CORNELIUS BOHRER, GEORGIA
BARBARA CUBIN, INDIANA
JOHN SHIMMUS, ALABAMA
HEATHER WILSON, NEW MEXICO
JOHN B. RANDEGGIO, ARIZONA
CHRISTOPHER COCHRAN, MISSISSIPPI
VITO ROSSELLA, NEW YORK
ROY BLUNT, MISSOURI
J. EVIE BUYER, INDIANA
GEORGE THOMAS, CALIFORNIA
SHARLENE S. SPASS, MISSISSIPPI
JOSEPH R. ANTIS, PENNSYLVANIA
MARY BONG, CALIFORNIA
DAN WALTERS, OHIO
LEE TERRY, NEBRASKA
ERNE FLETCHER, KENTUCKY
MIKE BERSHON, NEW JERSEY
MIKE RODGERS, MICHIGAN
FRANK R. LEE, CALIFORNIA
C. MITCHELL, TEXAS

ONE HUNDRED EIGHTH CONGRESS
U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515-6115

W.J. "BILLY" TAUZIN, LOUISIANA,
CHAIRMAN

February 3, 2004

Tab 28

Mr. Vincent Chhabra
Chief Executive Officer
C/O Guy Regalado
Vice President of Sales and Marketing
Dynamic Health Products
1485 North Park Drive
Weston, FL 33326-3215

Dear Mr. Chhabra:

The Committee on Energy and Commerce has jurisdiction over matters relating to the regulation of food and drugs, advertising and marketing practices and consumer protection, generally. Pursuant to this authority, the Committee is undertaking a review of non-prescription dietary supplements marketed to children. We have learned that Dynamic Health Products ("Dynamic Health") is involved in the development, manufacturing and marketing of a product called "Pedia Loss." According to your website, www.dynamichealthproducts.com, (which defaults to the website of DBS Labs, www.dbslabs.com) "Pedia Loss" is an appetite suppressant for children six years of age and older, designed to assist in weight loss. Your website also includes a "Pedia Loss" product label which states that the product contains a "proprietary blend" of ingredients, including inulin, glutamine and fructo-ogliosaccarides. It is our understanding that shortly after DBS Labs received a letter from this Committee inquiring about the safety and efficacy of "Pedia Loss," DBS Labs, at the direction of Dynamic Health, stopped the distribution and sales of "Pedia Loss" and the product is now unavailable for purchase on the various distributors' listed on your website. These distributors include FeelingWell.com, MedPharmacy.com, USAPrescription.com, ePrescribe and CVS (collectively "Distributors"). Further, you and DBS Labs have made oral representations to Committee staff that "Pedia Loss" will be part of a clinical trial by the University of Miami involving the targeted group of children ages 6-16 years old to determine its safety and efficacy. We are seeking information on the development and marketing of the "Pedia Loss" product, as well as, more detailed information concerning the proposed clinical trial of "Pedia Loss."

In addition, we are concerned that despite the oral representations made by DBS Labs and you to Committee staff that "Pedia Loss" is no longer available for public

JOHN D. ONGELL, MICHIGAN
HENRY A. WAXMAN, CALIFORNIA
EDWARD J. MARKEY, MASSACHUSETTS
BETH W. HALL, TEXAS
RICK BOUCHER, VIRGINIA
EDDY PAUL TOWNS, NEW YORK
FRANK RAYBURN, NEW JERSEY
SILVANO BROWN, OHIO
BART STUPAK, MISSISSIPPI
PETER GUTTUSI, FLORIDA
BOB BYRNE, MISSOURI
ANNA C. ESCHER, CALIFORNIA
BART STUPAK, MISSISSIPPI
ELIOT L. ENGEL, NEW YORK
ALLIEN H. WATSON, MARYLAND
GENE GREEN, TEXAS
KARL L. BROWN, MISSOURI
TED CRUZ, TEXAS
DIANA DIGGETTE, COLORADO
LOIS CARR, CALIFORNIA
MICHAEL F. ROY, PENNSYLVANIA
CHRISTOPHER J. BROWN, LOUISIANA
TOM ALLIN, TEXAS
JIM DEMME, ILLINOIS
JANE SCHAGROWITZ, ALABAMA
MELBA C. SOULS, CALIFORNIA
DAN A. BRADUNLETTE, STAFF DIRECTOR

consumption, the "Pedia Loss" product description continues to appear on your website. This raises questions about your intent to completely remove "Pedia Loss" from the marketplace, pending positive results from the safety and efficacy clinical trial of the product. Finally, we are seeking clarification of the corporate relationship between Dynamic Health Products, DBS Labs and Chhabra International Ltd.

In order to obtain additional information about these matters, we are requesting that, pursuant to Rule X and XI of the U.S. House of Representatives, you provide the Committee with the information requested below by Tuesday, February 17, 2004.

- ✓ 1. A listing of all ingredients and the amount of each ingredient contained in the current marketed formulation of "Pedia Loss," and any other formulations of the product marketed to or tested in humans, as well as, all records that relate to any research and/or testing of any and all ingredients in the product, whether conducted by your company or any other person or entity.
- ✓ 2. Identify the person(s) responsible for determining the ingredients and amount of each ingredient contained in "Pedia Loss." Include in your response the name of the person, the most recent address and telephone number, the name of the company with which the person is affiliated and title within the company.
- ✓ 3.) State the date upon which you ordered "Pedia Loss" removed from the marketplace and describe the process by which you removed the product from the marketplace and ordered all production to cease. Provide all records that relate to the removal of "Pedia Loss" from the marketplace, including, but not limited to correspondence with your Distributors and contract laboratories indicating that production of the product should cease and procedures for removing the product from the marketplace. New 1
Dec 5
- ✓ 4. Describe the corporate relationship between Dynamic Health and DBS Labs and between Dynamic Health and Chhabra International Ltd. Provide all corporate records for Dynamic Health Products that reflect the ownership of the company and the officers of the company (and their titles).
- ✓ 5. Provide the date(s) upon which Dynamic Health (or any of its predecessor corporate entities) was registered as a corporate entity within the United States and include in your response the name of the corporate entity that was registered, the state in which it was registered and the name of the registered agent.
- ✓ 6. All records relating to the development, manufacturing and marketing of "Pedia Loss," including, but not limited to, all

internal correspondence relating to dosage, ingredients, adverse health effects and efficacy.

- ✓7. Provide a list of any other brand names under which the current or any previous formulation of "Pedia Loss" is or has been marketed, produced or sold by Dynamic Health, a related firm, or supplied under contract to an unrelated firm for marketing under their brand.
- ✓8. State whether "Pedia Loss" (or any of its active or inactive ingredients) has been tested for either safety or efficacy purposes in children to whom it is being marketed —namely, children ages 6-16 years old. Include in your response a description of the group that was tested (as well as those who were excluded from such testing and the reasons therein), the specific ingredient(s) that was tested and the duration and results of the test(s). Provide all records that relate to such tests, including but not limited to the clinical trials referenced on your Distributors' websites for the ingredients contained in "Pedia Loss."
- ✓9. Provide a list of all persons who were involved in the development of "Pedia Loss" and include in your response the following information:
 - a. Name of the person and whether he/she is a physician or scientist;
 - b. Address and telephone number for each person;
 - c. Identification of States in which the physician is licensed to practice medicine (if applicable);
 - d. Whether the person received any compensation or benefit, monetary or otherwise, for agreeing to speak on behalf of your product. If the person received compensation, identify the type and amount and any and provide all records that relate to such compensation or benefit, including, but not limited to, any written contracts between the person and you or any corporate entity with which you are affiliated;
 - e. Whether the physician or scientist has prior experience in pediatric care and if so, explain their medical credentials (if applicable);
 - f. Provide a curriculum vitae for each person identified in Question 8(a) above; and
 - g. Provide all of the information about "Pedia Loss" that was given to such physician or scientist.
- ✓10. State whether you have received consumer complaints or notifications concerning adverse health events associated with

"Pedia Loss." If so, for each year beginning when your product was first available for consumption, provide the following information:

- a. The name of complainant;
- b. The date of complaint;
- c. A summary of consumer's adverse event(s);
- d. A summary of company's response to complaint;
- e. Whether any information about the complaint was reported to the Food and Drug Administration ("FDA") or any other government entity, and if so, a summary of the information that you provided; and
- f. All records relating to such complaints.

- ✓ 11. State whether your company has reporting or tracking procedures for adverse health events reported by consumers of your products. If so, identify the entities to which these reports are made, the individual(s) responsible for retaining such information, and describe the specific procedures. Provide a copy of all procedures described in this question.
- ✓ 12. State whether a customer has filed any lawsuits against your company alleging health-related problems associated with taking "Pedia Loss." If so, provide the following information:
 - a. The name of complainant(s);
 - b. The date the lawsuit was filed;
 - c. A summary of health-related allegations of lawsuit; and
 - d. The status of the lawsuit (i.e. pending, settled, verdict).
- ✓ 13. Identify all corporate entities, whether for-profit or not-for-profit, that are related to Dynamic Health Products.
- ✓ 14. All records relating to any proposed clinical trial involving "Pedia Loss," including but not limited to, all correspondence between Dynamic Health, DBS Labs and/or the University of Miami concerning the proposed clinical trial of "Pedia Loss" and/or the ingredients contained therein.
- ✓ 15. Provide a list of the names and titles of senior management in DBS Labs and Dynamic Health Products, including those individuals involved in developing and marketing "Pedia Loss" and any of the ingredients used therein.

Received Fax : Feb 03 2004 2:55PM Fax Station : CHHABRA GROUP p. 6
 Feb-03-04 01:48pm From- T-364 P 006/006 F-721

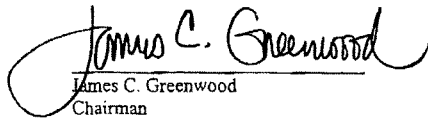
5

- ✓ 16. From 1998 through the present, state the annual revenue for Dynamic Health and the amount of revenue per year generated from sales of "Pedia Loss."
- ✓ 17. Provide the name of any company(ies) (other than you) producing and/or manufacturing "Pedia Loss" and the name of the company(ies) distributing "Pedia Loss" in the United States.
- ✓ 18. For each year from 1998 through the present, identify and describe all investigations by state or Federal agencies of your company relating to your products, including but not limited to "Pedia Loss." Include in your response the name of the product being investigated; the identity of the investigating agency; the nature of the investigation; and, if applicable, the resolution of the investigation.

Please note that for purposes of responding to this request, the terms "records" and "relating" should be interpreted in accordance with the attachment to this letter. The term "product" refers to "Pedia Loss," unless otherwise noted; the term "you" or "your" means Dynamic Health Products or one or more of its divisions, subsidiaries or affiliates, or related entities.

If you have any questions, please contact Kelli Andrews, Majority Counsel, at (202) 226-2424, or David Nelson, Minority Investigator, at (202) 226-3400.

Sincerely,



James C. Greenwood
 Chairman
 Subcommittee on Oversight
 and Investigations




Peter Deutsch
 Ranking Member
 Subcommittee on Oversight
 and Investigations

Attachment

Saved Fax : Feb 03 2004 2:55PM Fax Station : CHHARRA GROUP p. 1

Feb-03-04 01:48pm From-

T-364 P 001/006 F-721



The Committee on Energy and Commerce
U.S. House of Representatives
W.J. "Bobby" Tauzin, Chairman

Fax Transmission

2125 Rayburn House Office Building
Washington, D.C. 20515
(202) 225-2927
Fax: (202) 225-1919



To: Mr. Guy Regalado

From: Subcommittee Chairman James C. Greenwood

Fax: (954) 659-2598

Date: February 3, 2004

Phone: (954) 888-4190

Pages: 6, including cover

Notes:

Dynamic Health

February 17, 2004

Tab 29

To: Kelli Andrews
Committee on Energy and Commerce
Washington, DC 20515

Sent via fax #202-226-2447 and mail.

From: Dynamic Health
1485 North Park Dr.
Weston, FL 33326

Dear Ms. Andrews:

Attached are the answers to your questionnaire dated February 3, 2004. We have mailed, per your request, back up documentation for all information requested to 9912 Parkwood Dr., Bethesda, MD 20814.

In addition to the responses requested I would like to address a few statements in your letter requesting this information.

In the first paragraph you state, "We have learned that Dynamic Health Products is involved in the development, manufacturing and marketing of a product called Pedia Loss." Dynamic Health Products does not exist; the name of the company is Dynamic Health of Florida, LLC and this company distributed and marketed Pedia Loss. The development and manufacturing are addressed in the responses to your questions numbers 9 and 17.

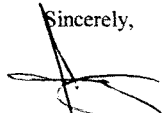
Also in the first paragraph you state, "It is our understanding that shortly after DBS Labs received a letter from this Committee inquiring about the safety and efficacy of Pedia Loss, DBS Labs, at the direction of Dynamic Health, stopped the distribution and sales of Pedia Loss ..." To our knowledge DBS Labs never received a letter questioning anything regarding Pedia Loss. Dynamic Health, of its own accord, elected to remove Pedia Loss from distribution due to the fact that we had the opportunity offered by the University of Miami to conduct a clinical study on the product and decided to remove Pedia Loss from distribution pending the outcome of that study.

You state, in your letter, that you are concerned that we have not removed Pedia Loss from distribution. Let me go on record that we control all fulfillment and distribution of Pedia Loss and no individual or entity has received Pedia Loss since it has been removed from distribution. Our site, where you may have seen Pedia Loss, is an informational site

only and nothing is sold from this site. Pedia Loss has since been removed from all sites that are in our control.

Also, please let me inform you of the fact that the structure of Dynamic Health is in the process of being changed, as I write this letter. Once that change is completed we will operate under the company name of DBS Labs, LLC. The corporation Dynamic Health will no longer exist. Please direct all future correspondence to DBS Labs, LLC at 1485 N. Park Dr., Weston, FL 33326.

Sincerely,

A handwritten signature in black ink, appearing to read "Guy Regalado", written over a horizontal line.

Guy Regalado
Vice President, Sales

1485 North Park Dr.
Weston, FL 33326

US House of Representatives
Committee on Energy and Commerce
Attn. Kelli Andrews
Washington D.C. 20515

RE: Dynamic Health Pedia Loss Inquiry

Dear Mrs. Kelli Andrews

Dynamic Health seeks to cooperate fully with the Committee on Energy and Commerce to resolve any concerns regarding the Company's products. Enclosed please find a voluntary submission of information made on behalf of Dynamic Health of Florida, LLC ("Dynamic Health" or "the Company"), a Sales and Marketing company of dietary supplement products.

Question 1

- Listing of ingredients for Pedia Loss are; Inulin – 500mg, Glutamine 400mg, FOS – 100mg, Lecithin – 100mg, HCA - 25mg
- See attached exhibit "A" for records that relate to research and testing.

Question 2

Dr. Guzman, e-mail addresses; durnes010@yahoo.com
David Wood e-mail address: dgwood@novia.net

Question 3

Pedia Loss was removed from the market December 5, 2003. Since we control all fulfillment and distribution we were able to notify our fulfillment warehouse to cease all shipments.

Question 4

DBS Labs is a trademark owned by Chhabra International Ltd, ("CIL"). DBS is licensed to CIL's affiliate Dynamic Health of Florida LLC ("Dynamic Health"). Attached please find printout from the Florida Secretary of State showing who the officers of the company are. Attached is also a copy of the Share Certificate showing that the owner of Dynamic Health is Chhabra Investment Group, LLC.

Question 5

Dynamic Health was organized in the State of Florida on December 4, 2002. Transmitted please find Articles of Organization for Dynamic

1485 North Park Dr.
Weston, FL 33326

Health, which shows the registered agent on December 4, 2002, which was when the company was formed. Please reflect to attached printout from the Florida Secretary of State for current registered agent information.

Question 6

See attached exhibit "A" for records that relate to research

Question 7

There are no other brand names for Pedia Loss

Question 8

There are no responsive documents

Question 9

1. Dr. Guzman, e-mail addresses; durnes010@yahoo.com]

- a. ALBERTO C. GUZMAN ROJAS, MD
- b. e-mail address; durnes010@yahoo.com
- c. There are no responsive documents
- d. Dr. Guzman has not received compensation
- e. There are no responsive documents
- f. Reference the CV (Exhibit "B")
- g. Reference (Exhibit "C")

2. David Wood e-mail address: dgwood@novia.net

- h. David Wood
- i. e-mail address; dgwood@novia.net
- j. There are no responsive documents
- k. David Wood has not received compensation
- l. There are no responsive documents
- m. There are no responsive documents
- n. Reference (Exhibit "E")

Question 10

Dynamic Health has received no consumer complaints regarding the subject products.

Question 11

To date we have had no adverse health events. Consequently, we have no reporting or tracking procedures for adverse health events.

1485 North Park Dr.
Weston, FL 33326

Question 12

No lawsuits have been filed against Dynamic Health

Question 13

The parent company of Dynamic Health is Chhabra Investment Group, LLC.

Question 14

Reference (Exhibit "D")

Question 15

DBS Labs, President, Jonathan Barash
Dynamic Health, VP Sales & Marketing, Guy Regalado

Question 16

Pedia Loss was only available and on the market for a short period of time in 2003 with total revenues of \$11,870.00.

Question 17

Nutrition Formulators is GMP certified with NNFA, located at 11005 NW 33rd Street Miami, Florida 33172, (305) 592-2111 Adolfo Graubard, President.

Question 18

December 2003 Federal Trade Commission – weight loss products investigation.

We are hopeful that you find this information useful in resolving any concerns you may have. To the extent that additional relevant information becomes available to the Company, we voluntarily will supplement this submission. Dynamic Health requests that all documents and information submitted pursuant to this voluntary submission remain confidential pursuant to 15 U.S.C. §§ 46(f) and 57b-2(f) and 16 C.F.R. §§ 4.10-4.11.

As submitted by;
Guy Regalado
Vice President, Sales
Dynamic Health of Florida, LLC

DBS Laboratories LLC

Thursday, March 25, 2004

US House of Representatives
Committee on Energy and Commerce
Attn. Kelli Andrews
Washington D.C. 20515

Tab 30

RE: Update Information on Pedia Loss DBS Laboratories LLC
Sent Via Fax to: 202-226-2447 U.222 226 2424

Dear Mrs. Kelli Andrews

DBS Laboratories LLC seeks to cooperate fully with the Committee on Energy and Commerce to resolve any concerns regarding the Pedia Loss Issue. Enclosed please find a voluntary submission of information made on behalf of DBS Laboratories, LLC, an operations company that oversees the manufacturing process of supplement products for companies like Dynamic Health LLC of Florida. Any submission made by any other than Jonathan Barash on behalf of DBS Laboratories LLC is not valid, no authorization has been given to any law firm or any other individual to respond to this inquiry.

It is important to note that while DBS Labs was incorporated in March 2003, that Company only facilitates the manufacturing process of products to companies like Dynamic Health LLC of Florida. This means that DBS laboratories LLC only oversees the operations process of the manufacturers of supplement products at contract manufacturers, packaging suppliers and printers nothing else.

In Reference to your opening statement on the letter sent to DBS dated 12/19/03, I must state that www.dbslabs.com is not owned or operated by DBS Laboratories LLC.

Dynamic Health of Florida is a sales and marketing company, for the Pedia Loss product. DBS Laboratories LLC is not responsible for statements, copy, marketing materials, PR and websites; for any claims made for Pedia Loss. As per our phone conversation; I had restated a statement from Guy Regalado, at Dynamic Health LLC, that Pedia Loss had been completely removed from the marketplace and has been available for sale since 12/1/03. DBS Laboratories LLC has no control of the removal of this product information from other sites or distributors like Dynamic Health of Florida.

DBS Laboratories LLC uses contract manufacturers like Nutrition Formulators of Miami to make nutraceutical products for Dynamic Health LLC. It was important to Dynamic Health LLC to used a GMP certified lab, so in my research in identify labs I had spoken to NNFA about their certified GMP Labs and the use of the logo. NNFA stated to me that if the products are manufactured at a certified NNFA GMP facility, they may use their GMP logo on the products. just as other companies do for USP, GMP and NNFA.

DBS Laboratories LLC**Question 1**

Inulin – 500mg, Glutamine 400mg, FOS – 100mg, Lecithin – 100mg, HCA - 25mg

Question 2

Dr. Guzman, David Wood

Question 3

No, we are not a member of NNFA, the contract manufacturer Nutrition Formulators is GMP certified with NNFA, located at 11005 NW 33rd Street Miami, Florida 33172, (305) 592-2111 Adolfo Graubard, President.

Question 4

No, we are not a member of NNFA, the contract manufacturer Nutrition Formulators is GMP certified with NNFA, located at 11005 NW 33rd Street Miami, Florida 33172, (305) 592-2111 Adolfo Graubard, President.

Question 5

Faxed e-mails and records from David Woods and new formulation from Dr Guzman.

Question 6

No other brand names.

Question 7

There are no responsive documents

Question 8

Dr Guzman is a Doctor used by Nutrition Formulators for reviewing formulations; DBS Laboratories LLC received the original formulation for Pedia Loss from a David Woods in 2002, he represented that he contract manufactured for Pfizer Pharmaceutical and this was a nutraceutical formula he discovered for them that they passed on; we don't have updated information on him.

- a. ALBERTO C. GUZMAN ROJAS, MD
- b. There are no responsive documents
- c. There are no responsive documents
- d. Dr. Guzman has not received compensation from DBS Laboratories LLC
- e. Reference the CV (included in fax)
- f. Reference fax
- g. Reference fax

Question 9

Please refer this question to the sales and marketing company for Pedia Loss Dynamic Health LLC.

DBS Laboratories LLC

Question 10

DBS Laboratories LLC is just the operations company for expediting products (Middle Man) We do not need that documentation.

Question 11

No lawsuits

Question 12

- In July of 2003 Chhabra International Ltd purchased 75% of DBS Laboratories LLC to help expedite the manufacturing process of products to Dynamic Health LLC Warehouse.

Question 13

DBS Laboratories LLC is just an operations company for expediting the manufacturing process of products to Dynamic Health of Florida.

Question 14

Names and Titles of Senior Management of Dynamic Health & DBS Laboratories LLC:
DBS Laboratories LLC, President, Jonathan Barash (had no involvement in the development of Pedia Loss) from 3-1-03 to 7-15-03
Dynamic Health, VP Sales & Marketing, Guy Regalado
Dynamic Health, President, Vincent Chhabra

Individuals involved in the developing and marketing of Pedia Loss:

1. Brian Yusem (Delta Body Systems)
2. David Woods (ABC Corp)
3. Guy Regalado (Dynamic Health)
4. John Reinbergs (Dynamic Health)

Question 15

DBS Laboratories LLC has no revenues from Pedia Loss. Dynamic Health LLC is the company that received the Pedia Loss product at their warehouse and profits from its sales.

Question 16

- a. Nutrition Formulators = contract manufacturer for Pedia Loss.
- b. Dynamic Health = sales and marketing company for Pedia Loss

Question 17

DBS Laboratories LLC was incorporated in March 2003, but has only sold products since August 2003

- a. December 2003 Federal Trade Commission – weight loss products investigation.

DBS Laboratories LLC

I'm hopeful that you find this information useful in resolving any concerns you may have as to the part DBS Laboratories LLC played in Pedia Loss product. To the extent that additional relevant information becomes available to the Company, we voluntarily will supplement this submission. DBS Laboratories LLC requests that all documents and information submitted pursuant to this voluntary submission remain confidential pursuant to 15 U.S.C. §§ 46(f) and 57b-2(f) and 16 C.F.R. §§ 4.10-4.11.

As submitted by:

Jonathan Barash
DBS Laboratories LLC

DBSLabs

March 30, 2004

Sent via fax #202-226-2447

Tab 31

To: Kelli Andrews
Committee on Energy and Commerce
Washington, DC 20515

From: DBS Labs, LLC
1455 North Park Dr.
Weston, FL 33326

Dear Ms. Andrews:

Per your request yesterday, below is my response addressing the questions that we discussed on the phone.


- You had asked me to define the new company and outline its relationship to the old companies.
 - The new company is DBS Labs, LLC of which I am a Manager and President. The actual ownership has not been finalized but will eventually consist of a mix of employees previously from the old companies that dealt exclusively with the Ovulite and the nutraceutical product.
 - There is no relationship between the old companies and the new DBS Labs, LLC. In December of 2003 Vincent Chhabra was indicted (case number 03-530-A) and all of his assets were frozen some of which consisted of the Ovulite and nutraceutical products.
 - At that time DBS Laboratories, LLC was a middle man that helped arranged product sourcing so that Chhabra International Ltd. could sell nutraceuticals through Dynamic Health (a sales company) to the major retailers in the United States. Once all of the assets were frozen these companies could not function and would lose their customer base and not be able to continue.
 - To prevent several employees, including myself, from becoming unemployed I flew up to DC to negotiate the release of the trade marks and inventory of these companies with the hope that we could resurrect any existing sales and move forward by securing new retailers as customers. These negotiations took place with Karen Taylor, Assistant US Attorney, Eastern District of Virginia (her phone number is 703-299-

3903). In these negotiations, we informed Ms. Taylor that we would form a new company and move forward with the trademarks and inventory, which she approved.

- We then formed the company DBS Labs, LLC because originally we used the name "DBS Labs" for marketing purposes and many retailers knew us under that name, which also explains why Jonathan used DBS Labs letterhead in his previous correspondence. Please let me reemphasize that the company DBS Labs, LLC has never sold Pedia Loss.
- Let me point out that Vincent Chhabra was required to give his consent before we could finalize the negotiations and he does not own any part of this company.
- You asked me to address the discrepancy between the Jonathan Barash's figure and my figure regarding the Pedia Loss sales.
 - Jonathan was not privy to sales figures. Please let me confirm that the figure of \$11,870 is the correct sales figure for Pedia Loss.
- Per your final request, the state documents for the incorporation of the new company, DBS Labs, LLC are attached.

I hope that this information answers all of your questions and if any new questions develop please do not hesitate to contact me directly at 954-888-4190.

Sincerely,



Guy Regalado
President
DBS Labs, LLC



Florida Limited Liability

DBS LABS LLC

PRINCIPAL ADDRESS
1455 NORTH PARK DR
WESTON FL 33326

MAILING ADDRESS
2665 S BAYSHORE DR, STE 703
MIAMI FL 33133

Document Number L04000013182	FBI Number NONE	Date Filed 02/18/2004
State FL	Status ACTIVE	Effective Date NONE
Total Contribution 0.00		

Registered Agent

Name & Address
WORLD CORPORATE SERVICES, INC. 2665 S BAYSHORE DR, STE 703 MIAMI FL 33133

Manager/Member Detail

Name & Address	Title
REGALADO, GUY 1455 NORTH PARK DR WESTON FL 33326	MGR

Annual Reports

Report Year	Filed Date



No Events

No Name History Information

Document Images

Listed below are the images available for this filing.

No images are available for this filing.

THIS IS NOT OFFICIAL RECORD; SEE DOCUMENTS IF QUESTION OR CONFLICT



Mar 30 2004 5:08PM DBS LABS 9548889429
FEB 20 2004 12:34PM HP LASERJET 3200
(((H04000035548)))

P. 6

P. 2

**ARTICLES OF ORGANIZATION
OF
DBS LABS LLC**

ARTICLE I

Name

The name of this limited liability company is DBS LABS LLC (hereinafter "the Company").

ARTICLE II

Address

The principal street address of the Company is: 1455 North Park Drive
Weston, Florida 33326

The mailing address is of the Company is: 2665 South Bayshore Drive
Suite 703
Miami, Florida 33133

ARTICLE III

Duration

The Company's existence shall commence upon the filing of these Articles of Organization with the Florida Department of State and said existence shall be perpetual.

ARTICLE IV

Initial Registered Office and Agent

The name and mailing address of the initial registered office and the initial registered agent of the Company is:

World Corporate Services, Inc.
2665 South Bayshore Drive
Suite 703
Miami, Florida 33133

Mar 30 2004 5:08PM DBS LABS 9548889429 p.7
FEB 20 2004 12:34PM HP LASERJET 3200 p.3
(((404000035548)))

ARTICLE V

Purpose

The Company shall be authorized to engage in and transact any and all lawful business within and without the State of Florida or United States for which Limited Liability Companies July be created under § 608.404, Fla. Stat., as amended and supplemented.

ARTICLE VI

Authorized Representative and Organizer

The name and street and mailing address of the person signing these Articles as authorized Representative and Organizer is:

Albert J. Lazo, Esq.
Richards & Polansky, P.A.
2665 South Bayshore Drive
Suite 703
Miami, Florida 33133

ARTICLE VII

Management

The Company will be managed by at least one (1) manager and is, therefore, a manager-managed company. The initial manager shall be:

Guy Regalado
1455 North Park Drive
Weston, Florida 33326

In accordance with Section 608.404(3), Florida Statutes, the execution of this document constitutes an affirmation under penalties of perjury that the facts stated herein are true.

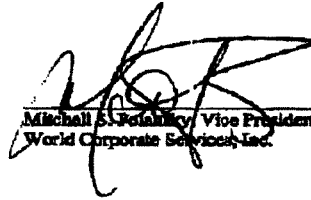

Albert J. Lazo, Authorized Representative

Mar 30 2004 5:08PM DBS LABS 9548889429 P. 8
FEB 20 2004 12:34PM HP LASERJET 3200 P. 4
((C404000035548)))

ACCEPTANCE OF REGISTERED AGENT

I HEREBY ACCEPT this appointment of, and designation as registered agent for service of process within the State of Florida of DBS LABS LLC named in the Articles of Organization herein above set forth and I do hereby further state that I may be found as registered agent for service of process upon said proposed corporation at the address set forth in Article IV of such Articles.

IN WITNESS WHEREOF, as said registered agent, I have caused this statement to be signed on this 13 day of February 2004.



Mitchell S. Potkin, Vice President
World Corporate Services, Inc.

Pricing- David Wood

Stress relief Capsules
5000 bottles
120 - Count
Bottle - 7.97ea
12 /cs

Tab 32

Arginine Power Capsules
5000 bottles
160 - Count
Bottle - 6.36ea
12/cs

Pedia Loss Grape Chewables
5000 bottles
120 - Count
Bottle - 2.90ea
12/cs

Reflux tablets (with peppermint flavor)
5000 bottles
180 - Count
Bottle - 4.72ea
12/cs

PRODUCT: Pedia Loss
Flavor - Natural Cherry

Claim per 2- tablets:

Inulin - 500mg
Glutamine 400mg
FOS - 100mg
Lecithin - 100mg
HCA - 25mg

Package size: 120
Tablet size 9/16 diameter x 3/16

Ingredients: Fructose, Inulin, Glutamine, Fructo-Oglisosaccharides, Lecithin, Natural flavor, Citric acid, Hydroxycitrate extract, Magnesium Stearate (releasing aid).

*Daily Value (DV) not established

EXHIBIT "D"

Tab 33 RESEARCH AGREEMENTE-2011
"D"

This Research Agreement (hereinafter the "Agreement"), effective as of January 29, 2004 (the "Effective Date"), is made by and between DBS Laboratories LLC, a Florida corporation having offices at 1485 North Park Drive, Weston, Florida, 33326 (hereinafter "DBS Labs") and University of Miami having offices at Rhodes House, Building 37A, 1204 Dickinson Drive, Coral Gables, FL 33124-5215 (hereinafter "Institution").

WHEREAS, DBS Labs and Institution have a mutual interest in studying Pedia Loss® (Inulin, Glutamine, FOS, Lecithin, HCA) tablets (hereinafter "Dietary Supplement"); and

WHEREAS, Institution represents:

1. That it has qualified personnel and adequate facilities and equipment to competently conduct the clinical research project known as "A 6 month study to assess the safety and efficacy of Pedia Loss® in obese adolescents" as described in the study protocol document ----- previously provided to Investigator (as hereinafter defined) and incorporated fully herein by reference as Appendix "A" (hereinafter the "Study"), according to the terms and conditions hereinafter set forth;
2. That it will appoint Arlette C. Perry, M.D. as principal investigator (hereinafter "Investigator") having the requisite education, experience and expertise to competently perform the Study according to the terms and conditions hereinafter set forth, and that said Investigator shall act as representative of the Institution for medical and scientific matters arising under this Agreement, and shall have primary responsibility for supervision of the Study. Institution shall notify DBS Labs within (10) days of any proposed change in its selection and appointment of an Investigator.

NOW, THEREFORE, in consideration of the mutual promises and covenants expressed herein, and intending to be legally bound, it is agreed as follows:

ARTICLE 1: Compliance

- (a) Institution acknowledges that DBS Labs intends to rely on the results of the Study for purposes of making reports or applications to the United States Food and Drug Administration (hereinafter "FDA") and the FTC Federal Trade Commission (hereinafter "FTC"), and represents that all work and duties to be performed by it under this Agreement shall be in compliance with all applicable federal and state statutes, regulations and policies, including the relevant requirements of 21 C.F.R. 312.50 to 312.70, inclusive ("Responsibilities of Sponsors and Investigators") and 21 C.F.R. Part 50 ("Protection of Human Subjects"), the terms of which FDA regulations are incorporated herein by references.

- (b) Institution represents that to the best of their knowledge neither it nor any person associated with the performance of the Study has, pursuant to 21 U.S.C. 335 (a) or (b), been debarred by the FDA from the conduct of clinical trials in human subjects.
- (c) Institution agrees that it shall require Investigator to certify that he/she has provided to DBS Labs all information concerning any and all "covered financial arrangements that exist between the investigator, the investigator's spouse and/or dependent children, and DBS Labs; and further agrees to promptly update such information with any changes that it becomes aware of during the course of the Study and for one year following its completion.

"Covered financial arrangements" that must be reported to DBS Labs are:

- 1) Any financial arrangement entered into between DBS Labs, and the investigator's immediate family, whereby the value of the compensation paid for conducting the Study could be influenced by the outcome of the Study;
- 2) Any payments (other than the costs of conducting the Study or other clinical studies) made to the investigator and/or immediate family by DBS Labs such as a grant to fund the investigator's ongoing research, compensation in the form of equipment, consulting arrangements, and any honoraria;
- 3) Any proprietary interest in the test product, including patent, trademark, copyright or licensing agreements, held by an investigator and/or his/her immediate family; and
- 4) Any steps taken to minimize the potential for bias resulting from any of these arrangements, interests or payments.

ARTICLE 2: Scope of Work

- (a) Institution shall strictly comply with the terms of the Study Protocol (the "Protocol"). In the event of conflict between the terms of this Agreement and the Protocol, the terms of the Protocol shall control in all matters affecting the conduct of the Study; otherwise, the terms of this Agreement shall control.
- (b) The Study shall be conducted in Investigator with the prior approval and ongoing review of a duly constituted Institutional Review Board ("IRB"). Any modifications to the Protocol recommended by the Investigator or IRB prior to the initiation or during the conduct of the Study shall be brought to the attention of DBS Labs. The Protocol may not be altered absent the prior written approval of DBS Labs, and a subsequent review and approval of the IRB.
- (c) Institution will have the opportunity to enroll up to 100 study participants capable of being evaluated and having analyzable data in the treatment portion of the Study, by 2/15/2004. The opportunity to enroll additional patients during and subsequent to this date will be at the discretion of DBS Labs. If DBS Labs approves additional patients,

- it will do so in writing to Institution. Personnel from DBS Labs (or DBS Lab's third party agent) will call on Institution periodically to monitor and determine the status of the Study, adherence to protocol, answer procedural questions, and retrieve completed case report forms.
- (d) DBS Labs shall provide Institution, without charge, sufficient quantities of Study Dietary Supplement and placebo in appropriately marked containers. Any unused Study Dietary Supplement or placebo supplies are to be returned promptly to DBS Labs upon completion of the Study, or, at DBS Labs' election, destroyed in a manner acceptable to DBS Labs.

ARTICLE 3: Budget Terms

- (a) Payment schedule is specified in Appendix "B" annexed hereto and incorporated by reference.
- (b) The total amount payable to Institution under this Agreement (including any reimbursable expenses allowable under this Agreement) may not exceed \$65,000.00 without the prior written consent of DBS Labs, even under a quantum meruit theory. Any procedures, visits, or other changes performed apart from those scheduled in the Study are subject to prior written approval of DBS Labs, and will be paid for as approved at the time of final payment.
- (c) Institution acknowledges and agrees that it shall be solely responsible for paying the appropriate amount of all federal, state, and local taxes with respect to all compensation paid pursuant to this Agreement, and that DBS Labs shall have not responsibility whatsoever for withholding or paying any such taxes for or on behalf of Institution.
- (d) For purposes of final payment, patients will be considered to have "completed" the Study upon retrieval by DBS Labs or its agent of satisfactorily completed case report forms, and resolution of any queries or requests for clarification made by DBS Labs to Institution concerning Study data or records.

ARTICLE 4: Communications

- (a) All communications pertaining to business matters under this Agreement shall be directed as follows:

If to DBS Labs:	Jonathan Barash President DBS Laboratories 1485 North Park Drive Weston, Florida 33326 Telephone Number: (954) 888-4013 Facsimile Number: (954) 337-8430
If to Institution:	Sandy Blanco

Assistant Director of Research Administration
Rhodes House, Building 37A, 1204 Dickinson Avenue
Coral Gables, Florida 33124-5215
Telephone Number: **(305) 284-4541**
Facsimile Number: **(305) 284-2032**

- (b) In the event DBS Labs or the FDA decides for any reason to suspend or withdraw the Study Dietary Supplement from further use, DBS Labs shall immediately notify Institution of such decision, and shall provide similar notice to the Chairperson of the IRB. Any such notice will be confirmed in writing within twenty-four (24) hours of oral notification.

ARTICLE 5: Confidentiality and Inventions

- (a) Upon execution of this Agreement a confidential relationship shall exist between DBS Labs and Institution, whereby Institution agrees to hold in confidence confidential information disclosed by DBS in connection with the Study. As used in this Agreement "confidential information" shall be understood to include information disclosed by DBS Labs which is not in the public domain, including but not limited to: technical, scientific, market and marketing information, know-how, data, formulae, processes, plans, assessments and methods for the Dietary Supplement and/or its uses or modes or action, as well as similar information relating to any other DBS Labs compound. For purposes of this Agreement, confidential information supplied by DBS Labs to Institution shall not be deemed to be in the public domain or in the possession of Institution merely because it is embraced by general disclosures in the public domain or in the prior possession of the Institution.
- (b) Institution shall make no use or disclosure of confidential information except as specified in this Agreement, and shall return to DBS Labs all written confidential information, together with written material incorporating confidential information, upon completion or early termination of this Agreement, or at the request of DBS Labs.
- (c) Institution agrees to disclose confidential information only to such of its employees and agents as are required to have access to the information in order to permit performance of the Study, and then only upon execution by such employee or agent of a Confidentiality Agreement in that form provided as Appendix "C" to this Agreement.
- (d) Confidential information shall not be deemed to include information which: (i) enters the public domain through no act or omission of Institution; (ii) is lawfully in Institution's possession prior to disclosure, which possession can be documented through business records maintained in the ordinary course of Institution's business; (iii) is obtained by Institution from a third party having the lawful right to provide such information and having no obligation of confidentiality of DBS Labs; or (iv) is required by law or court order to be disclosed.

- (e) The disclosure of confidential information to Institution shall not be construed in any way as a license or transfer of other rights. Institution assigns and agrees to assign any improvement, invention, and/or discoveries that are made by Institution as a result of the work performed under the Study. Institution shall ensure that all improvements, inventions, and/or other discoveries (whether patentable or not) which arise out of this Agreement and the Study or Protocol are promptly communicated to DBS Labs, and Institution shall be willing at any time at DBS Labs expense to assist DBS Labs in obtaining patent protection and/or other forms of protection for said improvement, inventions and/or discoveries in any territory in the world. Upon request, Institution shall use its best efforts to assign or secure the assignment to DBS Labs, at DBS Labs' expense, of any right and title to such improvement, inventions, and/or discoveries which is not at that time vested in DBS Labs, and shall execute or cause to be executed any and all documents necessary to secure or transfer such property rights to DBS Labs.

Article 6: Term and Termination

The term of this Agreement shall be for the period beginning with the Effective Date and ending with completion of the Study, unless terminated sooner pursuant to the following:

- (a) The parties may terminate the Study and this Agreement at any time by mutual written agreement.
- (b) Either party may terminate this Agreement for cause upon thirty (30) days written notice. Notices shall be deemed delivered upon receipt by the recipient designated for each party in Article 4 of this Agreement. "Cause" shall be defined to include a material breach of this Agreement, a material violation of the Study Protocol, a determination by Institution or Investigator that the Study poses an unreasonable risk to the health and safety of a participant, or a lack of enrollment of the stated Study participant population.
- (c) DBS Labs may terminate this Agreement:
- (i) immediately upon notice to Institution if DBS Labs determines that continuation of the Study is not in the best interest of Study participants or DBS Labs, or if the FDA suspends investigational use of the Study Dietary Supplement for any reason, or
- (ii) without cause upon thirty (30) days written notice to Institution.
- (d) This Agreement may be terminated immediately upon notice to Institution if DBS Labs determines that continuation of the Study is not in the best interests of Study participants or DBS Labs, or if the FDA suspends investigational use of the Study Dietary Supplement for any reason. If DBS Labs terminates this Study prior to the normal conclusion of the Agreement, it will pay to Institution all fees earned for completed procedures in accordance with Appendix B, and, in addition, all

documented costs resulting directly from early termination of this Agreement, such termination costs not to exceed ten percent (10%) of the "not to exceed" costs stated in Article 3(b), supra.

- (e) The obligations specified in Articles 5, 7, 8, and 10 of this Agreement (including executed copies of Appendix "C") shall survive termination of this Agreement for a period of five (5) years. All other obligations of either party shall be excused upon termination of this Agreement, saving obligations which have arisen prior to the date of termination.

ARTICLE 7: Access to Records

Data and records compiled by Institution under this Study shall be freely available to DBS Labs at Institution's office during normal business hours upon reasonable notice and request. Institution agrees to retain with the records of the Study either the originals or copies of all Study participant forms and the records, and to make these available for comparison with case reports for review and/or copying if requested by DBS Labs or representatives of the FDA. Neither DBS Labs nor Institution shall at any time disclose to any third party the name of any Study participant unless required to do so by law (including lawful request of the FDA).

ARTICLE 8: Clinical Study Report/Publication Policy

- (a) DBS Labs will ensure the preparation of a comprehensive final report of this study suitable for regulatory purposes that will be kept on file within DBS Labs.
- (b) By signing the Research Agreement, the Investigator agrees that the results of this study may be used for submission to national and/or international regulatory and supervising authorities. The authorities will be notified of the Investigator's name, address, qualifications, and extent of involvement.
- (c) Publication and the disclosure of information shall be governed by the terms of the Research Agreement. Any proposed publication, lecture, manuscript, poster presentation or other dissemination of the data and results of this study must be submitted to DBS Labs prior to its submission for publication for DBS Labs' review and comment.
- (d) All Study data and results shall be the exclusive property of DBS Labs, and DBS Labs reserves the right to use the Study data and results for any corporate purpose.

ARTICLE 9: Adverse Events

In the event a Study participant suffers an illness or injury which DBS Labs and Investigator reasonably or study procedures determine to be an adverse event caused by exposure to the Dietary Supplement or Study placebo, DBS Labs shall pay all medical and hospital expenses reasonably associated with the

medical treatment of such adverse event in excess of that portion covered by the participant's own insurance.

ARTICLE 10: Claims and Indemnity

- (a) DBS Labs agrees to indemnify and hold harmless the Principal Investigator, University of Miami, its Trustees, officers, faculty, employees and students (hereinafter "University") against any and all losses, expenses, claims, actions, lawsuits and judgments thereon (including attorney fees through the appellate levels), which may be brought against the University by reason of personal injury, illness or death to any person as a direct result of administration of the medication or otherwise arising out of or reasonably attributable to the activities to be carried out in this research study provided that any loss, liability or damage resulting from (1) failure to adhere to the terms of the Protocol or DBS Labs' written instructions relative to the use of the investigational drug, (2) failure to comply with any applicable FDA, NIH or other governmental requirements, or (3) acts of negligence, omission or willful malfeasance or misconduct by the Principal Investigator or University of Miami is excluded from this agreement to indemnify, defend and hold harmless. In the event an illness or injury, which the University and DBS Labs reasonably determine to be an adverse reaction to administration of medication pursuant to the protocol or other study procedure should occur, medical treatment for such adverse reaction will be provided free of charge by DBS Labs.
- (b) Administration of medication of placebo, or other treatment pursuant to the protocol shall not be considered negligence by the University.
- (c) In the event any such claim is made or lawsuit is initiated, the University shall notice Company within ten days of receipt of notice of claim in writing and shall cooperate fully in the defense of such lawsuit and permit Company or its insurance carrier to defend such a claim or lawsuit.
- (d) The provisions of this paragraph and paragraph 7 shall continue after the termination of this Agreement.

ARTICLE 11: Miscellaneous

- (a) Institution shall perform its duties and obligations under this Agreement as an independent contractor, and Institution and employees of Institution shall not be considered employees of DBS Labs, nor shall Institution have the authority to hold itself out as having the authority to speak for, represent, obligate or legally bind DBS Labs in any way.

- (b) This Agreement shall be binding upon and inure to the benefit of the successors and assigns of the parties hereto. Institution shall not assign any part of its interest or obligations hereunder without the prior written consent of DBS Labs.
- (c) No modification or waiver of any of the provisions of this Agreement shall be binding unless made in a writing signed by the parties hereto.
- (d) Institution acknowledges that it understands that DBS Labs is an Equal Opportunity Employer, and warrants that unless exempted by law, it complies with the Fair Labor Standards Act of 1938, as amended. If this Agreement is construed to be a subcontract within the meaning of the rules and regulations approved by the United States Secretary of labor pursuant to Executive Order 11246, as amended, the Vietnam Era Veterans Readjustment Act of 1974, as amended, the Rehabilitation Act of 1973, as amended, or of regulations as well as Equal Opportunity and Nondiscrimination provision of Section 202 of Executive Order 11246 shall be incorporated herein by reference.
- (e) This Agreement (together with all documents expressly incorporated herein by reference) comprises the entire agreement entered into between the parties, executed in duplicate originals.

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed in

duplicate originals by their duly authorized representatives.

DBS LABORATORIES

UNIVERSITY OF MIAM

By: _____

By: _____

Printed Name: _____

Printed Name: _____

Title: _____

Title: _____

Date: _____

Date: _____

Acknowledged:

APPENDIX C

CONFIDENTIALITY AGREEMENT

The undersigned, _____ declares that he or she has read and is familiar with the provisions of the Research Agreement between DBS Laboratories ("DBS Labs") and University of Miami, dated January 25, 2004, and related to the clinical research project known as "A 6 month study to assess the safety and efficacy of Pedia Loss® (Inulin, Glutamine, FOS, Lecithin, HCA) tablets in obese adolescents" (hereinafter the "Research Agreement"). The undersigned agrees to be bound by the terms and conditions of the Research Agreement, and further agrees to keep confidential any information received from DBS Labs; provided that this obligation shall not apply to any information which:

- (a) is already in the possession of the undersigned at the time of disclosure thereof, and can be documented by written records to then be in the undersigned's possession;
- (b) is or later becomes part of the public domain through no act or omission of the undersigned;
- (c) is lawfully received from a third party having no obligation of confidentiality of DBS Labs; or
- (d) is required by law to be disclosed.

Upon completion or early termination of the Research Agreement or this Confidentiality Agreement, the undersigned agrees to promptly return to DBS Labs all written confidential information, as well as, all written material which incorporates any confidential information, which is then in his or her possession.

Signature

Printed Name

Title

Date

DBS Labs


HOME COMPANY PRODUCTS WHERE TO BUY FAQ's CONTACT U

COMPANY

Tab 34

SHOW PRODUCT MENU

LIBIDO ENHANCERS



This product is designed to increase sexual desire and improve sexual performance.

description	directions	supplement facts
MASCULINE MALE Virility, performance and prowess can be attained at any age. These can all be attributed to Masculine Male. Masculine Male utilizes Tongkat Ali, the one ingredient that is completely focused on giving you maximum performance anytime the opportunity arises, and enhancing your libido to new levels you and your partner will revel in. Two tablets, twice a day can help you discover an arousal level that will make sex more intense and exhilarating. Get the most out of your sexual experiences with Masculine Male.		

DBS Labs

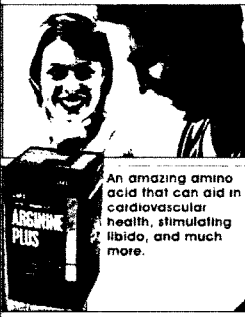
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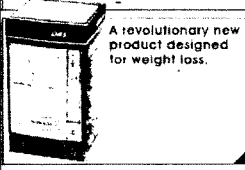
Tab 35

SHOW PRODUCT MENU


description	directions	supplement facts
 <p>An amazing amino acid that can aid in cardiovascular health, stimulating libido, and much more.</p>	<p>ARGININE PLUS</p> <p>Now youthful energy can be yours at any age with ARGININE PLUS. ARGININE PLUS is an amazing amino acid that can increase growth hormone, boost cardiovascular energy, and pump up your libido. By building collateral arteries, ARGININE PLUS can give you all the cardiovascular power you need to feel vibrant, healthy, and aroused - always on. Build the stamina that will help you enjoy life and everything it has to offer with just 3 capsules, twice a day.</p>	

DBS Labs					
	HOME	COMPANY	PRODUCTS	WHERE TO BUY	FAQ's CONTACT U
COMPANY					
WEIGHT LOSS			Tab 36		SHOW PRODUCT MENU
ThermoLean	Carb Control	Fat Fighter	Apimin AM	Apimin PM	
 <p>Boost energy and burn fat with Apimin-PM</p>		<h2>APIMIN PM</h2> <p>description directions supplement facts</p> <p>APIMIN PM Burn the fat you never wanted with APIMIN-PM. By increasing fat metabolism, maintaining normal glucose levels, suppressing appetite, and lowering the production of cholesterol and fatty acids, APIMIN-PM helps you shed excess weight. APIMIN-PM is an ephedra-free non-stimulant, so it supports fat metabolism while keeping you relaxed and allowing you to get a good night's sleep. One capsule of APIMIN-PM before each meal is a safe, easy way for you to lose weight. The powerful all-natural formula of APIMIN-PM works best with a low fat, low calorie diet and regular exercise. Get the formula you need to feel healthy and look fit in APIMIN-PM.</p>			

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DBS Labs										
HOME	COMPANY	PRODUCTS	WHERE TO BUY	FAQ's						
Tab 37										
SHOW PRODUCT MENU										
WEIGHT LOSS										
ThermoLean	Carb Control	Fat Fighter	Apimin AM	Apimin PM						
 <p>A revolutionary new product designed for weight loss.</p>		<h2 style="text-align: center;">FAT FIGHTER</h2> <table border="1"> <thead> <tr> <th>description</th> <th>directions</th> <th>supplement facts</th> </tr> </thead> <tbody> <tr> <td colspan="3"> <p>NEW FAT-FIGHTER Have that second slice of cheesecake and avoid having to go to the gym because studies now point to all-natural weight loss supplements to prevent flab.</p> <p>Only DBS Labs combines the latest technologies to bring us "Liposan Ultra" which we are proud to offer only in our Fat-Fighter product. Although laboratory results show the Liposan is a superior fat binder compared to a number of representative chitosans, the true benefit of New Chitosan occurs in the digestive tract. Liposan complexes up to 5 times more fat than regular chitosan, which may still not be fully dissolved. The complexed fat is trapped in the Chitosan gel and protected from enzymatic (lipase) breakdown into absorbable free fatty acids. This trapped fat cannot be absorbed and is effectively eliminated from the body.</p> </td> </tr> </tbody> </table>			description	directions	supplement facts	<p>NEW FAT-FIGHTER Have that second slice of cheesecake and avoid having to go to the gym because studies now point to all-natural weight loss supplements to prevent flab.</p> <p>Only DBS Labs combines the latest technologies to bring us "Liposan Ultra" which we are proud to offer only in our Fat-Fighter product. Although laboratory results show the Liposan is a superior fat binder compared to a number of representative chitosans, the true benefit of New Chitosan occurs in the digestive tract. Liposan complexes up to 5 times more fat than regular chitosan, which may still not be fully dissolved. The complexed fat is trapped in the Chitosan gel and protected from enzymatic (lipase) breakdown into absorbable free fatty acids. This trapped fat cannot be absorbed and is effectively eliminated from the body.</p>		
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DBS Labs		HOME	COMPANY	PRODUCTS	WHERE TO BUY	FAQ's	CONTACT U
COMPANY		Tab 38				SHOW PRODUCT MEN	
WEIGHT LOSS		ThermoLean	Carb Control	Fat Fighter	Apimin AM	Apimin PM	
		CARB CONTROL					
Lock out fat and trade excess weight for a new confidence.		description		directions		supplement facts	
		CARB CONTROL Lock out fat and trade excess weight for a new confidence. CARB-CONTROL works by inhibiting the enzyme responsible for breaking down carbohydrates, so the sugars in carbohydrates can't be absorbed into your body and stored as fats. Combined with a sensible diet and regular exercise, CARB-CONTROL allows you to safely trim fat without extreme dieting. One capsule of CARB-CONTROL twice a day keeps the fat away.					

MedPharmacy

Tab 39

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PEDIA LOSS

Non-Prescription All-Natural Health Product From Dynamic Health

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Child obesity is a growing problem in North America. Pedia Loss is an appetite suppressant for children 6 years and older. Allow children to enjoy their favorite foods without gaining weight. This revolutionary new formula slows the absorption of carbohydrates, allowing more to be burned for energy and less to be stored as fat. This highly effective and natural dietary supplement comes in berry-flavored chewable tablets for easy consumption. In conjunction with a proper diet and exercise program, Pedia Loss can keep your child from becoming a statistic.

Please consult your healthcare provider before giving PEDIA LOSS to your child.

To understand the difference between Dynamic Health weight loss products click here.

PEDIA LOSS \$79.95

[1] [Add]



View Supplement Facts



This product has been made at a Good Manufacturing Practices certified laboratory. To read more about it click here

Product Information

Pedia Loss is safe and effective for children of all ages....

This synergistic formula was designed to aide in a child's glucose metabolism. Since many of their favorite foods are rich in carbohydrates but very low in dietary fiber, their digestive tracts and insulin never function properly. Now with Pedia Loss children can still enjoy their favorite food but with the help of Inulin their bodies will slow down the absorption of carbohydrate, allowing more to be burned for energy and less to be stored as fat, and give a great source of soluble fiber. In addition to this highly advanced ingredient, we have included supplemental amounts of both glutamine and FOS, which have both been proven to drastically improve intestinal health. Finally this products contains a highly effective compound called HCA, this compound has been shown to safely burn fat without any form of stimulants.

DIRECTIONS

Suggested Use:

Children ages 6-10: Two (2) chewable tablets twice a day, 15 minutes before lunch & dinner. Children ages 11-16: Three (3) chewable tablets twice a day, 15 minutes before lunch & dinner. Consume with 6-8 ounces of water, juice or other liquid.

As with all dietary supplements if you are taking medication consult your health care professional

before taking this product.

Storage: Store in a cool dry place. Keep out of reach of children. Do not use if seal is broken.



Supplement Facts

Serving Size: 2 Chewable Tablets
Servings Per Container: 30

Amount Per Serving %DV†

Proprietary Blend Containing:	1125 mg	*
Fructose, Inulin, Glutamine, Fructo- Ogliosaccharides (FOS), Lecithin, Citric Acid, Hydroxycitrate Extract.		

† Percent Daily Value * Daily Value not established

Other Ingredients: Magnesium Stearate (releasing aid).



* These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

Pedia Loss

INULIN

OVERVIEW

Inulin is a polysaccharide derived from the Jerusalem artichoke and Dahlia tuber. It is formed by linking 30 fructose monomer units together in a long chain. A natural fiber, it helps to moderate blood sugar levels in the body. Not only can inulin analog help avoid "sugar rushes and crashes" commonly experienced, but it may also help reduce sugar craving, a frequent source of calories. Inulin analog is not absorbed by the digestive tract and therefore contributes no extra calories while improving energy levels.

METHOD OF ACTION

Inulin analog is a water-soluble fiber and the ultimate complex carbohydrate. It is a storage carbohydrate as well as one of the few known soluble fibers. It is the only carbohydrate that extends carbohydrate-derived energy over extended periods without significant increases in blood sugar level and does not require insulin in order to be metabolized. Inulin analog can help reduce insulin dependencies and requirements as well as provide better blood sugar control. The long-term energy release that inulin analog provides not only prevents low blood sugar levels in diabetics but enhances endurance for the normal active individual.

Inulin analog spreads the absorption of carbohydrates over a longer period of time than absorption without inulin analog. This is important because stretching carbohydrates over periods of 2 to 10 hours delays the pangs of hunger that result from the sugar rush and low experienced with carbohydrate consumption. For athletes, this capacity increases endurance levels as well. For diabetics, the fact that inulin analog does not increase blood sugar levels and prevents low blood sugar levels is important in preventing diabetic ketoacidosis.

Supplement: INULIN

Scientific Names:

Beta(2-1)fructans.

People Use This For:

Orally, inulin is used for hypercholesterolemia, hypertriglyceridemia, hyperlipidemia, obesity and weight loss, improving gastrointestinal function, and as a food additive

Safety:

POSSIBLY SAFE ...when used orally and appropriately, short-term. Doses of 8 to 14 grams daily have been safely used for up to eight weeks (7604,7605,7606,7607,8451).

PREGNANCY AND LACTATION: Insufficient reliable information available; avoid using.

Effectiveness:

POSSIBLY EFFECTIVE ..when used orally for hypertriglyceridemia. There is some evidence that inulin can reduce triglycerides by up to 19% after eight weeks of treatment (7604).

Mechanism of Action:

Inulin is an oligosaccharide, composed of chains of 2 to 60 glucose and fructose molecules. Although inulin is found in many fruits, vegetables, and herbs, it is usually obtained by hot water extraction from chicory root (7606). Because it contributes very little in dietary calories, inulin is used as a food additive to increase bulk and palatability (8449).

Inulin is related to short-chain oligosaccharides (SCO), which are often referred to as fructo-oligosaccharides. Partial hydrolysis of chicory inulin yields SCO, which are usually 2 to 7 sugar molecules in length and have many of the same effects as inulin (7606)

Inulin has a prebiotic effect, meaning that it is not digested or absorbed and it promotes the growth of specific types of bacteria in the large intestine. Inulin preferentially promotes the growth of bifidobacteria. Fermentation of inulin decreases fecal pH and increases fecal volume (7605,8447). The products of fermentation are short chain fatty acids, that are absorbed and metabolized (8449).

Inulin decreases serum triglycerides by decreasing fatty acid synthesis and reducing production of very low density lipoproteins (VLDL) (7604). Preliminary evidence indicates that SCO can reduce the formation of very low density lipoproteins (VLDL) (8448)

Adverse Reactions:

Orally, inulin can commonly cause flatulence, bloating, gastrointestinal cramps, and intestinal noises. These symptoms become more bothersome at doses over 30 grams (7604,8450,8509).

References: 7604 Williams CM. Effects of inulin on lipid parameters in humans. *J Nutr* 1999 Jul;129(7 Suppl):1471S-3S. 7605 Roberfroid MB, Van Loo JA, Gibson GR. The bifidogenic nature of chicory inulin and its hydrolysis products. *J Nutr* 1998;128:11-9. 7606 Menne E, Guggenbuhl N, Roberfroid M. Fr-type chicory inulin hydrolysate has a prebiotic effect in humans. *J Nutr* 2000;130:1197-9. 7607 Hoeger WW, Harris C, Long EM, Hopkins DR. Four-week supplementation with a natural dietary compound produces favorable changes in body composition. *Adv Ther* 1998;15:305-14. 7608 Gay-Crosier F, Schreiber G, Hauser C. Anaphylaxis from inulin in vegetables and processed food. *N Engl J Med* 2000;342(18):1372. 8447 Roberfroid MB. Functional effects of food components and the gastrointestinal system: chicory fructo-oligosaccharides. *Nutr Rev* 1996;54(1 Pt 2):S38-42. 8448 Kok N, Roberfroid M, Delzenne N. Dietary oligofructose modifies the impact of fructose on hepatic triacylglycerol metabolism. *Metabolism* 1996;45:1547-50. 8449 Dysseler P, Hoffem D. Inulin, an alternative dietary fibre. Properties and quantitative analysis. *Eur J Clin Nutr* 1995;49(Suppl 3):S145-52. 8450 Pedersen A, Sandstrom B, Van Amelsvoort JM. The effect of ingestion of inulin on blood lipids and gastrointestinal symptoms in healthy females. *Br J Nutr* 1997;78:215-22. < 8451 Abrams SA, Griffin IJ. Calcium absorption is increased in adolescent girls receiving enriched inulin. World Congress of Pediatric Gastroenterology, Hepatology & Nutrition, Boston, MA, August 5-9, 2000: Abstract 821. 8509 Cummings JH, Macfarlane GT, Englyst HN. Prebiotic digestion and fermentation. *Am J Clin Nutr*. 2001;73(2 Suppl):415S-420S.

Supplement: FRUCTO-OLIGOSACCHARIDES

Scientific Names:

Beta-D-fructofuranosidase.

People Use This For:

Orally, fructo-oligosaccharides are used for constipation, increasing fecal mass, and reducing serum cholesterol. Fructo-oligosaccharides are also used as prebiotics.

In foods, fructo-oligosaccharides are used as a sweetener.

Safety:

POSSIBLY SAFE ...when used orally and appropriately in amounts less than 30 grams per day (741,745,8505)

PREGNANCY AND LACTATION: Insufficient reliable information available, avoid using.

Effectiveness:

There is insufficient reliable information available to rate the effectiveness of fructo-oligosaccharides. However, some evidence suggests that fructo-oligosaccharides may relieve constipation by increasing fecal mass (8505). More evidence is needed to rate fructo-oligosaccharides for this use.

Mechanism of Action:

Fructo-oligosaccharides (FOS) are plant sugars that occur in a wide variety of fruits, vegetables, and cereals. Chemically, fructo-oligosaccharides are made up of a glucose molecule joined to fructose molecules. They are produced commercially from sucrose using an enzymatic process, or they can be produced by partial hydrolysis of chicory inulin (750,8507,8563).

Fructo-oligosaccharides have prebiotic activity. Prebiotics are substances that selectively promote the growth and activity of specific species of bacteria in the gut. Fructo-oligosaccharides pass undigested through the small intestine. Colonic bacteria that produce acids, such as bifidobacteria and lactobacilli, are symbiotic with fructo-oligosaccharides. In the colon, fructo-oligosaccharides specifically promote the growth of beneficial bacteria, which in turn produce enzymes that metabolize fructo-oligosaccharides (750,8505,8507,8508,8509,8563). Fructo-oligosaccharides are not hydrolyzed by human digestive enzymes (746), and they are not recoverable in the feces. This suggests complete metabolism by colonic microflora (747).

Colonic fermentation leads to increased fecal biomass, decreased ceco-colonic pH, and production of short chain fatty acids. The short chain fatty acids exert systemic effects on lipid metabolism similarly to dietary fiber (744).

Preliminary evidence suggests that fructo-oligosaccharides might protect against colon cancer (748). In experimental models of colon cancer, fructo-oligosaccharides seem to stimulate local immune surveillance to inhibit tumor formation (8506).

FOS are derived from asparagus, Jerusalem artichokes, and soybeans, or produced synthetically (746,8563). FOS pass undigested through the small intestine and are fermented in the colon.

Adverse Reactions:

Orally, the use of fructo-oligosaccharides can cause flatulence, belching, abdominal pain, intestinal sounds, and bloating (740,750,8609). These symptoms occur commonly but are generally mild at lower doses (less than 10 grams per day) (745,750,8509).

Interactions with Herbs & Supplements:

BIFIDOBACTERIUM BIFIDUM Concomitant use of fructo-oligosaccharides can promote the growth of supplemental bifidobacteria.

Dosage/Administration:

ORAL. For treating constipation, a dose of 10 grams per day has been used (8505). For prebiotic effect (to increase fecal bifidobacteria), the typical dose is 4 to 10 grams per day (749,750).

Comments:

Fructo-oligosaccharides are used as prebiotics, food constituents that increase the number of beneficial bacteria in the intestine. Don't confuse prebiotics with probiotics such as lactobacillus, bifidobacteria, and saccharomyces, which are live organisms used to re-colonize beneficial intestinal microorganisms (8509)

References: monograph: **FRUCTO-OLIGOSACCHARIDES 740** Stone-Dorshow T, Levitt MD. Gaseous response to ingestion of a poorly absorbed fructo-oligosaccharide sweetener. *Am J Clin Nutr* 1987;46:81-5. **741** Bornet FR. Undigestible sugars in food products. *Am J Clin Nutr* 1994;59(Suppl):763S-9S. **744** Roberfroid M. Dietary fiber, inulin, and oligofructose: a review comparing their physiological effects. *Crit Rev Food Sci Nutr* 1993;33:103-48. **745** Briet F, et al. Symptomatic response to varying levels of fructo-oligosaccharides consumed occasionally or regularly. *Eur J Clin Nutr* 1995;49:501-7. **746** Mitsouka T, Hidaka H, Eida T. Effect of fructo-oligosaccharides on intestinal microflora. *Nahrung* 1987;31:427-36. **747** Alles MS, et al. Fate of fructo-oligosaccharides in the human intestine. *Br J Nutr* 1996;76:211-21. **748** Pierre F, et al. Short-chain fructo-oligosaccharides reduced the occurrence of colon tumors and develop gut associated lymphoid tissue in Min mice. *Cancer Res* 1997;57:225-8. **749** Gibson GR. Dietary modulation of the human gut microflora using prebiotics. *Br J Nutr* 1998;80:S209-12. **750** Bouhnik Y, et al. Short-chain fructo-oligosaccharide administration dose-dependently increases fecal bifidobacteria in healthy humans. *J Nutr* 1999;129:113-6. **8505** Chen HL, Lu YH, Lin JJ, Ko LY. Effects of fructooligosaccharide on bowel function and indicators of nutritional status in constipated elderly men. *Nutr Res* 2000;20:1725-33. **8506** Pierre F, Perrin P, Bassonga E, et al. T cell status influences colon tumor occurrence in min mice fed short chain fructo-oligosaccharides as a diet supplement. *Carcinogenesis* 1999;20:1953-6. **8507** Menne E, Guggenbuhl N, Roberfroid M. Fn-type chicory inulin hydrolysate has a prebiotic effect in humans. *J Nutr* 2000;130:1197-9. **8508** Bouhnik Y, Ouarne FF, Riottot M et al. Effects of prolonged ingestion of fructo-oligosaccharides (FOS) on colonic bifidobacteria, fecal enzymes and bile acids in humans. *Gastroenterol* 1994;106:A598. **8509** Cummings JH, Macfarlane GT, Englyst HN. Prebiotic digestion and fermentation. *Am J Clin Nutr*. 2001;73(2 Suppl):415S-420S. **8563** Losada MA, Olleros T. Towards a healthier diet for the colon: the influence of fructooligosaccharides and lactobacilli on intestinal health. *Nutr Res* 2002;22:71-84. **8609** Circosta C, Occhiuto F, Ragusa S, et al. A drug used in traditional medicine: Harpagophyllum procumbens DC. II. Cardiovascular activity. *J Ethnopharmacol* 1984;11:259-74.

Supplement: Glutamine**Description**

Glutamine is the most abundant amino acid in the body – comprising approximately half of the free amino acids in the blood and muscle. As a non-essential amino acid, glutamine can be produced in the body by conversion from another amino acid - glutamic acid (primarily by the skeletal muscle and liver). Glutamine's main functions in the body include serving as a precursor in the synthesis of other amino acids and glucose for energy. Cells of the immune system, the small intestine and the kidney are the major consumers of glutamine.

Claims

- Boosts immune system function
- Maintains muscle mass
- Prevents muscle catabolism (breakdown)
- Enhances glycogen storage
- Aids recovery from exercise

Theory

Intense exercise training results in a well-described drop in plasma glutamine levels. Chronically low glutamine levels have been implicated as a possible contributing factor in athletic overtraining syndrome as well as the transient immunosuppression and increased risk of infections that typically affects competitive athletes during intense training and competition. Under conditions of metabolic stress, the body's need for glutamine may exceed its ability to produce adequate levels – meaning that a dietary source is required to prevent catabolism of skeletal muscle – the primary source of stored glutamine in the body.

Scientific Support

A significant body of scientific literature exists to support the beneficial effects of glutamine supplementation in maintaining muscle mass and immune system function in critically ill patients and in those recovering from extensive burns and major surgery. When plasma glutamine levels fall, skeletal muscles may enter a state of catabolism in which muscle protein is degraded to provide free glutamine for the rest of the body. Since skeletal muscle is the major source of glutamine (other than the diet), prolonged deficits in plasma glutamine can lead to a significant

loss of skeletal muscle protein and muscle mass

In recent years, at least a half-dozen studies have been conducted on glutamine supplementation in athletes and a strong basis exists for the efficacy of glutamine supplements in athletic populations. For example, glutamine's role in immune system support has been shown to prevent infections following intense bouts of physical activity – which tend to reduce plasma glutamine levels. Glutamine supplements have also been shown to play a role in counteracting the catabolic (muscle-wasting) effects of stress hormones such as cortisol, which are typically elevated by strenuous exercise. The function of glutamine in stimulating glycogen synthase, the enzyme which controls the synthesis and storage of glycogen fuel storage in muscles and liver, may provide a mechanism by which glutamine supplements promote enhanced fuel stores. Glutamine supplements cause a rapid rise in cellular glutamine levels and glutamine stores in muscle. Glutamine is also thought to increase cell volume, where it may stimulate the activity of enzymes in the liver and muscles involved in glycogen storage as well as those involved in anabolic activities such as protein synthesis. Glutamine supplements have also been hypothesized to increase levels of growth hormone, which may be expected to help stimulate protein synthesis and encourage gains in muscle mass and strength, but reliable evidence for this effect of glutamine supplements has not been demonstrated by clinical studies.

Safety

Glutamine supplements are well tolerated at levels up to at least 20 grams per day and intakes of as much as 40 grams per day should induce no significant adverse effects outside of mild gastrointestinal discomfort. As with any isolated amino acid supplement, consumption in divided 2-4 divided doses throughout the day should increase total body stores without posing significant absorption issues.

Value

Glutamine supplements are relatively inexpensive compared to other amino acid supplements. For anybody exposed to heightened levels of stress, such as those recovering from injury, surgery, or intense exercise, glutamine supplements represent an economical way to promote tissue repair, reduce muscle catabolism and help prevent infections.

Dosage

For the immune system support and anti-catabolic actions that are of interest to most athletes, recommended doses range from 1-10 grams.

References 1. Alvestrand A, Bergstrom J, Furst P, Germanis G, Widstam U. Effect of essential amino acid supplementation on muscle and plasma free amino acids in chronic uremia. *Kidney Int.* 1978 Oct;14(4):323-9. 2. Aoki TT, Brennan MF, Fitzpatrick GF, Knight DC. Leucine meal increases glutamine and total nitrogen release from forearm muscle. *J Clin Invest.* 1981 Dec;68(6):1522-8. 3. Aoki TT. Metabolic adaptations to starvation, semistarvation, and carbohydrate restriction. *Prog Clin Biol Res.* 1981;67:161-77. 4. Bonau RA, Jeevanandam M, Moldawer L, Blackburn GL, Daly JM. Muscle amino acid flux in patients receiving branched-chain amino acid solutions after surgery. *Surgery.* 1987 Apr;101(4):400-7. 5. Calder PC, Yaqoob P. Glutamine and the immune system. *Amino Acids.* 1999;17(3):227-41. 6. Carli F, Webster J, Ramachandra V, Pearson M, Read M, Ford GC, McArthur S, Preedy VR, Halliday D. Aspects of protein metabolism after elective surgery in patients receiving constant nutritional support. *Clin Sci (Colch).* 1990 Jun;78(6):621-8. 7. Castell LM, Newsholme EA. The effects of oral glutamine supplementation on athletes after prolonged, exhaustive exercise. *Nutrition.* 1997 Jul-Aug;13(7-8):738-42. 8. Elia M, Folmer P, Schiattmann A, Goren A, Austin S. Amino acid metabolism in muscle and in the whole body of man before and after ingestion of a single mixed meal. *Am J Clin Nutr.* 1989 Jun;49(6):1203-10. 9. Giesecke K, Magnusson I, Ahlberg M, Hagenfeldt L, Wahren J. Protein and amino acid metabolism during early starvation as reflected by excretion of urea and methylhistidines. *Metabolism.* 1989 Dec;38(12):1196-200. 10. Gleeson M, Bishop NC. Elite athlete immunology: importance of nutrition. *Int J Sports Med.* 2000 May;21 Suppl 1:S44-50. 11. Greenhaff PL, Gleeson M, Maughan RJ. The effects of diet on muscle pH and metabolism during high intensity exercise. *Eur J Appl Physiol Occup Physiol.* 1988;57(5):531-9. 12. Haymond MW, Strobel KE, DeVivo DC. Muscle wasting and carbohydrate homeostasis in Duchenne muscular dystrophy. *Neurology.* 1978 Dec;28(12):1224-31. 13. Lundeborg S, Belfrage M, Wernerman J, von der Decken A, Thunell S, Vinnars E. Growth hormone improves muscle protein metabolism and whole body nitrogen economy in man during a hypoproteinogenic diet. *Metabolism.* 1991 Mar;40(3):315-22. 14. McKenzie DC. Markers of excessive exercise. *Can J Appl Physiol.* 1999 Feb;24(1):66-73. 15. Newsholme EA, Calder PC. The proposed role of glutamine in some cells of the immune system and speculative consequences for the whole animal. *Nutrition.* 1997 Jul-Aug;13(7-8):728-30. 16. Nieman DC. Exercise immunology: future directions for research related to athletes, nutrition, and the elderly. *Int J Sports Med.* 2000 May;21 Suppl 1:S61-8. 17. Ruderman NB, Berger M. The formation of glutamine and alanine in skeletal muscle. *J Biol Chem.* 1974 Sep 10;249(17):5500-6. 18. Ruderman NB. Muscle amino acid metabolism and gluconeogenesis. *Annu Rev Med.* 1975;26:245-58. 19. Russell DM, Walker

PM, Leiter LA, Sima AA, Tanner WK, Mickle DA, Whitwell J, Marliss EB, Jeejeebhoy KN. Metabolic and structural changes in skeletal muscle during hypocaloric dieting. *Am J Clin Nutr.* 1984 Apr;39(4):503-13. 20. Schedl HP, Maughan RJ, Gisolfi CV. Intestinal absorption during rest and exercise: implications for formulating an oral rehydration solution (ORS) Proceedings of a roundtable discussion April 21-22, 1993. *Med Sci Sports Exerc.* 1994 Mar;26(3):267-80. 21. Shephard RJ, Shek PN. Heavy exercise, nutrition and immune function: is there a connection? *Int J Sports Med.* 1995 Nov;16(8):491-7. 22. Shephard RJ, Shek PN. Immunological hazards from nutritional imbalance in athletes. *Exerc Immunol Rev.* 1998;4:22-48. 23. Smith DJ, Norris SR. Changes in glutamine and glutamate concentrations for tracking training tolerance. *Med Sci Sports Exerc.* 2000 Mar;32(3):684-9. 24. Walsh NP, Blannin AK, Robson PJ, Gleeson M. Glutamine, exercise and immune function. Links and possible mechanisms. *Sports Med.* 1998 Sep;26(3):177-91. 25. Young LS, Bye R, Scheltinga M, Ziegler TR, Jacobs DO, Wilmore DW. Patients receiving glutamine-supplemented intravenous feedings report an improvement in mood. *JPEN J Parenter Enteral Nutr.* 1993 Sep-Oct;17(5):422-7. 26. Zanker CL, Swaine IL, Castell LM, Newsholme EA. Responses of plasma glutamine, free tryptophan and branched-chain amino acids to prolonged exercise after a regime designed to reduce muscle glycogen. *Eur J Appl Physiol Occup Physiol.* 1997;75(6):543-8.

Supplement: Lecithin

Description

Choline is an essential nutrient, a B-vitamin. It can be manufactured in the body (from the amino acid methionine), although there is some debate whether it can be made in sufficient amounts for optimal health. Folic acid and vitamin B12 are also needed to process choline. Choline plays a role in brain development (as an amine precursor for the neurotransmitter acetylcholine), liver function and cardiovascular health. The recommended amount of choline is 425mg/day for women and 550mg/day for men. Food sources of choline include egg yolks (the major dietary source), organ meats and legumes. Choline is available in supplemental form as lecithin (or phosphatidylcholine) as well as purified choline capsules and as an ingredient in sports bars and drinks.

Claims

- Memory aid
- Brain development
- Cardiovascular protection
- Cancer prevention
- Promotes energy
- Delay fatigue

Theory

Choline is an important constituent of cell membranes, so choline has functions in virtually every bodily system. Choline participates in lipid (fat) transport in the body and may reduce accumulation of fat in the liver. As a dietary supplement and ergogenic aid, however, claims surrounding choline are due mostly to its role as a component of acetylcholine, the neurotransmitter needed for conduction of nerve signals and brain function. Claims in this area typically involve mental performance, memory and reaction time.

Scientific Support

During pregnancy, choline intake of the mother may influence memory and brain development in the growing infant. Studies on choline and lecithin supplementation clearly show an increase in blood choline levels following supplementation with 1 – 5 grams of choline (or 5-15 grams of lecithin). Choline supplements have also been shown to improve marathon performance and endurance cycling ability (time to exhaustion), but they have failed to demonstrate a beneficial effect on shorter duration high-intensity exercise such as sprinting.

Safety

No adverse effects of choline supplements are noted at levels of 1-2 grams, whereas doses closer to 5 grams may be associated with side effects such as diarrhea, nausea, and abdominal discomfort.

Dosage

The "average" diet supplies about 400 – 900mg of choline daily, which is presumed to be adequate. Choline was designated as an essential nutrient by the Food and Nutrition Board of the National Academy of Sciences in April of 1998. The recommended amount of choline is 425 mg/day for women and 550 mg/day for men. Supplemental levels of 1-5 grams of choline may help improve exercise performance and promote adequate mental function.

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Supplement: Garcinia (Hydroxycitrate acid)

Description

Hydroxycitric acid (HCA), is the active ingredient extracted from the rind of a little pumpkin-like fruit, *Garcinia cambogia*, from India and Southeast Asia. Dietary supplements and a wide variety of weight loss formulas, contain *Garcinia* extract to inhibit fat production and suppress appetite. A number of products include extracts (about 50% HCA) under the brand names Citrin (Sabinsa) and CitriMax (InterHealth) and a new one called Regulator is a 98% pure potassium HCA from a small Irish supplement company.

Claims

- Promotes weight loss
- Suppresses appetite
- Reduces blood lipids
- Increases fat oxidation/mobilization
- Promotes glycogen synthesis
- Increases energy levels

Theory

HCA can inhibit an enzyme in cells, citrate lyase, which is needed for the conversion of carbohydrates into fat. In the cell, carbohydrates are broken down into citrate compounds, which are then converted (by citrate lyase) into another compound; acetyl coenzyme A (acetyl CoA)—the metabolic building block for fat synthesis. By blocking the conversion of citrate into acetyl CoA, HCA can suppress fat synthesis. Acetyl CoA is further converted into malonyl CoA, a compound which may block the actions of carnitine acyltransferase in shuttling fatty acids into the mitochondria to be burned.

It is important to note, however, that the citrate lyase enzyme, is only significantly active under conditions of carbohydrate overconsumption. In other words, unless you're eating a lot of

carbohydrate-type foods (bagels, pasta, potatoes), and overloading your carbohydrate storage capacity (muscle and liver glycogen stores) there is no significant conversion of carbohydrates into fatty acids anyway (and HCA may not work for you). If, however, you're chowing down on low-fat high-carb foods at every meal, then your glycogen stores will be over-flowing and your citrate lyase enzymes are going to be working over time converting those excess carbs to fat.

OK, so now that you've blocked the fat production, you have to do something with those excess carbs. They can't be stored as glycogen because those stores in liver and muscle are already full, so it is thought that the body disposes of them by increasing carbohydrate oxidation (burning them). As a result of these fully loaded glycogen stores, some researchers have suggested that a "side effect" of HCA supplementation may be a suppression of appetite – which would reduce food intake and promote weight loss.

Scientific Support

Animal studies have shown that hydroxycitrate decreases weight gain – primarily by suppressing appetite and reducing food intake. At least one rat study has also shown a loss of body weight and reduced fat mass due to an 11% increase in daily energy expenditure. HCA appears to be effective in both lean and obese rats, where it can reduce food intake, body weight, body fat accumulation, fat cell size, and serum triglycerides.

Studies of HCA supplementation in humans have been equivocal. In some studies, 1000-2400mg of HCA per day led to a doubling or tripling of weight loss compared to placebo groups. Just last year, however, the Journal of the American Medical Association (JAMA) published a study showing no effect of *Garcinia cambogia* on weight loss in overweight men and women. In the study, a commercially available product and weight loss plan was used (Thermogenic Ultra Lean – Herbal weight loss plan with *Garcinia cambogia* – from Great American Nutrition, Salt Lake City, Utah). A total dose of 1500mg of HCA per day for 12 weeks did not augment weight loss compared to the placebo group.

The JAMA study has been criticized by pro-HCA camps on a number of criteria including the restrictive nature of the diet (low energy – 1210 kcal per day), the high fiber content (which decreases absorption of HCA) and the failure to assess HCA absorption (to see if it actually got into the cells where it becomes active). In defense of the study, however, is the authors' assertion that they wanted to test the compound under conditions in which people might normally try to lose weight (like a low calorie diet) – not exactly a bad idea. They also noted that the possibility for HCA to be effective in blocking fat synthesis may be more evident when people "fall-off" their diets or relapse and start consuming lots of high carbohydrate foods.

Safety

There are no serious adverse side effects associated with intake of *Garcinia cambogia* or hydroxycitric acid supplements aside from some minor gastrointestinal distress induced by high doses.

Value

For weight loss, regular intake of *Garcinia cambogia* and HCA is supported by animal studies (and high carbohydrate diets), where it reduces food intake and body fat accumulation. Some data from human trials support the effectiveness of HCA for weight control in humans.

Given the apparent safety profile of *Garcinia*/HCA supplements and the clear difficulty associated with maintaining a reduced body weight following weight loss, HCA may be most effective as an aid to preventing weight re-gain – rather than as an approach to stimulating significant fat loss (which is best achieved by lifestyle modifications in diet, behavior and exercise patterns). Those individuals who have succeeded in losing body weight and fat mass (not an easy task) may be better able to adhere to their new diet and maintain their new lower body weight more effectively with the help of HCA dietary supplements.

Dosage

Typical doses associated with suppression of appetite and reductions in body weight are 750-1500 mg of *Garcinia cambogia*, (standardized for at least 50% HCA) taken in 2-3 divided doses about 30-60 minutes before eating.

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Usefulness of Highly Purified Extract of *Proteinophallus Rivieri* Fibers in Childhood Obesity

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Tab 40

Index words: obesity, *Proteinophallus rivieri*, cholesterol

Abstract

To evaluate the effectiveness of highly purified extract of *Proteinophallus Rivieri* fibers in childhood obesity, a study has been carried out in 23 obese children (12 boys and 11 girls, aged 5.2 – 15.8 years), with excess weight of $51 \pm 16\%$, treated with 2-3 caps twice a day of the *P. rivieri** extract (Pediatropin***: 2-3 g/day), and in 30 obese children (aged 5 – 18 years) with excess weight of $51 \pm 10\%$, studied as controls. After a three-days food recall, a balanced diet with adequate caloric intake was provided to all obese children. In all patients before and 2-4 months after the auxological data (weight, height, weight excess) and laboratory data (serum levels of cholesterol, HDL, triglycerides, glucose, fructosamine, glycosylated hemoglobin, RBC, WBC, hemoglobin, iron, calcium, Cu and Zn) have been determined. Excess weight and triglycerides levels were significantly decreased in treated obese patients than in obese controls 4 months after the beginning of the study. A decrease of cholesterol levels was observed in treated obese patients, but not in controls, whereas serum iron, calcium, copper and zinc persisted unchanged. No important side effects were observed in treated patients. On the basis of our results highly purified *P. rivieri* fibers may be employed with effectiveness in obese and dislipidemic children together with diet.

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*** Pediatropin™ is the trademark of Klein-Becker usa for DICOMAN 5: a highly purified high molecular weight fibrous extract of *P. rivieri*

Introduction

Child obesity is in continual increase in countries with a high standard of living and constitutes a reason for pediatric consultation ever more frequently.

The frequency of obesity reaches approximately 14%¹ in European school populations and in the United States 25% or more, above all among adolescents^{2, 3, 1, 5}.

Obesity has a complex exopathogenesis characterized by the interaction of genetic⁷, psychosocial and metabolic^{8, 9} factors which cause important endocrine alterations¹⁰.

Recent studies have showed a relation between some forms of obesity, accompanied by bulimia and hyperphagia, and the production of endogenous opiates, specifically of β -endorphin and β -lipotropine, which show higher levels than controls¹¹.

The psychological aspects of obesity have been amply studied and described by Hilde Bruch¹². Even in a group of our own obese adolescents we have been able to show a high incidence of disturbance in body image characterized by the sensation that one's own body is grotesque and repugnant and for this reason merits the hostility and contempt of the outside world^{5, 9}.

In children, the majority of clinical cases concern simple obesity due to overeating or bad diet, as seen from a careful dietary recall, almost always associated with reduced physical activity^{1, 2, 3}.

Bad dietary habits acquired in infancy can not only provoke the onset of overweight, but can also play a significant role in the onset of pathological conditions in adulthood, such as cardiovascular illnesses,

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gastrointestinal disorders, diabetes mellitus and maybe some neoplasias^{2, 5, 8, 13}. Independently of the origin of obesity, above all in the face of the relevant weight excesses it is the duty of the pediatrician to appropriately correct diet.

One should also try to change dietary habits at the level of all the components of the family, advising the reduction of caloric intake, consumption of fats above all animal fats, of simple sugars and increasing the intake of fruit, vegetables and foods rich in starches and fiber, following the guidelines suggested by the National Institute of Nutrition¹⁴.

In addition to an incorrect diet and an elevated caloric intake in the recall of obese children, persistent constipation and excessive cholesterol levels are often seen; on the basis of these recalled data and experiments conducted in adults on the use of fiber supplements in the diet,^{13, 16} we administered vegetable fibers composed of highly purified *P. rivieri*, along with adequate dietetic treatment, to 37 obese subjects.

Patients and Methods

To evaluate the efficacy of the *P. rivieri* based fiber 37 subjects, 18 males and 19 females, between approximately 5 and 18 years old, with average excess weight of $52 \pm 14\%$ (range 30-81) were examined at random. All the patients were affected by simple obesity and did not take any drugs.

Before initiating the *P. rivieri* treatment all the patients underwent clinical and laboratory evaluations. Auxometry was carried out via Holtain's stadiometer with reference to Tanner's tables and with evaluation of the pubertal stages according to Tanner¹⁵. Excess weight was evaluated by considering the difference between actual weight and the ideal weight for the stature, divided by the ideal weight X 100 (AW-IW/IW%)

The measurement of arterial pressure was taken according to standard methods⁸. A blood sample was taken in the morning before eating between 9 and 10 to determine the serum levels of hemochrome, nitrogen, glucose, creatinine, bilirubin, electrolytes, calcium, protein, iron, transferin, glycosilated haemoglobin, fructosamine, triglycerides, total and HDL cholesterol, electrophoresis of lipoproteins, trace elements such as zinc and copper (Zn and Cu).

Before consigning the patient to the diet, the recording of the dietary intake was requested by means of a pre-prepared form to be filled in for three non-consecutive days including one weekend day. The diet suggested by us was normocaloric for the age and size of the subject and anticipated the percentages of nutrients suggested in the physiological diet of the child: about 15% protein, 30% lipids, and 55% sugars. All patients were advised to take regular physical exercise⁵.

The fiber was given to the patients in capsules of 500mg of highly purified, concentrated *P. rivieri* of high molecular weight and consequently high viscosity (mw approximately 1,600,000 and viscosity 62000 cps) and without any excipient.

The *P. rivieri* based compound was prescribed in the following doses: 2 capsules twice a day (equal to 2 g/day) to patients younger than ten years old, and 3 capsules twice a day (equal to 3g/day) to patients over ten years old, taken with approximately 150-200 ml of water or other liquids from half an hour to an hour before lunch and dinner.

A control group of 39 obese children and adolescents, 19 males and 20 females, between the ages of 5 years and 5 months and 18 years (average 11.8 years), with average excess weight of $50.3 \pm 11.5\%$ (range 35-75) for whom only diet and physical exercise were advised, underwent the same studies.

Patients and controls were re-evaluated to check the drop in weight and blood chemical parameters: all after two months, 50% after 4-6 months and 10% after 12 months.

The Student t-test for paired and unpaired data was used for statistical evaluation of the data.

Results

Of the 37 subjects (18 males and 19 females) who were prescribed the fiber based product (TO), 9 (24%) did not present themselves for examination and 5 (14%) stopped taking the fiber capsules because they complained of abdominal discomfort or because they had not noticed any reduction in appetite. The study was therefore effectively carried out on 23 patients (12 males and 11 females) of average age 10 years and 2 months (range 5.2-15.8), with average excess weight of $51 \pm 16\%$ (30-81) (males EW $55.2 \pm 15.8\%$, females EW $46.5 \pm 16.5\%$). Of the 39 obese subjects chosen as a control (CO), 9 (23%) did not present themselves at the next examinations; therefore 30 control subjects were effectively followed for comparison with obese patients undergoing treatment (TO).

The 3-day dietary recall showed both overeating and bad diet across the two groups of obese subjects.

Excess weight (EW)

At the beginning of the study no significant difference was present between the EW of the obese patients to be treated with the fiber (TO) and that of the obese patients chosen as a control (CO)(TO 51±16% vs. CO 51±10.6%, p ns). After two months from the beginning of the treatment, the 23 patients (11 females and 12 males) who had regularly taken the *P. rivieri* based capsules showed a weight drop from 51±16%(30-81) to 41.3±15% (20-80) (p<0.0005). Specifically the obese girls went from an EW of 46.5±15.6% (32-81) to that of 38.7±15.8% (20-80) (p<0.0005) and the boys from 55.2±15.8% (30-77) to 43.8±14.7% (25-68) (p<0.005). After 4-6 months the EW of the TO patients successively significantly decreased with respect to initial EW (p<0.005) (table 1).

In the CO patients, after 2 months of treatment the EW decreased but not significantly (51±10.6% vs 49.3±12.4, p n.s.) and it remained constant even after 4-6 month (51±10.6 vs 49.2±13.3, p n.s.); consequently both after 2 and 4-6 months, the EW of the TO patients was significantly lower than that of the CO patients (TO 41.3±15% vs CO 49.3±12.4%, p<0.005; TO 40.1±14.9 vs CO 49.2±13.3, p<0.005) (table 1).

Table 1
 EXCESS WEIGHT (EW), SERUM CHOLESTEROL AND TRIGLYCERIDES VALUES (MEAN ± SD) IN OBESE PATIENTS BEFORE, AFTER 2 AND 4 MONTHS AFTER TREATMENT WITH DIET AND *P. RIVIERI* (TO) AND IN OBESE PATIENTS WITH ONLY DIETETIC TREATMENT (CO)

	Before Treatment	After 2 months	After 4 months
EW% (TO)	51±16	41.3±15	40.1±14.9
	-----<0.0005-----		
	-----<0.005-----		
EW% (CO)	51±10.6	49.3±12.4	49.2±13.3
	-----ns-----		
	-----ns-----		
Cholesterol mg% (TO)	187.1±26	177.6±27	173.1±20
	-----<0.005-----		
	-----<0.005-----		
Cholesterol mg% (CO)	184±38	185.5±33	180.6±32
	-----ns-----		
	-----ns-----		
Triglycerides mg% (TO)	81.9±40	69.3±2	69.5±2
	-----ns-----		
	-----ns-----		
Triglycerides mg% (CO)	83.3±34	93.7±46.9	103.7±62
	-----ns-----		
	-----ns-----		

Blood Chemical Parameters

At the beginning of the study (before treatment) the cholesterol of the TO patients was comparable with that of the CO patients (TO cholesterol $187.11 \pm 26 \text{ mg\%}$ vs $184 \pm 38 \text{ mg\%}$, p n.s.). After 2 months and 4-6 months of treatment, the 23 TO patients had significantly lower total cholesterol levels to those found before treatment (TO cholesterol before treatment, at 2 and at 4-6 months: $187.1 \pm 26 \text{ mg\%}$ vs $177.6 \pm 27 \text{ mg\%}$ vs $173.1 \pm 20 \text{ mg\%}$, $p < 0.005$) (table 1), and the decrease was much more noticeable in female patients (F) than in the males (M).

In the CO group of patients, on the other hand, the total cholesterol remained unvaried or it decreased, but not significantly, with respect to the initial measurement (CO cholesterol before treatment, at 2 and 4 months, $184 \pm 38 \text{ mg\%}$ vs 185.5 ± 33 vs 180.6 ± 32 , p n.s.) (table 1).

Comparison between the TO and CO patients revealed a significant difference between the treated patients and those of the control after 4-6 months of treatment. (TO cholesterol F 162.7 ± 18.3 vs CO F 188 ± 32.7 , $p < 0.05$).

The HDL cholesterol increased in 15 out of 23 TO subjects (65%), decreased in 3 and remained the same in 5; in the group of CO patients the HDL cholesterol increased in 3 (13%), decreased in 4 and remained the same in 16 subjects.

The serum levels of triglycerides in the TO patients were comparable with those of the CO patients at the beginning of the study, but were significantly lower at the second and third measurements (TO triglycerides $81.9 \pm 40 \text{ mg\%}$ vs CO 83.36 ± 34 , p n.s.; TO 69.3 ± 2 vs CO 93.76 ± 46.9 $p < 0.025$; TO 69.5 ± 2 vs CO 103.7 ± 62 , $p < 0.05$) (table 1). The glycosylated haemoglobin, elevated in 7 patients at the beginning of the study, was normalized in 6 patients at the end of the study ($9.55 \pm 2\%$ vs $7.91 \pm 0.6\%$, p n.s., normal range (v.n.) for the laboratory 5.5-8.5%)

Table 2

SERUM IRON, ZINC AND COPPER LEVELS BEFORE, 2 AND 4 MONTHS AFTER TREATMENT WITH *P. RUVIERI*

		Before Treatment	After 2 months	After 4 months
Iron gamma%	M	79.66 ± 20.8	80.16 ± 13.8	86.08 ± 15.1
	F	78 ± 23	81 ± 19.2	91.45 ± 20.7
Zinc gamma%	M	108.7 ± 18	97.7 ± 17	100 ± 16
	F	110.2 ± 13	99.7 ± 11.7	106.7 ± 12.2
Copper gamma%	M	118.4 ± 17.1	117.3 ± 22	120 ± 20
	F	112.4 ± 13	109.7 ± 14	119 ± 19
Calcium mg%	M	9.9 ± 0.3	9.4 ± 0.4	10 ± 0.4
	F	9.8 ± 0.3	10 ± 0.3	9.7 ± 0.2

Serum Iron (normal range - v.n.) = 50 - 120 gamma%

Serum Zinc v.n. = 55 - 136 gamma%

Serum Copper v.n. = 55 - 120 gamma%

Serum Calcium v.n. = 9-10.8 mg%

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The serum levels of iron, calcium and of trace elements such as zinc (Zn) and copper (Cu), evaluated only in the TO patients, always remained within normal ranges (table 2). The other blood chemical parameters taken into consideration also did not show significant variation. In the TO patients who complained of constipation at the beginning of the study an improvement of bowel voidance was shown.

Conclusion and Discussion

It has been noted for years that a diet based on excessively refined foods, almost totally lacking in fiber, with reduced consumption of fruit and vegetables in favor of prepackaged products can be responsible for numerous pathologies^{19, 20, 21}. Obesity, the increase in cardiovascular illnesses and maybe even some intestinal tumors are attributable to changes in diet that have occurred between the post war period and now. It has lost the genuine characteristics of the Mediterranean diet and is ever more in conformity with that of the Anglo-Saxon countries or in any case with the highly industrialized countries.

The daily intake of fiber, which, according to Burkitt should be 30g, a day or approximately 10g per 1000 calories, rarely reaches those levels today^{19, 22}. In the recall of the obese child, who habitually acts like an obese adult, consumption of fresh vegetables and fruit is often lacking. To bad dietary habits chronic sedentarity is typically added aggravating the tendency to chronic constipation, symptoms often reported by mothers during the compilation of the clinical recall of the child. In addition obese patients have a preference for foods that are rich in animal fat, which often bring, even in childhood, grave alterations in lipid levels.

All of these considerations have induced us to evaluate the efficacy of *P. rivieri*, in the form of a capsule in a group of children affected by simple obesity.

This treatment was shown to work both by contribution to the decrease in excess weight, and in causing a significant decrease in the levels of total serum cholesterol in particular in females²⁰. Indeed, while on first observation in 60% (7/12 males) of the obese patients treated, cholesterol levels were less than 180 mg %, a limit considered normal by the Consensus Conference^{20, 23}, cholesterol levels were higher than 180mg% in 54%(6/11 females) of the obese patients that were treated, for the most part in puberty.

Even in relation to triglycerides, the females at the beginning of the study had base levels that were higher compared to the males, at the end of the study a significant decrease was shown that was not observed in the subjects of the control group.

The increase of HDL cholesterol took place in higher percentages in the obese patients treated with the *P. rivieri* compared to those treated only with diet.

The serum iron and trace element values did not undergo variation in the subjects who had taken the fiber-based product, even for a long period of time, indicating the absence of any malabsorption. Indeed it has been noted that excess or insufficient intake of fiber can cause malabsorption^{19, 21}.

According to our experience, the best treatment of childhood obesity was obtained in the subjects who, besides dietary treatment and physical exercise, took the *P. rivieri* based product, which, if accepted and tolerated can function to alter excess weight and dyslipidemia.

As regards compliance, some difficulty was observed in the children, with the exception of the cases where the product was administered as if it were a "drug". In the smallest children, when the mother can manage the diet of her own child, compliance can be optimized. As for undesired effects of the *P. rivieri*, some patients at the beginning of the treatment complained of feelings of bloatedness accompanied by abdominal discomfort with increased frequency of bowel voidance. Those effects were no longer evidenced after a short suspension in the administration of the product followed by gradual re-introduction of the capsule.

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A REPORTER AT LARGE

Tab 41 MIRACLE IN A BOTTLE

Dietary supplements are unregulated, some are unsafe—and Americans can't get enough of them.

BY MICHAEL SPECTER

One day last September, as Britney Spears was about to board a flight to Los Angeles from London, a rectangular blue bottle fell out of her purse. She quickly stuffed it back in, but not before the paparazzi recorded the event. Neither Spears nor her spokesman was willing to comment on the contents of the bottle, but the next morning London's *Daily Express* published a page of pictures under the headline "EXCLUSIVE: POP PRINCESS SPOTTED AT AIRPORT WITH POT OF SLIMMING TABLETS." Spears was apparently carrying Zantrex-3, one of the most popular weight-loss supplements currently sold in the United States. The pill, which retails at about fifty dollars for a month's supply, contains a huge dose of caffeine, some green tea, and three common South American herbs that also act as stimulants. It hit the U.S. market last March and has had a success that would be hard to overstate. Millions of bottles have been sold, and during the Christmas season it was displayed in the windows of the nation's largest chain of vitamin shops, G.N.C. (It is so highly sought after that many of the stores keep it in locked cabinets.) Zantrex-3 is also sold at CVS, Rite Aid, Wal-Mart, and other chains, and over the telephone and on the Internet. If you type "Zantrex" into Google, more than a hundred thousand citations will appear. At any moment, there are scores of people auctioning the stuff on eBay.

Perhaps the most interesting element of Zantrex-3's success story, however, is that it is far from unique. There are hundreds of similar products on the market today, and they are bought by millions of Americans. And though Zantrex's manufacturer makes some heady claims ("the most advanced weight control compound period"), so do the people who sell Stack 2 and Anorex (whose publicity assures us that the "genetic link" to obesity means that repeated diet failure is "not your fault"), along with those who sell Carb Eliminator and Fat Elimina-

tor. Almost all of these compounds suggest that they can help people lose weight and regain lost vigor, and often without diet, exercise, or any other effort.

The diet-pill business may be the most visible segment of the vitamin-, mineral-, and herbal-supplement industry, but it is by no means the largest. Thousands of different tablets, elixirs, potions, and pills are sold in the United States, and remarkably little is known about most of them. That doesn't deter consumers. Since 1994, when Congress passed a law that deregulated the supplement industry and opened it to a flood of new products, the use of largely unproved herbal remedies—from blueberry extract for impaired vision to saw palmetto for the treatment of enlarged prostates and echinacea to prevent colds—has increased as rapidly as the use of any commonly prescribed drug.

Since that legislation, the Dietary Supplement Health and Education Act, became law, companies have been able to say nearly anything they want about the potential health benefits of what they sell. As long as they don't blatantly lie or claim to have a cure for a specific disease, such as cancer, diabetes, or AIDS, they can assert—without providing evidence—that a product is designed to support a healthy heart (CardiAll, for example), protect cells from damage (Liverite), or improve the function of a compromised immune system (Resist). There are almost no standards that regulate how the pills are made, and they receive almost no scrutiny once they are, so consumers never truly know what they are getting. Companies are not required to prove that products are effective, or even safe, before they are put on the market.

Still, there is more to the growing reliance on supplements than the lapses of a single law: Americans long ago wearied of taking doctors' orders, and, increasingly, they are skeptical about the motives of big pharmaceutical compa-

nies. People want to feel in control of their own health. Supplements, with their "natural" connotations and cultivated image of self-reliance, let them do that. There is even a word to describe all the things—other than plain food—that people consume in the pursuit of health: nutraceutical.

Nutraceuticals are found everywhere today, in foods fortified with "extra" vitamins, in sports drinks, in "enriched" water, and now even in candy. Six out of ten adults in the United States take one or more supplements each day. Often, these include multivitamins, which are frequently recommended by physicians, but a staggering number of amino acids, weight-loss cures, and herbal tonics are also swallowed every day, all in the belief that they will improve health, fend off disease, or make up for dietary and behavioral habits that have placed obesity and indolence among the leading health problems facing the United States. Last year, Americans spent nineteen billion dollars on dietary supplements—nearly five times as much as they did just a decade ago. And they spent that money on everything from Vitamin C to garlic (the uses of which vary, with benefits that are never clear), from kava (which the F.D.A. says may cause severe liver damage but which is still widely available in health-food stores as a remedy for stress) to comfrey (an herb of dubious value commonly used to quell irritated stomachs), and even ephedra, which the federal government only recently decided to ban, despite reports over the last eight years implicating it in scores of deaths and hundreds of strokes, seizures, and other severe maladies.

"For many people, this whole thing is about much more than taking their vitamins," Loren D. Israelsen, the executive director of the Utah Natural Products Alliance, and a principal architect of the 1994 legislation, told me not long ago. "This is really a belief system, almost a



religion. Americans believe they have the right to address their health problems in the way that seems most useful to them. Often, that means supplements. When the public senses that the government is trying to limit its access to this kind of thing, it always reacts with remarkable anger—people are even willing to shoulder a rifle over it. They are ready to believe anything if it brings them a little hope.” Frequently, such products come veiled in a cloak of science. Ads for Zantrex-3, for example, claim that its “superior power is validated by a direct comparison of published medical studies . . . scientific fact . . . irrefutable clinical data.” The people who sell the pills on the telephone don’t rely on science at all, however, when they tell callers that the capsules in those blue bottles could change their lives.

“When I train salespeople, I say to them, ‘Do you know what people are calling you for? It isn’t the pill. They are calling you for hope. That is really what they want from you,’” Don Atkinson, who is the vice-president of sales for Basic Research, the privately held conglomerate that distributes Zantrex-3, told me recently. I spoke with him in his office in Salt Lake City, which regards itself as the Silicon Valley of the dietary-supplement industry. Atkinson, a hearty and engaging man with a graying buzz cut and a firm handshake, slowly wrote the word “hope” on a lined piece of paper soon after I came in. “The customer has been overweight for years. And they have tried everything. And they have been on Atkins and everything else and nothing has worked. And some of these people are so incapacitated by their weight and their problems associated with it that they would like to die. Just wish they could just die. And they dial up and they are unhappy people. And they think, O.K., if I take this and it doesn’t work it’s further evidence that I am a failure. Our job is to give them hope. To say, ‘You know what? You can do this.’” Atkinson stopped for a moment and pumped his right fist in the air. “I love my job,” he said. “And do you know why? Because when I get up in the morning I know that somebody’s life is better because we are here. Somebody today got some hope.”

Atkinson told me that he was delighted by the Britney Spears news, not

so much because of the publicity windfall but for the larger message it conveyed. “You know what is great about that? It’s the fact that she is using a weight-loss product and she looks terrific. Just the fact that we are even talking about what Britney Spears uses or doesn’t use to keep her weight down tells the whole wide world that it’s O.K. to be a little overweight and it’s O.K. to work on it. And it’s O.K. to use things to help you get there. That’s what it all says to me, and that is why we are here.”

Herbs have been ingested regularly, in every conceivable combination, for thousands of years, and many are clearly beneficial. Vitamins and minerals are essential for human health: calcium supplements have prevented perhaps millions of cases of osteoporosis; folic acid helps prevent neural-tube defects; insufficient amounts of Vitamin B₁₂ can lead to dementia. Simply eating citrus fruit, and the Vitamin C it contains, was enough to vanquish scurvy, which in the mid-eighteenth century killed more British sailors than the wars that Britain fought.

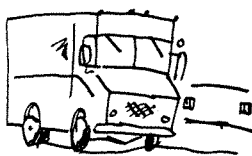
The way that nutrients work in foods has come to be properly understood only in the past hundred years. Because of the lack of specific knowledge, the preceding era had been one of open and unapologetic quackery. Throughout the eighteenth and nineteenth centuries, patent-medicine men roamed the United States. For every illness imaginable, they promised wondrous products and magical cures.

The rapid growth of patent medicines was largely a result of two unrelated events, and they eerily foreshadowed the 1994 Dietary Supplement Act and the rise of the Internet as a commercial tool. In 1793, Congress passed patent legislation that permitted manufacturers to protect their formulas (without requiring that they even work). Around the same time, the number of newspapers published in the United

States began to increase dramatically. By the beginning of the twentieth century, the patent-medicine business accounted for more newspaper advertising than any other kind of product. Many manufacturers became rich; some became famous. Lydia E. Pinkham’s Vegetable Compound, advertised as “A Positive Cure” for “all those Painful Complaints and Weaknesses so common to our best female population,” made Pinkham’s face as recognizable then as Martha Stewart’s is today.

In 1914, officials of the American Medical Association decided to analyze Pinkham’s compound. It turned out to be twenty per cent pure alcohol and eighty per cent common vegetable extracts. Most patent medicines had similar ingredients. Sometimes they were laced with cocaine, caffeine, opium, or even morphine. It’s not surprising that they provided a few hours’ worth of relief. There was no restriction on the vast armamentarium of remedies on the market until 1906, when the Pure Food and Drug Act was passed, mainly as a result of the revelations in Upton Sinclair’s book “The Jungle.” The act permitted the Bureau of Chemistry, which preceded the Food and Drug Administration, to insure that labels contained no false or misleading advertising. For a while, at least, snake-oil salesmen went the way of the Conestoga wagon.

Since then, the pendulum has swung between unregulated anarchy and restrictions that outrage many Americans. It has usually taken a disaster to persuade Congress to adopt strict regulations. Sulfanilamide, a drug prescribed to treat streptococcal infections, was used safely and effectively for years in tablet and powder form. Most children can’t swallow pills, though, and in June, 1937, researchers at one company found that the drug would dissolve in diethylene glycol; they tested the mixture for flavor, appearance, and fragrance—but not for toxicity—and then shipped it all over the country. They overlooked one important characteristic of the solution: diethylene glycol, normally used as an antifreeze, is a deadly poison. Within weeks, scores of children were dead. The victims experienced severe abdominal pain, nausea, vomiting, stupor, and convulsions. In a letter to President Franklin D. Roosevelt, one woman described the death of her



child: "Even the memory of her is mixed with sorrow for we can see her little body tossing to and fro and hear that little voice screaming with pain and it seems as though it would drive me insane." The next year, after a hundred and thirty-seven deaths, Congress passed the Food, Drug and Cosmetic Act, which finally gave the F.D.A. the authority it needed to regulate such products.

For many years afterward, there was little controversy about drugs or about dietary supplements, which mostly meant vitamins and minerals. "It didn't use to be so complicated," Annette Dickinson told me. She is the president of the Council for Responsible Nutrition, which is the most influential of the many groups that look after the interests of the supplement industry. Each year, supplement manufacturers contribute millions of dollars to political candidates. The industry has been remarkably successful in arguing that, because the First Amendment protects commercial speech, it can be used in defense of any claim that includes even a hint of truth. Dickinson is an aggressive supporter of supplements, yet she acknowledges that charlatans have proliferated wildly in the past decade, making her job, and that of most reputable manufacturers, much harder. In Dickinson's view, the industry would be better served if it returned its focus to the core nutrients—basic vitamin and mineral supplements. "In the beginning, you had your one-a-days, and there were minerals and herbal products, too. A drug was something intended to treat or cure a disease, and you needed to have proof that it could do those things; the line between foods and drugs was absolutely bright and clear. If you made a disease-related claim for something that was not approved, the F.D.A. would come down on you like a ton of bricks. All through the forties and the fifties and the sixties, that was true."

By the middle of the nineteen-seventies, as the complex relationship between diet and health became more fully understood, the distinctions between foods, drugs, and supplements began to blur. First, with a major report issued in 1977 by the Senate Select Committee on Nutrition and Human Needs, and then with studies by the National Academy of Sciences and other research groups, the government started

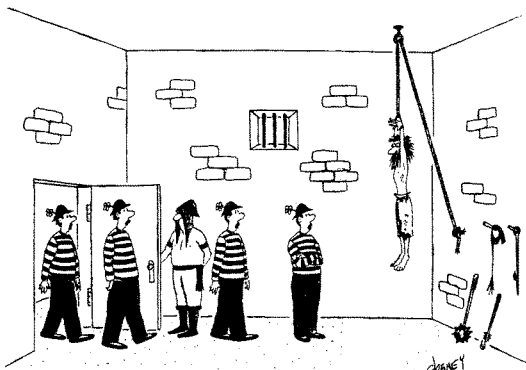


"It saddens me to think that so many of my customers are going to Hell."

telling Americans to alter their diets if they wanted to have long and healthy lives. Advice about ways to reduce the risk of heart disease, diabetes, and many cancers and other chronic illnesses became routine: eat less salt and fat and add fibre and whole grains; eat more fruits and vegetables and watch the calories. Food companies were eager to promote many of their products as medically beneficial. It was illegal, however, to suggest that there was a relationship between the ingredients in a commercial food and the treatment or prevention of a disease. Then, in 1984, the Kellogg Company launched a campaign, in conjunction with the National Cancer Institute, in which All-Bran cereal was used to illustrate how a low-fat, high-fibre diet might reduce the risk for certain types of cancer. These days, it is almost

impossible to pass by a supermarket shelf and not encounter such claims; but All-Bran was the first case in which a manufacturer issued a statement that was interpreted widely as "Eat this product because it will help prevent cancer." It led to the era of product labels, and completely changed the way Americans think about not only foods but dietary supplements as well.

Since then, the English language has been stretched to its limits in the attempt to link products to health benefits. Even claims that are true may be irrelevant. Vitamin A, for example, is important for good vision—as supplements for sale in any health-food store will tell you. Insufficient consumption of Vitamin A causes hundreds of thousands of cases of blindness around the world each year, but not in the United States; here people



don't have vision problems arising from a lack of Vitamin A. Although statements advertising Vitamin A for good vision may, like many others, be legally permissible, they are meaningless. "The laws allow manufacturers to make fine legalistic claims," Paul M. Coates, the director of the Office of Dietary Supplements at the National Institutes of Health, told me. "What we now have is an entire cottage industry of creative linguistics dedicated solely to selling these products." Instead of mentioning a disease (which in most cases would be illegal without F.D.A. approval), companies make claims that a food can affect the structure or function of the body. Such claims can appear on any food, no matter how unhealthy it is. You cannot assert that a product "reduces" cholesterol, but you can certainly say that it "maintains healthy cholesterol levels." You cannot state that the herb echinacea cures anything, since it has never been shown to do that. But there is no prohibition on stating that it "has natural antibiotic actions" and is considered "an excellent herb for infections of all kinds." Ginkgo biloba has been recommended to Alzheimer's patients because it "supports memory function." Does it? Since research is not required before a supplement is released, there are not nearly enough data to know.

In a report published in the *Journal of the American Medical Association*, sci-

entists compared the effects of echinacea with a placebo in treating colds. Echinacea is one of the most commonly used cold remedies in the United States. But the study, of more than four hundred children over a four-month period, showed that a placebo worked just as well, and that children treated with echinacea were more likely to develop a rash than those who took nothing. Studies like that are rare, since they cost money that manufacturers are not required to spend. But they are at least as likely to disprove benefits as to confirm them. Ginseng has long been promoted as an energy booster, for example, yet the military, in studies of possible energy enhancements for troops, has found it worthless. Still, in my local health-food store not long ago I saw more than a dozen supplements advertising the "fact" that ginseng improves energy.

"It was all done for crass commercial reasons," Marion Nestle told me. Nestle, the former chairman of the Department of Nutrition, Food Studies, and Public Health at New York University, is the author of "Food Politics," which examines in detail the ways in which the food and supplement industries influence the nutritional policy of the United States and the health of its citizens. "In the name of health! The companies have masked it in an argument for freedom of speech. And look at some of the ways it all plays out. Obesity is an epidemic in

our country. Is this helping? Not a bit." She went on, "I was staying in California this summer at the house of some friends. They had all sorts of health-food products for kids, and, to my surprise, among them were shark-shaped fruit snacks with Vitamin C and gummy bears with echinacea. It's *candy* masquerading as something that will improve a child's health. It comes in one-ounce packages. Just the right size to throw in a lunch pail. It's brilliant marketing. Just brilliant."

One recent Harris poll found that most people believe that if a supplement is on the market it must have been approved by some government agency (not true); that manufacturers are prohibited from making claims for their products unless they have provided data to back those claims up (no such laws exist); and that companies are required to include warnings about potential risks and side effects (they aren't). "When something goes wrong, though, most people expect government health officials to find a solution," David A. Kessler told me. Kessler, who is the dean of the School of Medicine at the University of California at San Francisco, was the F.D.A. commissioner when Congress passed the Dietary Supplement Act, which he adamantly opposed. "This is really the classic American ambivalence, and it has always been part of our nature," he said. "The view of most people is simple: I want access to everything and I want it now." The Federal Trade Commission—not the F.D.A.—regulates supplement advertising. But the F.T.C. is principally concerned with commerce, not science: it focusses on the content of the labels, not the content of the pills. Although since 1994 the agency has sued more than a hundred diet-pill companies, in 2002 it found that at least half of all weight-loss ads contained false or misleading statements. Despite its vigilance, the agency has an impossible job; for each success, ten new companies seem to appear.

When people get sick, Dr. Kessler pointed out, the refrain is always "Where the hell is the F.D.A. to protect me?" The supplement industry doesn't have to report adverse events, so the F.D.A. doesn't have the data it needs to protect people. You cannot prove something is unsafe if you don't have the data. It's the ultimate Catch-22. It is also a

colossal failure to protect the public health of this country."

Until a year ago, when Steve Belcher, a twenty-three-year-old pitcher for the Baltimore Orioles, died of heatstroke after taking an over-the-counter product that contained ephedra, it was by far the most popular supplement in the United States, bringing in a billion dollars a year and accounting for more than ten per cent of the supplement industry's annual sales. Ephedrine, the herb's active ingredient, boosts adrenaline, stresses the heart, raises blood pressure, and increases the rate of a person's metabolism. Derived from the Asian herb ma huang, it seems to help with short-term weight loss and with increasing physical stamina. When used in combination with caffeine, as it often is, ephedra is associated with an increased risk of heart attack, stroke tachycardias, palpitations, anxiety, psychosis, and death. Even though it was cited as a contributing factor in Belcher's death, only three states—New York, California, and Illinois—subsequently banned supplements containing ephedra. After numerous studies and nearly a year of review, the F.D.A. announced, on December 30th, that it would prohibit the sale of such supplements. Yet, because ephedra is not a drug, it will be several months before the ruling works its way through the federal bureaucracy. (The agency has recognized for years that ephedra can be dangerous; its use in over-the-counter medicine has been regulated since 1983.)

Despite the risks, the appeal of diet pills is not hard to understand. Each year, obesity kills millions of Americans and costs billions of dollars. Data from the National Health and Nutrition Examination Survey show that almost sixty-five per cent of the adult population is overweight. The prevalence of obesity among children is spreading, and if current trends continue more than forty per cent of Americans will be clinically obese within five years. The burden on the health system, not to mention the weakened quality of life that obesity causes, will be enormous.

I stumbled across an advertisement for Zantrex-3 while riding on the subway in New York one day. The name seemed coolly futuristic, and the ad was inviting, featuring an impossibly lithe

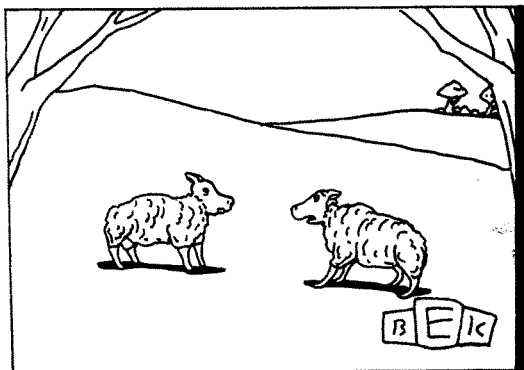
and attractive couple dancing the tango. The copy beneath them promised—in "one amazing superpill"—both weight loss and incredible energy. "You are not obese," Zantrex-3 ads say. "You just need to lose a quick ten to fifteen pounds . . . and you want energy . . . plenty of energy."

Who could argue with that? I looked for the name of the company at the bottom of the ad: Zoller Laboratories. When I called the 800 number printed on the advertisement, the woman who answered told me that the company was based in Salt Lake City, but I couldn't find it listed in any of the databases that I normally use for research. Then I noticed, in an article about Britney Spears's "weight problems," that the chief scientist at Zoller was quoted by name. I dialled the 800 number again and asked to speak with him. He answered the phone, but was startled when I asked if I could fly out and talk with him. He promised to call me back. He never did, but eventually the public-relations representative for a company called Basic Research invited me to visit Basic's headquarters, in Salt Lake City. He told me that Basic was the exclusive distributor of Zantrex-3. Zoller Laboratories does exist, but there are no offices and no labs. It's a company created by the marketing team at Basic because its name sounds scientific.

Basic Research is a privately held con-

glomerate based in a modern, hundred-and-fifty-thousand-square-foot factory that was previously the U.S. assembly headquarters for Palm Pilot. Having tripled in size in the last year alone, the company is looking for more space nearby. The headquarters is a five-minute drive from the Salt Lake airport, and there are more than a dozen similarly squat industrial buildings scattered along the highway among the Days Inns and Guest Quarters. Most are home to companies with names like Utah Scientific, Cephalon, and Compeq. With the vigorous help of Senator Orrin G. Hatch, a principal sponsor of the Dietary Supplement Health and Education Act, the area has become a magnet for supplement companies. Hatch has been the industry's greatest champion and has consistently fought tighter regulations on products like ephedra. (So has his son, Scott, who has earned millions of dollars for firms that lobby on behalf of supplement companies.)

Arriving early for my meetings, I waited in the lobby, which was festooned with flyers and advertisements for a stupefying variety of herbal tonics and miracle cures. A banner bearing the company motto—"We help people feel great about themselves"—was stretched across an open bullpen area, where dozens of salespeople worked the phones. Basic has a remarkably high "closure" rate; more than sixty per



"Sometimes I worry I'm a wolf dressed as me."

cent of callers make a purchase. An advertisement for Zantrex-3 on the wall declared, "Dietary Supplement Industry Pinning Hopes on New 'Super Stimulant,' Non-Ephedra Diet Pill. Decline in Ephedra Diet Pill Sales Reversed by Zantrex™-3's Sudden Popularity."

Basic puts out scores of products, which are marketed under the names of nearly a dozen companies—a practice that, according to Dennis Gay, the president and C.E.O., is intended to confuse competitors and "protect our brands in the Wild West atmosphere that exists today in the supplement industry." With Zantrex-3, Basic has seized cleverly on the fears about ephedra—marketing the pills as the "high-tech" substitute. But the company has many similar products; the cynically named Anorex, for example, is "the first weight-control compound designed to mitigate the profound effect that variations in the human genetic code have on the storage, use, and disposition of body fat," and Relacore is the "most significant weight-control advancement in more than a decade." ("Excess tummy flab is not your fault.") There is also Söavage Breast Augmentation Serum, a topically applied bust cream ("Yes They Are Real Breasts," one highly illustrative ad says), and Söavage Lip Plumper, to increase the fullness of one's lips. The company also markets tummy gels that promise "ripped abs" (NutraSport Cutting Gel), and a variety of tonics to help one think, relax, or sleep more soundly.

One product, Strivectin-sd, a cream that is sold for more than a hundred dollars a tube in Nordstrom, Lord & Taylor, and other stores, is made by a company called Klein-Becker USA, which calls itself "the industry leader in providing patented and exclusive weight-control and life-enhancement products that meet your individual needs." There is, however, neither a Klein nor a Becker, nor are there any specific employees who work there. Like Zoller Labs, it's a company created by Basic because the name sounds impressive and pharmaceutical. Strivectin was originally intended for use by women to reduce stretch marks (and in many stores it is still marketed that way), but people soon began to rub it on their faces as well; Strivectin now asks, without any data to justify the compari-

son or the question, "Even better than Botox?"

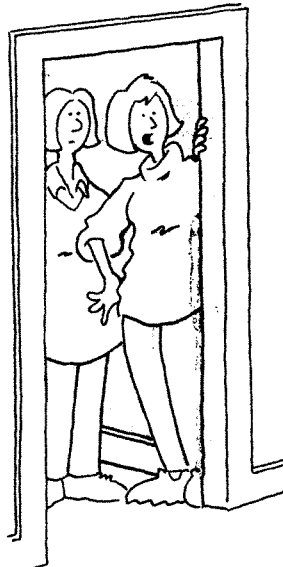
Daniel B. Mowrey, the man responsible for creating most of these products, is a gentle-looking figure with blue eyes and gray hair that is thinning at the top. The day I met him, he was dressed in chinos, a denim work shirt, sneakers, and a loud paisley tie. "I used to be a hippie," he said, shrugging, when he saw me staring at the tie. He told me he bought it long ago in Haight Ashbury. Mowrey is the director of scientific affairs at Basic and one of the three owners. Everyone calls him Dr. Dan. He received a Ph.D. in psychology from Brigham Young University, and although he never studied botany formally, he has written widely on the medicinal uses of herbs. He laid out his philosophy quite clearly in his book "The Scientific Validation of Herbal Medicine," published in 1986:

The scientific method is a powerful tool, but it has its limits. . . . Medical science in America is a unique combination of economic and political factors, which fuse together almost religiously to promote synthesized, highly active chemicals.

Mowrey told me he believes that there is almost always a "natural" alternative to synthetic drugs: "One that is cheaper, safer, and, often, more effective."

Mowrey came up with the components of Zantrex-3 the way he comes up with the elements of most of the company's products: by surfing the Internet. "I never understand why my competitors don't spend more time just looking at the information on the Web," he told me. "It's all out there," he said, showing me how he uses public databases—such as those kept by the National Institutes of Health—to see what's new in fields like weight control, memory, and aging.

Basic makes two major claims for Zantrex-3: that it will provide an immediate and sustained burst of energy, and that it will help people lose weight rapidly. For the first claim, Mowrey relied on a study by the U.S. military that examined the effects of caffeine on Navy SEALs who had been deprived of sleep and exposed to the extreme stresses of a training week. The study concluded that it is more effective in combating fatigue than a placebo. One dose of Zantrex-3 is like drinking four cups of strong coffee. Whatever the merits of that study, al-



most anyone who takes the pills is sure to feel the jolt—and many people buy them for that reason alone. (The clerk at my local G.N.C. warned me to take the pill with food, or I might get “too high.”)

The company attaches a tiny brochure to the neck of each bottle which says that Zantrex-3 caused “546 per cent more weight loss” than America’s No. 1 ephedrine-based diet pill—“without diet and exercise.” It goes on, “Published clinical studies don’t lie.” I asked Mowrey to show me the data he used to arrive at that figure. He acknowledged that the figure was based not on a direct comparison of the two diet products but on extrapolations of results from unrelated studies.

One of the studies, which Mowrey describes as a “groundbreaking” paper, published in 2001 by two Danish researchers in the *British Journal of Human Nutrition*

and *Dietetics*, evaluated the effectiveness of a mixture of three South American herbs—now used in Zantrex-3—in aiding weight loss by making people feel too full to eat. The study followed forty-six subjects for forty-five days. Half were given a placebo and the others received the herbal mix. At the end of the study, the herbal group had lost eleven pounds, on average, whereas the other group had lost less than one. Seven participants were followed for another year, during which they neither gained nor lost more weight.

The subject of obesity, after being largely ignored by the medical establishment, has finally gained currency in the United States, and many major medical schools and scientific institutes now are pouring research money into the field. Yet, despite thousands of weight-loss studies and an increasingly focussed search for solutions, there is

no evidence that any prescription, over-the-counter product, or supplement has ever kept a person’s weight down for much more than a few months. At best, such drugs or supplements are short-term answers to lifelong problems; at worst, they intensify the disorders they attempt to cure. I asked Mowrey if it was fair to assert, as he has, that “whether weight management or energy management is your goal, Zantrex-3 represents the very best options available anywhere.”

“What options are better?” he asked. “We have to look at the study. We are not free to go beyond it, but it’s not fair to ignore it, either.”

Losing eleven pounds in forty-five days certainly sounds promising, but the results of a single six-week study involving fewer than fifty people would almost never provide enough meaningful data to prove the value of a drug or supplement of any kind. It usually takes years and involves hundreds, if not thousands, of subjects before a study of a new drug can yield clear evidence that it is effective. The main herbs in Zantrex-3—guarana, yerba maté, and damiana, coupled with caffeine, zanthene, and green tea, among other ingredients—are stimulants, laxatives, and diuretics. You do not need a degree in nutritional sciences to realize that if you take a combination of stimulants, laxatives, and diuretics for six weeks you are going to lose weight, or to know that, over the long run, such a diet plan is certain to fail. “The idea that a pill, a mixture of herbs, or anything else will allow people to lose weight and keep it off without any other effort is completely ridiculous,” Kelly Brownell told me when I called to ask his opinion of Zantrex-3. Dr. Brownell is the chairman of the psychology department at Yale, and he is also the director of the Yale Center for Eating and Weight Disorders. “You look at a study that, in the end, followed seven people for a year and you can conclude nothing from that.”

Mowrey argues that Americans ought to have the chance to make decisions about the value of supplements for themselves. “There are a lot of pharmaceuticals derived from plants,” he said. “Lots of times, the safety issues are not important. And you have to remember what you have to do if you develop a drug

TV FOR ONE SITCOMS FOR THE NON-SOCIAL

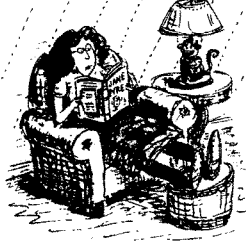
One of a Kind

Show about a gal who minds her own beeswax, with hilarious results.



Just Us Chickens

Thirty minutes of sidesplitting comedy as a young woman keeps to herself.



Me, Myself, and I

Laughfest about a guy who doesn't quite see the point of "relationships."



Single Serving Size

You'll love this new mith-plosion about a fellow who is tired of dealing with others.

Hi! I'm not home right now, so please leave a message.
BEEEEEEEEP!



R. C. W.

today. Say you do a small study of maybe a hundred and fifty people and you find that as a result of the study eighty-five of the women who take this who would otherwise get breast cancer don't. The F.D.A. demands that the company spend several billion dollars and fifteen years of research answering every little question that comes along. Every nitpicky little question. Now, how many people have you *killed* before you introduce this drug to the market?

"Drug companies don't offer money-back guarantees," he continued, emphasizing one of Basic's main policies. "We do. And if it isn't going to work, if it's not effective, then we have the ability to give money back. There is satisfaction guaranteed here. Can you imagine a drug company doing that? We are in the business of wellness, not of curing sick people. A lot of dietary supplements are designed to prevent problems from ever happening. There is no drug that is going to prevent illness. Drugs treat illness. They are going to be very, very invasive. Whereas dietary supplements are not invasive. You can combine vitamins with minerals and plants together in a thousand ways without anything happening that is bad."

The notion that herbal combinations are "natural" and therefore can't cause harm serves as a first principle for many people who take supplements as a solution to their medical problems. Even the most seemingly benign substances, however, can turn out to have significant and wholly unexpected effects. Perhaps the best example is grapefruit juice, which can disrupt the work of a series of enzymes that are found in the small intestine and which serve to break down drugs before they are absorbed into the bloodstream. Taking medicine with grapefruit juice permits it to enter the bloodstream in dangerously high concentrations, which keeps it from doing its job and can intensify many side effects. Many common pharmaceuticals—including antidepressants, antihistamines, and cholesterol medications—are not metabolized properly if they are taken with grapefruit juice.

There are numerous examples of herbs, drugs, and supplements that cause reactions or that when taken together

are harmful. Beta-carotene, found in carrots, has always been considered purely beneficial, yet recent research has shown that, for men with certain types of cancer, those who took beta-carotene supplements had a significantly worse prognosis than those who did not. There is a scientific maxim that the dose makes the poison—that any substance, no matter how useful, can cause trouble if you take too much of it. Most physicians don't even know what supplements their patients are taking, let alone how much, so trying to warn people about possible interactions among them is impossible. "The remedy for all this is to stop dangerously pretending that pharmacologically active substances called dietary supplements should be treated completely differently from pharmacologically active substances called drugs," Sidney Wolfe, the director of Public Citizen's Health Research Group, told me. "You cannot determine if they are safe or effective without doing the studies. And with supplements the studies are almost never done."

Some herbs do work, of course, yet the absence of effective manufacturing standards in the United States means that even then consumers can't rely on commercial formulas. Black cohosh has been used for centuries to treat a variety of common ailments, including, most recently, menstrual and menopausal problems. In Europe, it is considered a drug—and many studies have shown that it can have value. Women often take some form of the root instead of using hormone-replacement therapy. Still, in the U.S. the herbal product that you buy tomorrow may be different biologically from the same product purchased next month. I have a friend who, at the onset of menopause, began to use a supplement that is composed principally of black cohosh. For several months, her symptoms disappeared. One day, however, she bought a new bottle, and within a week her symptoms had returned so severely that she called her doctor from a car on the West Side Highway. "I demanded a prescription for hormone-replacement therapy," she told me, even though she considers it dangerous. Her doctor guessed correctly that she had just bought a

new bottle of the supplement, and advised her to switch to a different product containing black cohosh—Remi-Femin—which is made, by Shaper & Brunner, in Germany, where it is regulated as a drug.

With herbal products made in the U.S., however, there is simply no way to know what you are getting in each bottle. In 2002, researchers at the New York Botanical Garden published a study in the journal *Economic Botany* in which they reported on using DNA-fingerprinting techniques to identify several species of black cohosh. They found great variation in the herbal mixtures that

were turned into products for the marketplace. It's hard to make a botanical product exactly the same way every time. Without rules, there is almost no incentive to try.

Since the standards for making diet pills are set largely by the people who sell them, I decided it would be useful to see how Zantrex-3 was made. "You go look at the factory," Dennis Gay told me. "If you think we are a sleazy operation, remember: we could do it for half the price." The next day, I drove to Cornerstone Nutritional Labs, in Farmington, about twenty minutes north of Salt Lake City on I-15. Cornerstone, an independent company that produces most of the Zantrex-3 sold in the U.S., pumped out 1.7 billion capsules, tablets, and pills last year, nearly two hundred thousand an hour for every hour of every day. I was greeted warmly by Brent Davis, Cornerstone's director of nutraceutical sales, who offered to show me around the plant. We slipped on disposable booties, gowns, and hairnets, and removed the metal from our pockets, so as not to contaminate the materials. Our first stop was the receiving area at the plant's loading dock, where dozens of fifty-kilogram drums of raw herbs—green tea, yerba maté, and pangea among them—were lined up and stacked nearly to the ceiling, forty feet high. As soon as the herbs arrive at the factory, they are sampled for color, consistency, density, and purity. The raw materials are then taken to a weighing room, where they are collected by men in moon suits and



sampled again. Most of the machines sit in clean rooms adjacent to the factory floor, cordoned off by walls of double-paned glass.

After the herbs are collected, they are mixed in a blender. This is not as easy as it might appear; natural organic compounds are far harder to combine than synthetically made drugs. A product like Vitamin E comes in tiny balls, and most herbs come in flakes. The same herb can vary in consistency, in provenance, and even, at times, in species. Some need water; others are ruined by the slightest exposure to moisture. Some supplements require a minute amount of an ingredient—less than a hundred and fifty micrograms, for instance—to be mixed evenly into more than a hundred cubic feet of powder. And each supplement must be made in such a way that every capsule in every bottle is identical in quality and strength. "It's a hell of a job to do," said Michael Meade, the director of operations for Basic Research, who was also on the tour. "There's a recipe, and once it's worked out it's fine. But it takes time to get it right, and many companies fail. The idea that you just throw it all into the soup and wait is ridiculous." He said that Cornerstone was unusually rigorous in its testing, and that Basic was pleased by the consistency of the results.

Like other manufacturers in the secretive and, for the most part, privately owned supplement industry, Cornerstone declines to talk about its revenues or even name its clients. (Basic Research, too, reveals almost nothing about its earnings, expenditures, plans, or goals.) But Zantrex-3 is obviously a big part of Cornerstone's current business. The factory's largest blender, which was given over completely to the production of Zantrex-3 when I was there, can turn five thousand kilograms of raw powder into the equivalent of fifteen million pills a day. As soon as the newly homogenized herbal material leaves the blender, it is pressed by another machine into blue capsules, which are dumped into giant drums—thirty-five thousand capsules in each drum. They are then collected in a hopper and fed into bottles.

Cornerstone's computer system monitors every gram as it passes down the line, and supervisors keep the floors spot-

less. Once the bottles are filled, they are capped and a tamper-proof seal is melted on. Labels are applied by the same machine. Finally, one of the brochures advertising Zantrex-3's "amazing power" is fastened by hand to the neck of every bottle on the assembly line. From there, the bottles are packed into boxes that are loaded into cartons, which are shrink-wrapped and ready to ship. If Basic Research were willing to cut a (totally legal) corner or two, there is no doubt that it could produce those pills for far less money.

When I left Cornerstone, I drove to a nearby Wal-Mart, which, along with such stores as Circuit City and Bed Bath & Beyond, anchors a mall in a suburb of Salt Lake City called Murray. Wal-Mart is the biggest of what Gay refers to as the "big boxes," the giant chains that can insure a product's success simply by stocking it. By summer, all four thousand Wal-Mart stores will carry Zantrex-3; many of them will feature displays with the tango-dancing couple that I had noticed on the subway in New York.

The Murray Wal-Mart has an extensive section devoted to supplements of all kinds: bottles, packets, and cartons promising the usual array of unproved benefits, and promoting the health of the eyes, the skeletal system, the urinary tract, the brain. A tiny asterisk appeared on every product—including Zantrex-3—that suggested a connection between its contents and better health: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease." If a product whose label promotes it as contributing to "wellness" is not intended to cure, treat, diagnose, or even prevent any health problem, what, one has to wonder, is it supposed to do? But there they all are, dozens of brands: Stacker 3, with chitosan, and Starch Away, which "blocks calories from

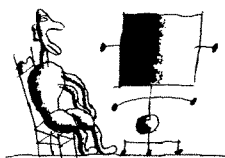
bread, pasta, pastries and other foods" ("Dieting has never been easier," the bottle says). Zantrex was for sale, along with ZN-3, a new product that advertises itself on the label as being like Zantrex. It has the same ingredients and costs half as much, but, since only the *names* of ingredients are listed, not the amounts, what comes in each capsule is anybody's guess.

As I walked out of the store, I heard an announcement on the loudspeaker: "Welcome, shoppers. Right now at the McDonald's inside this Wal-Mart you can get two cheeseburgers for only one dollar. This offer is for a limited time only. Also at this McDonald's we accept MasterCard and Visa."

Dennis Gay is a fifty-seven-year-old, pear-shaped man who has been waging an unsuccessful war on his weight for years. The first time I met with him, he was dressed in shades of green: olive pants, pale, pine-colored shirt, and loden tie. He had a short, neatly trimmed graying beard. At that meeting, Gay was accompanied by a man who was described as a "consultant" but who obviously played a significant role in the company, because he did most of the talking. (Nearly every time I asked Gay a question, he deferred to his colleague.) The man spoke fast, and had a New York accent. He didn't give me his name, although I asked him for it three times.

I wondered whether Basic Research believed that new laws requiring more regulation and stricter standards would be bad for the industry. "They are simply not needed," the man who wouldn't identify himself blurted out. "The F.D.A. has the authority to act today if it wants to remove something from the market. But it always prefers to use the media." He went on to say that although he assumed that ephedra would be banned there were really no significant problems with the herb, which Basic Research continues to sell, and which its salespeople told me on the telephone was the "best way by far to lose that weight fast." He said that Zantrex-3 increased "metabolism without increasing the heart rate or blood pressure"—which, as it happens, is almost never the case.

After the interview, I learned that the man's name was Mitchell K. Friedlander, and that he had made false claims about diet pills, and in the nineteen-eighties



was prohibited by the U.S. Postal Service from selling them through the mail.

When I spoke to Gay a second time, Friedlander was not there. I said it was hard to ignore the fact that his most trusted adviser—Gay described him to me as a “marketing genius”—had been found to have made false claims about diet pills. Gay told me that he had hired a private investigator to “check Mitch out” and that he was comfortable with the report. “Mitch is valuable,” Gay said. “He doesn’t desire to become a part of the company, and I don’t think we want him to be.” I asked if working with a man with Friedlander’s past bothered him, since he was trying to establish Basic Research as one of the more reputable companies in an extremely irregular business.

“Remember the old days when the banks hired safecrackers to protect them?” Gay said. “Is this that different? What are the standards in this industry? Tell me what they are, because I really wish I knew, so that I could abide by them. We try to do better, but there are no clear rules. None.” He went on, “We would welcome standards as long as they don’t take the choice away from the public. I wouldn’t welcome the standards that exist on the drug side. Because then you have no choice. And the American consumer is not stupid. He deserves to make his own mind up about what he does.”

This is Gay’s bottom line, and that of the industry as well. “I have to get into my lecture,” he said, and walked over to a whiteboard in the office. “Let’s say I’ve got ninety-nine people that have a fatal form of cancer. The way the F.D.A. regulates drugs now, a study would typically look like this.” He drew three big circles and wrote the number thirty-three in each of them. “A third will get nothing, and they are going to die. Then another thirty-three we are going to give a placebo. The last third get the active ingredient they are testing as a new drug.”

“Let’s assume the first thirty-three die. What about placebo? Well, most studies show that placebo survival rate is thirty-six per cent. That suggests that eleven of the people on placebo will survive at least long enough to be significant. And now let’s say that of the third who receive the active ingredient eleven survive. Based on today’s regulations,



"In the store it was kitschy—in my apartment it was tacky."

that drug would not be approved. It's no better than placebo. And it would be tossed in the trash. But this is what I want to ask: What about these twenty-two people here?" Gay drew a big line under the eleven placebo and eleven drug recipients who, in his reckoning, would have lived. "What the government of the United States says is that those twenty-two people don't have the benefit of a placebo or of the active ingredient. So you have zero people surviving out of ninety-nine when you could have had twenty-two surviving." Gay looked mournful. "All I am saying is that I want to have the right to appeal to those twenty-two people. I want to give them a chance to live."

There is a demonstrable placebo effect in most clinical studies, although the idea that placebo could save even eleven patients with fatal cancer is ludicrous. But Gay and Basic make their money by selling the dream of wellness, not the reality. If their products could really swell breasts, banish wrinkles, and erase fat, Basic would probably become the most successful company in Ameri-

can history. After all, is Zantrex-3 any different from Lydia Pinkham's miraculous concoctions?

This year, Congress will consider a bill that would modify the 1994 law so that thousands of unregulated botanical substances would be treated more like drugs than like foods. Supplement manufacturers—and their customers—are preparing to fight any such change with every resource they can muster. The bill has been advertised as an assault on the First Amendment. The alarm has sounded across the Internet, and congressional offices have been besieged with protests. Walk into any health-food store and you'll see leaflets warning that the government is about to deny you the right to choose your own fate.

Gay went back to his chair and sat silently for a moment. "We put disclaimers in our ads, and we give people the results of the studies and a money-back guarantee," he said. "What more could you want? Don't prevent people from using their own judgment. Let them try it. If it doesn't work, they can return it. That's what's fair. That's what's American." ♦

January 2002

Tab 42

NBG 00555-11RK9-24

PediaLean™
(Pediatorpin™)



Specifically Developed
for the Weight-Loss
Needs of Children and
Adolescents Ages 6-16.*

**Dietary
Supplement**
120 capsules



PediaLean™

Active ingredient: **Pediatorpin™**, a specially prepared, high molecular weight, microcrystalline fiber concentrate available exclusively from Klein-Beccker USA.

Supplement Facts

Ages 6-10		Serving Size: 2 capsules	
Serving Per Container: 60			
Ages 11-16		Serving Size: 3 capsules	
Serving Per Container: 60			
		Amount Per % Daily	
		Serving	Value
Phenolphthalein (Active Ingredient)	500mg	1	
<i>(Daily Value not established)</i>			

Other ingredients are the Klein-Beccker USA products exclusively distributed throughout the USA by: Basic Research, LLC, Provo, Utah 84604 1-800-898-6788 www.PediaLean.com www.WeightLossForChildren.com

*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

PediaLean™ Directions:
Children (ages 6-10): Two (2) capsules, twice a day - 30 to 60 minutes before lunch and dinner, with 8 ounces of water, juice or other liquid.
Children (adolescents) (ages 11-16): Three (3) capsules, twice a day - 30 to 60 minutes before lunch and dinner, with 8 ounces of water, juice or other liquid.

SPECIAL NOTE: If your child has difficulty swallowing capsules, don't worry. The PediaLean™ formula can be sprinkled between a small piece of bread, onto a spoonful of applesauce, plain yogurt, or yogurt - just about any food. PediaLean™ is odorless and tasteless, making it perfect for even the pickiest child. Clinical trials show PediaLean's™ weight-loss compound is well tolerated by children and adolescents ages 6 - 16.* However, if your child should experience mild abdominal discomfort (bloating), temporarily discontinue use of PediaLean™. After two days, give your child one (1) capsule twice a day. Continue the reduced plan for three days, then resume the recommended daily regimen.

To Parents: Before your child begins using PediaLean™, we strongly suggest that you visit www.WeightLossForChildren.com, Klein-Beccker's online information and support site for PediaLean™ parents. Along with expert advice and information, you'll get a personalized, easy-to-follow eating and exercise plan for your child that takes into account your child's gender, height, weight, and age.

For additional information call 1-800-898-6788. Use only as directed. Store at controlled room temperature 15°-30°C / 59°-86°F



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Your Child Is Overweight...

And it's destroying both your lives.

European Breakthrough Gives Hope To You And Your Overweight Child

On Thursday, November 8, 2001, at a Washington, D.C. conference hosted by The American Obesity Association, a frightening study entitled "Stigma and Childhood Obesity: Forty Years and Counting" was presented to some of this nation's most prominent obesity experts. In the study, children were shown photographs and asked to pick the person they liked the most - the thin person was almost always chosen first, and the obese person... always chosen last. While the study's findings may have been groundbreaking news to some "experts," the results are no surprise to your overweight child. Rejection because of body size is real - it hurts, and it lasts a lifetime.

Additionally, years of published research confirm that an overweight child will grow up to earn less money, be less likely to marry, more likely to be divorced, complete fewer years of school, and more likely to become a burden on an aging parent (even if that child becomes leaner in adulthood). The stigma of rejection never goes away... never!



"It's just baby fat," "She'll grow out of it," and "Oh, he's just a growing boy..." these are the traditional excuses parents use to justify their child's overweight condition.

*The old excuses can no longer stand... especially now that there is a safe, natural weight loss compound designed and developed specifically for children. Combined with a preventive program specifically created to support both parent and child - this natural weight-control compound resulted in significant weight loss in virtually every child studied. For your child's sake, for **YOUR** sake, you must take advantage of this clinically proven solution.*

Dr. Michele Green, Ph.D. D.D.
Director of Research, Klein-Becker USA

Your Child Is Not the Only Victim

All parents cry for their children. But as difficult as being overweight is for your child, there's another victim - the invisible victim of childhood obesity... it's you. Why? Because nobody blames your child for being overweight - they blame you - the parent. Regardless of how cruel, unfair, or misplaced the blame may be... parents of overweight children are judged harshly (although always in the quietest of whispers) by their friends, neighbors, and relatives. A recent study showed that most people see your child's obesity as evidence of YOUR ignorance and sloth. They blame you... "It's your fault for feeding your child too much"... "your fault for letting your child lounge around the house"... "your fault for working too late, leaving your child to TV, video games, and never ending bags of chips." Just as your child is stigmatized - so are you. We all know these cruel perceptions aren't true - but they still hurt - your quality of life suffers.

At last, there's a safe and effective compound clinically proven to help children lose weight. It's called Peshalcan™, a specially prepared high molecular weight, micronized fiber concentrate, available exclusively from Klein-Becker USA.

Redbook
February, 2002

*Peshalcan™ is 100% vegetarian. No animal products or by-products are used in the production of this product.

When Your Child Needs More Than Diet And Exercise

**Safe, Natural Weight-Control Compound
Specifically Developed for Children,
Clinically Proven in Europe – Finally Available in America**

Although PedialLean™ is the first and only weight control compound proven safe and effective for overweight children, a success rate of 100% for each and every overweight child who completed the clinical trial, see study results below). PedialLean™ is no "miracle" pill. No weight-control program can succeed without parental support. That's why the professionals at Klein-Becker created www.WeightLossForChildren.com.



of children's health, as well as practical answers to difficult problems... how to maintain good nutrition using today's "fast foods."

But that's not all. The most popular feature of WeightLossForChildren.com is our wonderful "Parents Only" Message Board and Chat Room... a place of compassion and practical help from a community of parents who have walked in your shoes... who understand how you feel because they've been there themselves. You will love it!

Professional Support and a Shoulder to Lean On

PedialLean™ is more than a great weight-loss formula for your child... it's a complete program of online support accessible to you from home, office, or anywhere you may be. Simply log on to www.WeightLossForChildren.com - the exclusive, easy-to-use, online service developed just for PedialLean™ parents - and you'll find a place where all your questions will be answered by our staff of MDs, PhDs, Registered Dietitians, and Exercise Specialists... each dedicated to help you and your child succeed.

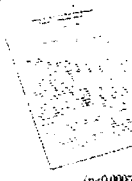
You get a personalized, easy-to-follow eating and exercise plan for your child or children that takes into account your child's gender, height, weight, and age (there's even a personalized weight-control plan for you). You'll get answers from professionals who know what you and your child are experiencing... and discover tips for getting your child motivated, important medical information on all aspects

A Winning Combination

The PedialLean™/WeightLossForChildren.com combination is a revolutionary approach to children's weight control that, simply stated, can not and **will not fail**. So get PedialLean™ today, then log on to www.WeightLossForChildren.com and begin a new life of health, happiness, security, and confidence for both you and your child. You will not be disappointed!

Of course, PedialLean™ comes with Klein-Becker's 100% Unconditional Money Back Guarantee: if for any reason you are not totally satisfied with PedialLean™ just return the empty bottle within 30 days for a full, prompt refund... no questions asked!

Clinically Proven Safe and Effective



Study Design To evaluate the efficacy of PedialLean's™ active compound, 23 children who completed the study, 12 males and 11 females of average age 10 years and 2 months (range 6.2-15.3), with average excess weight of 51±10%, were given PedialLean™ (in conjunction with a suggested noncaloric diet for the age and size of each child [about 10% protein, 30% lipids, 57% carbohydrates], and modest physical exercise), were then compared to 30 controls (average excess weight of 50.3±11.7%, average age of 11.3 years) for whom only diet and physical exercise were advised.

Results After eight weeks, the 23 PedialLean™ children showed a drop of excess body weight from 51±10% to 41.3±13% (p<0.0006). Specifically the obese girls went from an excess weight of 46.5±13.0% to 38.7±15.8% (p<0.006) and the boys from 53.2±15.8% to 43.8±14.7% (p<0.05). In the Control Group, no meaningful decrease occurred (51±10.6% vs 49.3±12.4, p n.s.).

More importantly, the weight loss persisted. After a 1 - 6 month follow up, the excess body weight of the children who used PedialLean™ continued to decrease significantly (PedialLean™ 40.7±14% vs Control 44.2±10% p<0.003).

What does this mean in plain English? Children who used PedialLean™ along with a healthy, but not extreme restricted, diet and modest exercise lost an incredible 26% of their excess body weight. Those who followed the same diet and exercise program, but did not take PedialLean™ failed to lose any significant excess weight at all. In other words, the only difference between success and failure was PedialLean™.

1-800-617-6080-24

PedialLean™
(PedialLean™)

Developed For
The Loss Needs of
Ages 6-16.

Supplement

Open 24 Hours
Order Now: 1-800-617-6080 ext. PL103
Visit online at www.PedialLean.com

\$79.00 USD
120 Capsules
Approx. 30-day Supply

www.KleinBecker.com

GNC Retail
 (In The Children's Section)
 Or Call: 1-800-617-6080
 ext. PL103



Tab 44

Klein-Becker usa™



Featured Products

Specialized Weight Control and Life Enhancement Formulations

Check Out Our Sport Nutrition Products!

Weight Control For Children










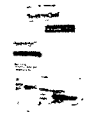
PedialLean™
Specifically Developed For the Weight Loss Needs of Children Ages 6-16

NEW • NEW • NEW



StriVectin-SE
Penetrating Cream Repairs Existing Stretch Marks In Weeks

Specialized Weight Control Formulations

<p>Transdermal Emulsifying Gel</p>  <p>Dermalin-APg™</p>	<p>Do You Need To Lose Over 20 lbs?</p>  <p>Anorex™</p>	<p>Are You Sensitive to Stimulants?</p>  <p>Anorex-SF™</p>	<p>Solution for Lower Body (Pear-Shaped) Adiposity?</p>  <p>Luprinol™</p>
<p>Prevent Breast Shrinkage Due To Weight-Loss</p>  <p>Mamralin-ARa™</p>	<p>Provides Thyroid Support During Dieting</p>  <p>Thyrovarin™</p>	<p>Increased Oxygen Saturation - Increased Endurance</p>  <p>Oxydrene™</p>	<p>Increased Sex Drive For You and Your Partner</p>  <p>TestroGel™</p>

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Tab 45

Specialized Weight Control and Life Enhancement Formulations

Check Out Our Sport Nutrition Products!


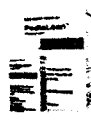
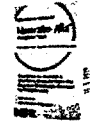



Featured Products

The Stretch Mark Reducer Cream Turned Anti-Wrinkle Phenomenon



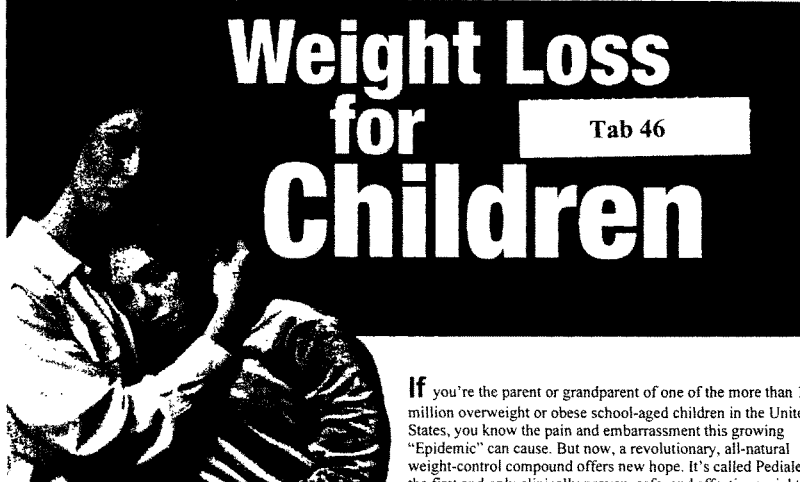
StriVectin-SD®

Specialized Weight Control Formulations

<p>Transepidermal Emulsifying Gel</p>  <p>Dermalin-APg™</p>	<p>Weight Control For Children</p>  <p>Pedialean®</p>	<p>Prevent Breast Shrinkage Due To Weight-Loss</p>  <p>Mamralin-ARa®</p>
<p>Provides Thyroid Support During Dieting</p>  <p>Thyrovarin®</p>	<p>Increased Oxygen Saturation - Increased Endurance</p>  <p>Oxydrene®</p>	<p>Increased Sex Drive For You and Your Partner</p>  <p>TestroGel®</p>

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New Product Update by Klein-Becker usa™



Weight Loss for Children

Tab 46

If you're the parent or grandparent of one of the more than 11 million overweight or obese school-aged children in the United States, you know the pain and embarrassment this growing "Epidemic" can cause. But now, a revolutionary, all-natural weight-control compound offers new hope. It's called Pedialean® the first and only clinically proven, safe, and effective weight-control compound designed for children and adolescents... and finally available in America exclusively from Klein-Becker usa

What is PediaLean?

The active ingredient in Pedialean® is Peditropin,™ an all-natural, micronized fiber concentrate derived from a plant (tuber called *P. rivieri*). This tuber has been used as a food source for thousands of years, but only recently have scientists discovered effective method for micro-processing the plant into a high-molecular-weight powder which makes it ultimately effective a children's weight-control tool.

Klein-Becker's proprietary micronization process guarantees Pedialean® is not only safe, but is the one and only weight-control compound designed, manufactured, and clinically proven safe and effective for use by overweight children and adolescents.

Does Pedialean® work? You bet it does! In a well-controlled double-blind clinical trial, each and every child who used Pedialean® as directed lost a significant amount of excess body weight... a success rate of 100%!

Professional Support and a Shoulder to Lean On

But Pedialean® is more than a great weight-loss formula for your child. It's a complete program of online support accessible from home, office, or anywhere you may be. Simply log on to www.WeightLossForChildren.com – the exclusive, easy-to-use online service developed just for Pedialean® parents – and you

Or Call 1-800-617-6080 Ext. KBWEB



"It's just baby fat," "She'll grow out of it," and "Oh, he's just a growing boy"... these are the traditional excuses parents use to justify their child's overweight condition. The old excuses can no longer stand... especially now

that there is a safe, natural weight-loss compound designed and developed specifically for children. Combined with a proactive program specifically created to support both parent and child – this natural weight-control compound resulted in significant weight loss in virtually every child studied. For your child's sake, for your sake, you must take advantage of this clinically proven solution."

Dr. Nathalie Chevreau, Ph.D., R.D. Director of Women's Health, Klein-Becker usa

**Published Medical Studies Don't Lie...
Clinically Proven Safe and Effective**

Study Design – To evaluate the efficacy of PediaLean's™* active compound, 23 children who completed the study, 12 males and 11 females of average age 10 years and 2 months (range 5.2-15.8), with average excess weight of 51±16%, were given Pedialean® (in conjunction with a suggested normocaloric diet for the age and size of each child [about 15% protein, 30% lipids, 55% carbohydrates], and modest physical exercise), were then compared to 30 controls (average excess weight of 50.3±11.5%, average age of 11.8 years) for whom only diet and physical exercise were advised.

Results – After eight weeks, the 23 Pedialean® children showed a drop of excess body weight from 51±16% to 41.3±15% (p<0.0005). Specifically, the obese girls went from an excess weight of 46.5±15.6% to 38.7±15.8% (p<0.0005) and the boys from 55.2±15.8% to 43.8±14.7% (p<0.005). In the Control Group, no meaningful decrease occurred (51±10.6% vs 49.3±12.4, p n.s.).

More importantly, the weight loss persisted. After a 4 - 6 month follow-up, the excess body weight of the children who used Pedialean® continued to decrease significantly (Pedialean® 40.1±14.9 Vs Control 49.2±13.3, p<0.005).

What does this mean in plain English?

Children who used Pedialean® along with a healthy, but not calorie-restricted, diet and modest exercise lost an incredible 20% of their excess body weight. Those who followed the same diet and exercise program, but did not take Pedialean®, failed to lose any significant excess weight at all. In other words, the only difference between success and failure was Pedialean®. (Individual results may vary.)

find a place where all your questions will be answered by our p of Doctors, Registered Dieticians, and Exercise Specialists... e dedicated to help you and your child succeed.

You'll also get full access to a personalized, easy-to-follow eating and exercise plan for your child based on gender, height, weight, and age. In addition, you will find information on all aspects of children's health as well as practical solutions to difficult problems – like how to maintain good nutrition using today's "fast foods." But that's not all. The most popular featur WeightLossForChildren.com is our wonderful "Parents Only" Message Board... a place of compassion and practical advice fi a community of parents who have walked in your shoes and are there to help. They understand how you feel because they've b there themselves. There's even a free personalized weight-cont plan for you at www.MyFreeDiet.com. You will love both sites

Order Pedialean® Today!

So order today, then log on to www.WeightLossForChildren.com and begin a new life for yo and your child. By the way, as with all Klein-Becker formulati Pedialean® comes with our no-nonsense, 100% money-back guarantee: simply stated, if you're not completely satisfied wit your Pedialean® purchase, return the unused portion within 30 days for a full, prompt, and complete refund... no questions ask Call now!

Ingredients!

Directions For Use!

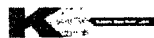
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Tab 47

Pedialean®

**Specifically Developed For The
Weight Loss Needs of Children Ages 6-16**



120 Capsules
(Approx. 30-Day Supply)

\$79.00

**Add To
Basket Now!**

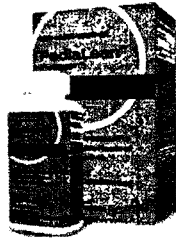
240 Capsules
(Approx. 60-Day Supply)
SAVE \$10.00

\$148.00

**Add To
Basket Now!**



Tab 48

Pedialean®**Specifically Developed For The
Weight Loss Needs of Children Ages 6-16****120 Capsules**
(Approx. 30-Day Supply)**Was ~~\$79.00~~ Now \$39.99****Add To
Basket Now!**

Basic Research is very pleased to assist voluntarily the Congressional Committee's understanding of childhood obesity and our effective treatment for this condition. Tragically, obesity has become a growing epidemic among children and adolescents in the United States. Basic Research's commitment to help alleviate this problem has led to its decision to reduce the price of Pedialean... a clinically proven, effective and safe dietary supplement for childhood weight control.

Q: What are the ingredients in Pedialean®, and are they safe?**Tab 49**

A: Pediatropin, the trade name for the active ingredient* in Klein-Becker's Pedialean®, is a proprietary, high molecular weight, micronized natural fiber concentrate and contains no ephedra or stimulants of any kind. The all-natural fiber concentrate is derived from a tuber (plant) called *P. rivieryi*. People have been using this tuber as a food source for thousands of years, but only recently have scientists discovered an effective method for micro-processing the plant in a way which makes it ultimately effective as a children's weight-control tool. The proprietary micronization process is exclusive to Klein-Becker usa, and guarantees that you and your child obtain the finest, highest-quality product available. Thus, Pedialean® is not only safe, but is the one and only weight-control compound designed, manufactured, and clinically proven safe and effective for use by overweight children and adolescents.

*Pedialean® also contains negligible amounts of an all-natural binding agent (rice flour) which aids in the encapsulation process.

[Close this Window](#)

Pedialean Directions: Tab 50

Children ages 6-10: Two (2) capsules, twice a day – 30 to 60 minutes before lunch and dinner, with 8 ounces of water, juice or other liquid.

Children ages 11-16: Three (3) capsules, twice a day – 30 to 60 minutes before lunch and dinner, with 8 ounces of water, juice or other liquid.

If your child has difficulty swallowing capsules, you may open the capsules and pour the contents in a spoonful of applesauce, yogurt or custard. Have the child drink an 8-ounces glass of water immediately after taking the PediaLean powder.

If your child's school does not allow your child to take pills without a doctor's prescription, you have 2 options: The best one is to empty the contents of the capsules in a small plastic pill carrier or other small container and instruct your child to pour the powder on his/her first bite of lunch, followed by 8 ounces of water or other liquid. *(This method may or may not be allowed by the school).*

Another option is to have your child take the first dose of PediaLean with 8 ounces of water upon awakening *(or 30 minutes before breakfast).*

[Close this Window](#)

Date: 31-OCT-03
To: Dr. Chevreau
From: Office of Extramural Research
Subj: Application Number: 1 R43 HD045097-01 A1
Program Code ENG -GG

Tab 51

The scientific merit review of application 1 R43 HD045097-01 A1 entitled Micronized fiber, natural weight loss agent for preteens is complete. The Scientific Review Group (SRG) designated your application as NOT RECOMMENDED FOR FURTHER CONSIDERATION. Applications so designated cannot be funded in their current form and they are not routinely scheduled for second level review by the National Advisory Council/Board.

A Summary Statement containing reviewers' comments will automatically be sent to you in approximately eight weeks. Until then, no further information is available. After receiving your Summary Statement, you may call the program administrator listed below to discuss the contents. Should a revised application be indicated, follow the instructions in the PHS 398 instructions (<http://grants1.nih.gov/grants/funding/phs398/phs398.html>). Current NIH policy limits the number of amended versions of an application to two.

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PL003410

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SUMMARY STATEMENT
 (Privileged Communication)

Release Date: 12/05/2003

Application Number: 1 R43 HD045097-01A1

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 SALT LAKE CITY, UT 84116
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Review Group: ZRG1 SSS-T (10)
 Center for Scientific Review Special Emphasis Panel

Meeting Date: 10/27/2003
 Council: JAN 2004
 Requested Start: 03/01/2004

PCC: ENG -GG
 Dual PCC: NRK OBSB
 Dual IC(s): DK

Project Title: Micronized fiber, natural weight loss agent for preteens

SRG Action: Not Recommended for Further Consideration

Human Subjects: 44-Human subjects involved - SRG concerns

Animal Subjects: 10-No live vertebrate animals involved for competing appl.

Gender: 1A-Both genders, scientifically acceptable

Minority: 1A-Minorities and non-minorities, scientifically acceptable

Children: 2A-Only Children, scientifically acceptable

Project Year	Direct Costs Requested
1	100,000
TOTAL	100,000

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PL003433

CHEVREAU R43HD045097-01A1

PROTECTION OF HUMAN SUBJECTS UNACCEPTABLE

RESUME AND SUMMARY OF DISCUSSION: The revised Phase I SBIR application proposes a 16-week, double-blind, randomized, clinical trial of overweight youth, ages 7-10 years of age. The intervention group will receive soluble, micronized fiber at a dose 1,000 mg twice daily, while the control group will receive identical capsules filled with Maltodextrin. Both treatment and control groups will receive a behavioral, family based, weight loss management program called Trim Kids™. Strengths of the application are the proposed behavioral intervention and a possible commercial potential for a cost-effective means to promote healthy weight loss in youth; the expertise of the team of investigators; and the adequacy of the research environment. Weaknesses are the lack of commercialization plan for phase II; a lack of innovation; and methodological concerns. The profound concerns over safety of children administered with the fiber were the focus of discussion at the study section meeting. The majority view was that the investigators have not adequately addressed or allayed concerns over toxicity in children administered with the fiber. A minority view was that the investigators had addressed the concerns in an appropriate manner; it is a product that is already on the market from health food stores and the minority group was unaware of reports of adverse effects. The motion for not recommending the application for further consideration was carried with 16 members voting for the motion and 2 against. While the application upon revision is somewhat improved, concerns over safety of children expressed by the study section should be addressed and overcome.

CRITIQUE 1:

SIGNIFICANCE: The increasing occurrence of childhood overweight and obesity has lead to the epidemic of type 2 diabetes in youth. A safe, efficacious, and cost-effective means to promote healthy weight loss in youth would be a welcomed approach to curtailing the occurrence of childhood obesity and type 2 diabetes.

APPROACH: This is a first resubmission of a Phase 1 SBIR application. The investigators have tried to be responsive to the previous comments. However, attempts by the investigators to discuss the safety of the currently proposed natural weight loss fiber formulation (Pediclean®) raised major safety and human subjects concerns about its use in a pediatric population. In this reapplication, the investigators first describe choking and death associated with a previous formulation of the fiber extract, the Konjac fiber extract reconstituted in tablet form (page 32). Further, the investigators' disclosure of their safety studies, (which included watching the capsules dissolve in water, acidic, and alkaline solutions), does not appear to be sufficiently rigorous to allay concerns. Thus, the safety issues raised sufficient concerns to prevent further consideration of this application.

The investigators propose a 16-week, double-blind, randomized, clinical trial of overweight youth, ages 7-10 years of age. The intervention group will receive soluble, micronized fiber at a dose 1,000 mg twice daily, while the control group will receive identical capsules filled with Maltodextrin. Both treatment and control groups will receive a behavioral, family based, weight loss management program called Trim Kids™. The use of this behavioral intervention is a strength to the application. The study design calls for the active treatment and placebo capsules to be given 30 to 60 minutes prior to lunch and to supper (although there is inconsistency in the timing of the dose as it is noted at both 30-60 and 60 minutes prior to the main meals). It seems problematic that the lunchtime dosage will be administered consistently to children 30 (or 60) minutes prior to lunch while they are attending school.

The soluble, highly purified, micronized fiber is an extract from a Japanese Tuber. Its efficacy stems from the fact that it expands to 200 times its original size once it is solubilized in water. The investigators speculate that the group provided the weight loss fiber will lose significantly more weight than the control group such that body mass index will be significantly lower at the end of the 16 week trial. The investigators now plan to follow measures of insulin resistance by obtaining not only fasting

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lipid levels, but also insulin and glucose levels at study entry and at the end of the 16-week trial. However, they have not reported their planned measure of insulin resistance such as the calculation of HOMA-insulin resistance. The investigators also aim to study the effect of the soluble fiber on multiple outcomes including body composition (measured with bioelectrical impedance, BMI, and waist and hip circumference) and satiety (ascertained with a questionnaire).

While the investigators have attempted to respond to comments from the previous reviewers, some questions remain unanswered. The application contains an extensive human subjects protection plan utilizing a questionnaire concerning the occurrence of adverse events along with the appropriate reporting mechanism and a data safety monitoring plan/board. However, the investigators still have not considered any potential impact on nutrient absorption with the use of a soluble dietary fiber (the fiber based Pedialean® formula). In addition, the investigators plan to utilize a pediatric nurse practitioner in their study rather than a physician as suggested by the previous reviewers.

Another issue relates to the testimonials in the application, which lack scientific rigor. Furthermore, there is a report of a pediatric nurse practitioner at a school in Connecticut utilizing this formulation in seven overweight girls. This anecdote begs the question as to whether the parents/legal guardians of these children were involved or even consented to the nurse's administration of the compound. This story raises additional red flags as to the investigators' understanding of the proper conduct of studies in children.

Another question involves the investigators' understanding of normal growth and development in prepubertal and pubertal children. It appears that pre-pubertal status is an inclusion criterion for enrollment. The investigators note that the youth can be Tanner Stage 1 or 2. However, Tanner Stage 2 defines early puberty, not pre-pubertal status. Furthermore, Tanner staging is described as being ascertained from self-report. While self-report is possible by questionnaire with accompanying photos, this is not fully documented. It would seem more appropriate for the Tanner staging to be an objective part of the physical examination required at study entry and performed by a professional.

There are also questions about the three-day dietary records (along with the physical activity log). It would seem that these should be part of the baseline data collection and not collected after one week of the intervention. There are also no data describing the validity of measuring body composition in children with the bioelectrical impedance measure proposed for use in this study. Also, it appears that while baseline lab work is intended prior to randomization, this seems to have been omitted from the description of the plans for screening or visit 1. It is also unclear how group orientation will be performed during visits 1 and 2. How many participants are planned for these group orientations? It appears that 12 subjects will be enrolled as part of the initial assessment of toxicity, performed by questionnaire, but it is unclear if all will be followed within the same group orientation.

In terms of measurement, weight and height are usually measured two to three times to ensure the accuracy of the measurement. Measurements of height, weight, and BMI (for growth) are usually reported as Z-scores to take into account expected variation based on gender and age.

Finally, there is no clear description of the potential for commercialization or a clear plan for Phase 2. While the use of a potentially safe fiber to assist with weight loss is an exciting area of study, there remain multiple concerns with the current application.

INNOVATION: The use of a safe, efficacious, and potentially cost-effective means to encourage healthy weight loss in youth is novel. However, multiple questions arise regarding potential safety issues in a pediatric population.

INVESTIGATORS: There is a strong research team lead by Nathalie Chevreau, Ph.D., who is the Principal Investigator and Director of Nutrition Research at Basic Research, LLC and American Phytotherapy Research Laboratory. She has assembled a group of experienced consultants in the

ZRG1 SSS-T (10)

4

1 R43 HD045097-01A1
CHEVREAU, N

fields of behavioral research, nutrition, exercise, biostatistics, and pediatrics. The investigative team appears capable of performing the study as proposed.

ENVIRONMENT: The environment appears adequate for the proposed investigation.

PROTECTION OF HUMAN SUBJECTS FROM RESEARCH RISKS: While there is a data safety monitoring plan as well as a data safety monitoring board, many major concerns remain about this clinical trial involving children. There are questions regarding the lack of attention to the absorption of various nutrients in a growing pediatric population taking a fiber extract prior to meals (while there may be no major impact, the investigators must demonstrate lack of an effect). This reapplication includes, for the first time, allusion to earlier versions of the Konjac fiber extract when it was reconstituted in tablet form. The earlier preparation was associated with choking and death. This new disclosure is certainly worrisome. The investigators attempt to allay fear by describing their safety assessment, which included placing the Pedialean® formulation with the gelatin capsules into aqueous (tap water), acidic, or alkaline solution with constant agitation. The investigators report that it took at least 15 minutes for the capsule to disintegrate, which was followed by the constitution of a soft gelatinous mass. Therefore, the investigators presume that safety is ensured because even "if (the capsule) temporarily lodged in a child's throat, (it) will not cause choking by sudden expansion should the child continue drinking water or other fluid." (page 32) However, the disclosure of the association of choking and deaths with an earlier formulation of this fiber raises many questions of safety for the proposed study. In addition, other concerns regarding safety involve the dearth of information with respect to the absorption of vitamins and minerals. There is no plan to measure iron, calcium, and other minerals and vitamins.

INCLUSION OF WOMAN PLAN: Acceptable.

INCLUSION OF MINORITIES PLAN: Acceptable. It is estimated that 50-60% of the participants will be from ethnic and racial minority populations.

INCLUSION OF CHILDREN PLAN: Only children between the ages of 7-10 years will be involved.

OVERALL EVALUATION: This prospective, placebo-controlled, randomized clinical trial offers a means to study a fiber-based nutritional supplement aimed at weight loss in youth. However, many questions remain regarding the safety of the intervention as described. Additional attention to details of the study design is also needed.

BUDGET RECOMMENDATIONS: The budget is appropriate.

CRITIQUE 2:

SIGNIFICANCE: Childhood obesity is a very important problem. Limited treatment modalities are available to clinicians. Most treatment strategies include a behaviorally focused intervention. Thus a proposal of an agent that can be used as an adjunct to a behavioral program, which is both safe and effective, would be appealing. An agent that works in the gastrointestinal tract, which is not absorbed systemically, also has some appeal for a pediatric population. The agent proposed in this study has many of these qualities. Thus, a study of this agent appears appropriate.

APPROACH: The applicants have proposed a randomized double blind placebo controlled clinical trial. This is ultimately the appropriate design, however a question arises regarding whether the applicants have collected sufficient safety data before proceeding with an efficacy trial.

There is also a concern about the length of the proposed trial. Four months will only provide short-term outcome data. It would be useful to consider a longer-term randomized trial. The expected outcome is not completely clear. It appears that the active treatment group is expected to lose 1 BMI unit more

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than the placebo group. This may be consistent with the small pilot study performed in Italy. However, it is not clear if the applicants have taken into account that the behavioral program will also result in weight loss in the placebo group. The expected BMI change with this program remains unclear.

There are some logistical concerns that have not been addressed by the applicants. The subjects are expected to ingest the agent or placebo and drink water prior to lunch. It is not clear how this will be accomplished in the context of school. In addition, many obese children skip lunch and consume most calories in the afternoon. How will this be addressed in the study?

The applicants plan for an attrition of 30 percent. This may be appropriate, however some clinical programs have attrition as high as 50% or more. What methods will be employed to reduce attrition?

It is not clear why the applicants have chosen a BMI above the 85th percentile. This represents the cut off for at risk of overweight. It is not clear that an agent such as the one proposed will be acceptable to clinicians for treatment of children below the 95th percentile (overweight). It is also unclear why children who were the product of a pregnancy with gestational diabetes or low birth weight should be excluded.

The measures are generally well described. However, the rationale for collection of both food frequency data and a 3-day record as proposed is unclear. It is also unclear that the proposed method of measurement of bioelectric impedance is acceptable. Reliability and accuracy data for overweight children are not provided. What equations are used to calculate the variables of interest?

The primary analysis will follow intent to treat principle and use a 0.05 level of significance. However, an interim analysis is planned. It is not clear whether this has been taken into account.

The applicants now propose a DSMB. It would be useful to consider what the prospective stopping rules would be.

INNOVATION: There are novel aspects to the proposed treatment strategy.

INVESTIGATORS: The investigative team appears appropriate for the proposed study.

ENVIRONMENT: The environment appears appropriate.

PROTECTION OF HUMAN SUBJECTS FROM RESEARCH RISKS: The issues of patient safety, benefits and importance of knowledge to be gained have been addressed. This reviewer does not find any concerns in regard to use of micronized fiber in children in the proposed intervention trial.

INCLUSION OF WOMAN PLAN: Acceptable. Equal number of female and male subjects will be recruited.

INCLUSION OF CHILDREN PLAN: Acceptable. All subjects will be children.

OVERALL EVALUATION: Summary: This proposal for a randomized controlled clinical trial addresses an important clinical question. The revised application is improved in many aspects. However, some methodologic concerns persist which do lower the level of enthusiasm.

ADDITIONAL ELEMENTS: The applicants do not present a detailed plan for commercialization of the product in phase II.

BUDGET RECOMMENDATIONS: No concerns.

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THE FOLLOWING RESUME SECTIONS WERE PREPARED BY THE SCIENTIFIC REVIEW ADMINISTRATOR TO SUMMARIZE THE OUTCOME OF DISCUSSIONS OF THE REVIEW COMMITTEE ON THE FOLLOWING ISSUES:

PROTECTION OF HUMAN SUBJECTS (Resume): UNACCEPTABLE

Profound concerns over safety of children who are given the micronized fiber in the randomized intervention trial was the majority opinion. It was stated that the investigators should attest lack of toxicity of the fiber product in the pediatric subjects.

INCLUSION OF WOMEN PLAN (Resume): ACCEPTABLE

Equal number of girls and boys are proposed to be recruited.

INCLUSION OF MINORITIES PLAN (Resume): ACCEPTABLE

Specific percentage details of minority representation are given (page 49).

INCLUSION OF CHILDREN PLAN (Resume): ACCEPTABLE

All subjects recruited will be children.

MEETING ROSTER

Center for Scientific Review Special Emphasis Panel
 CENTER FOR SCIENTIFIC REVIEW
 ZRG1 SSS-T (10) B
 October 27, 2003 - October 28, 2003

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PL003439

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Consultants are required to absent themselves from the room during the review of any application if their presence would constitute or appear to constitute a conflict of interest.

NOTIFICATION OF SCIENTIFIC REVIEW ACTION

Release Date: 12/05/2003

CHEVREAU, NATHALIE PHD
BASIC RESEARCH, LLC
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Our Reference: 1 R43 HD045097-01A1 ZRG1 SSS-T (10)

The scientific merit review of your application, referenced above, is complete, and the review group has recommended that no further consideration be given to this application. Applications so designated cannot be funded in their current form; therefore, they are not routinely scheduled for second-level review by a National Advisory Council/Board.

Enclosed is your summary statement containing the reviewers' comments. You should call the program official listed below to discuss your options and obtain advice.

GILMAN GRAVE M.D.
(301) 496-5593
graveg@mail.nih.gov

If you choose to resubmit, it is important to respond specifically to comments in the summary statement, as outlined in the instructions in the PHS 398 application kit (<http://grants1.nih.gov/grants/funding/phs398/phs398.htm>).

Enclosure

cc: Business or institutional official of applicant organization

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Tab 52 Principal Investigator: Chevreau, Nathalie

INTRODUCTION

This is the revised version of the PediaLean[®] proposal of December 1st, 2002, which received a priority score of 306. We deeply appreciated the reviewers' comments and enthusiasm for the project, and are grateful to be able to re-submit our proposal. We wholeheartedly agree that our original proposal would benefit from more rigorous medical oversight and the inclusion of an independent Data Safety Monitoring Board. We are confident that we have addressed these and all other concerns in this revision. Changes to the Research Plan are summarized below:

1. Issue regarding "inadequate safety monitoring, protection of human subjects and lack of medical oversight":

In response to this concern we have established an independent Data Safety Monitoring Board (DSMB) composed of Dr. Julia Steinberger (a pediatric cardiologist at UMIN and an advisor to the www.weightlossforchildren.com Website), Dr. Daniel Jackson, pediatric gastroenterologist at Primary Children's Medical Center in Salt Lake, and a local pediatrician. The DSMB will oversee the safety of the study and monitor any adverse events, as detailed on pages 37 and 46-48 of the proposal. The previous reviewers also raised concern regarding the lack of physician oversight in this study. As a cost-effective solution, we have recruited Debbie Sandt, a highly qualified pediatric nurse practitioner (PNP), to provide medical oversight of the children. She has worked in Pediatrics for over 20 years and has assisted Dr. Jackson in his pediatric gastroenterology practice for 3 years. It is important to note that Nurse practitioners in Utah have full prescriptive practice, can work independently of pediatricians, and have become highly respected, invaluable members of the medical community.

2. Issue regarding "Minority children not adequately represented":

Children's Hospital in Salt Lake enrolls about 90 families per month for weight management and 50% of them are Hispanic. Therefore, we anticipate that at least 50% of our sample will be Hispanics.

3. Issue regarding "the lack of power calculation and criteria for assessing success":

Success at the end of the 4-month trial will be measured by change in body mass index as the main outcome variable. We expect the children receiving PediaLean[®] to reduce their BMI by at least one BMI unit beyond any reduction experienced by the placebo group. Therefore, an 80-children sample (40 in each group) with a potential attrition rate of 30% will have 80 percent power to detect a reduction of 1 BMI unit in the treatment group versus the placebo group at the end of the trial.

4. Issue regarding "lack of measurement for insulin resistance, blood glucose levels and concern with using different labs to analyze the samples":

We will measure fasting blood insulin and glucose levels at the beginning and at the end of the study. Children will go to one of the 5 designated centers to have their blood drawn but all the samples will be analyzed by the same laboratory (Lab Corp), one of the 2 main labs in the Salt Lake area.

5. Issue regarding the "lack of measure of nutrition status or monitoring growth":

We will also measure the effect of the formula on nutritional intake to ensure adequate nutrition for appropriate growth. Height will be plotted on the CDC chart and both the dietitian and the PNP will review the data to ensure that any increase in height over the 4-month period is appropriate and that height increments are normal for the subjects' respective chronological ages.

6. Issue regarding "the role of funding this research since the formula is already on retailers' shelf":

The formula has not been tested in a rigorous manner in the United States or on a minority population. Funding this clinical trial and demonstrating the efficacy of this formula would provide the medical community with another tool to treat the growing pediatric obesity problem especially in minority adolescents.

7. Issue regarding "preliminary evidence lacking the description of problem encountered":

A small number of parents have bought the formula and most have reported success for their children. There has been occasional bloating and gas, but no serious adverse effects have been brought to our attention. However, we want to test the safety aspect of this formula in a more systematic fashion so it may be used on a larger scale and be recommended by the medical community.

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The revisions made to the research plan are in italics.

RESEARCH PLAN

A. Specific Aims:

For both adults and children, obesity has reached epidemic proportions in the United States. From 1976 to 1987, the prevalence of obesity in children 6 to 11 years old increased by 54% and the prevalence in those aged 12 to 21 years increased by 64%^{1,2}. The latest report in 1998 from Strauss et al³ suggests that overweight prevalence in children ages 4 to 12 was 21.5% among African Americans, 21.8% among Hispanics, and 12.3% among Caucasians. The health risks associated with excess weight in childhood include "pre-diabetes," type 2 diabetes, and high blood pressure. These symptoms or conditions were, until recently, typically seen in adults. Treating the obesity problem as early as possible will have a subsequent impact on the health risk factors described above and is of the highest priority. This proposed highly innovative study will demonstrate efficacy and effectiveness of the first and only weight loss agent for preteens in the United States, paving the way for its targeted marketing and distribution in an efficient manner, thereby lowering costs and enabling reduction in pricing.

This specialized, highly micronized all-natural fiber-based formulation (*PediaLean*[®]) has been shown in a European study to be a safe and effective adjunct to weight loss therapy, and it *improved lipid profiles* in overweight children 6 to 16 years of age. It is therefore of utmost importance to test its effects in a rigorously controlled trial of American overweight children so that the medical community (and associated health insurance companies) will have an empirical justification to include this safe, stimulant-free, all-natural fiber formula in the treatment of overweight preteen patients. In this Phase I trial, we would like to narrow the age range of the children tested (7 to 10) to avoid the variability associated with puberty and to treat the child before any weight increase linked to maturation occurs.

The overall objective of this research is to conduct a 4-month randomized and placebo-controlled intervention trial in overweight 7-10 year old children (preteens). The outcomes to be assessed in this intervention include *safety of the formula*, body mass index (BMI), body composition, waist and hip circumference, satiety, *nutritional intake, fasting blood lipids, insulin and glucose levels, and compliance with Pedialean*[®]. Both the treatment and the control groups will follow a family based weight loss program to minimize or eliminate family difference and allow better detection of the effect of *PediaLean*[®]. The program developed by our consultant, Dr. Sothorn (and her collaborators), is described in the newly published book⁴ entitled *Trim Kids*[™].

The specific aims are as follows:

1. *To assess the safety of the highly micronized oral fiber formula (PediaLean[®]) in children, 7-10 years of age, compared to an age and gender-matched placebo group who will receive identical capsules filled with maltodextrin.*
2. *To determine whether PediaLean[®] will result in a significantly greater reduction of BMI (main outcome variable) in those preteen children, compared to an age and gender-matched control group receiving a placebo.*
3. *To determine the effect of PediaLean[®] on the following secondary outcome variables:*
 - a. Body composition
 - b. Waist and hip circumference

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- c. Satiety
- d. Nutritional intake
- e. Fasting blood lipid level
- f. Fasting blood insulin and glucose levels
- g. Compliance to Pedialean®

Hypothesis:

Children receiving PediaLean® will have a significantly greater reduction in BMI, waist and hip circumference, significantly greater improvement in body composition, fasting blood lipids, insulin and glucose levels, increased satiety, appropriate nutritional intake, and significantly higher compliance to the treatment when compared to a control group of age and gender matched children receiving a placebo.

In Phase II, we plan to extend the duration of the trial to one year and measure the above variables plus growth velocity, blood vitamins, and minerals status. We will involve another site with a large African-American and Hispanic population so that minorities with a high incidence of obesity are well represented in the study sample. We will also run a preliminary 4-month trial on young adolescents (11-14 years old).

B. Background and Significance

B1. Prevalence of Obesity

The recently released NHANES (1999-2000) results showed that a large percent of the population (adult or children) is overweight with a significant increase in the very overweight children. As many as 15% of children between ages 6 and 19 are overweight, nationwide⁵, with an age-adjusted BMI greater than the 95th percentile. This represents a 4% increase from the overweight estimates of 11% obtained from NHANES III (1988-94)^{6,7}. Another 22% of children are at risk for overweight (age-adjusted BMI between the 85th percentile and the 95th percentile)⁸. The reasons are multifactorial, but clearly, as Dr. James Hill put it at a conference of the American Dietetic Association (October 21, 2002) the increased prevalence is the result of a "successful" environment that supplies plenty of cheap foods, and in which technology contributes toward making adults and children more sedentary—whether at work, school, home, or participating in popular entertainment. The increase is even more alarming in minority groups, with a prevalence of 21.5% among African-Americans, 21.8% among Hispanics and 12.3% among non-Hispanic Caucasians in 1998. In Utah, data collected in 1993 by the Health Department showed a large population of overweight adults and children matching the national trend at that time, and we have no reason to believe that this trend has changed today. Based on the 2000 census, this would translate into about 45,000 children being overweight in the greater Salt Lake City area (Salt Lake, Utah, and Davis counties), which would provide an ample number of subjects to be recruited for the study. *A local obesity treatment center at the Primary Children's Medical Center reports seeing about 90 families per month, 50% of them are Hispanics. Despite the make up of Utah population (89% Caucasian, 9% Hispanics, and the balance of Native Indians, Pacific Islanders, Asians and African Americans), this implies that we will be able to recruit an ethnically diverse sample.*

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B2. Interventions for Overweight Children

Research shows that family environments and parenting practices might significantly contribute to childhood obesity^{9,10}. Parents provide an overall food environment for their children's early eating experiences. Family eating environments include parents' own eating behaviors and child-feeding practices. Parents who are overweight, who have problems controlling their own food intake, or who have concerns about their child's risk for overweight may adopt controlling child-feeding practices^{11,12}. The combination of these control attempts with genetic predisposition may promote the development of the types of eating habits that result in an overweight child. By the time the child has reached adolescence, the excess weight may be so great that it demands tremendous effort to adopt a healthier lifestyle. Many experts believe that the sooner the intervention occurs, the greater the likelihood of success.

Successful interventions for overweight children have targeted the entire family. They have been based on the Social Cognitive Theory, which includes changes in behavior, diet and physical activity^{13,14}. Dr. Epstein and his collaborators showed that encouraging the parents and their obese children to consume more foods with a higher nutrient density (*i.e.*, fruits and vegetables) and/or less of the energy-dense ones (*i.e.*, fats) yielded significant weight loss in both parents and children without a significant increase in the cost of the diet^{15,16}. Dr. Sothorn and collaborators have used a family-based, multi-disciplinary approach in outpatient clinical settings and have reported similar weight-loss results in children^{17,18,19,20,21}. Based on their experience, Dr. Sothorn and collaborators have written the book Trim Kids™²² that provides the framework for a family home-based program. The book describes education on diet and nutrition, exercise, behavioral changes, motivational exercises along with a complete set of processes and forms to allow a child and his/her family to follow the program at home and for clinicians to follow their progress. It is a 12-week plan that we will extend to 16 that requires parents to read a section every week, follow the prescribed exercise routine, utilize the psychological tips, menu/meal plans, and recipes. This will be the ideal companion to the testing of the fiber-based PediaLean® formula. The Trim Kids™ program will minimize the variations across families and across treatment groups. Dr. Sothorn will serve as a consultant on this study and will train Basic Research, LLC staff on the Trim Kids™ program.

B3. Fiber as a Weight-Loss Agent

The use of fiber as a weight-loss agent in adults is known to be effective as an adjunct to weight loss/energy controlled programs. *Subjects on fiber supplemented diets experienced greater weight loss than placebo controlled groups in double-blind studies*^{23,24,25}. Soluble fibers also are known to help to improve the blood lipids profile²⁶. However, none of the typical fibers (psyllium, oat bran, guar, etc.) is specifically recommended for children.

In Japan, fibers extracted from the tuber *Proteinophallus Rivieri* or Konjac root have been used as thickening agents and additives in foods for hundreds of years. The technique to extract and purify the fibers has improved over the years to yield purer and smaller fiber particles. PediaLean® is a highly micronized, unique fiber, unlike common, ordinary konjac or glucomannan compounds. In 1992, a 4-month clinical trial involving 53 obese Italian children was conducted to test the effectiveness and efficacy of this fiber in *decreasing weight and improving lipid profiles*²⁷. Among the 23 children in the treatment group, those between 6 to 10 years were given two 500 mg capsules twice a day 30 to 60 minutes before the 2 main meals and children aged 11 to 16 received 1.5 gram dose (3 capsules), also twice a day. They were matched with controls who received a placebo. All participants followed the same diet and physical activity recommendations. The children in the treatment group lost up to 20% of their excess weight, *which corresponded to a decrease of about 1*

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BMI unit. Their lipid profile (total cholesterol, triglycerides, HDL, LDL) clearly improved and few side effects (such as gas) were reported. The children reported a decrease in appetite and increase in satiety. The formation of a high-viscosity, gelatinous soft mass in the stomach after the capsule has disintegrated is speculated to slow gastric emptying, help control the postprandial glycemic response, improve the lipid profile and increase stool softness. This formula, when tested over a continuous period of 4 months, did not show any decrease of absorption of minerals. PediaLean® uses the identical micronized fiber as in the Italian study. This proposed grant should render the results garnered in the Italian study. In addition, this grant proposal specifically will include a very large proportion of minority subjects.

The micronized fiber has the unique capability of expanding up to 200 times its original volume after 30 to 60 minutes when mixed in water, and yields a soft gelatinous mass that helps children feel fuller faster and longer after consuming the fiber. The effect extends over a period of a few hours. The slight delay in gelling in a soft mass is of benefit for children who cannot swallow capsules. The capsules may be opened and the content placed in a tablespoon of applesauce or yogurt and taken orally followed by a glass of water to get the full effect. The micronized fiber is a bland white powder with no taste and no grittiness.

The safety of the mode of delivery of PediaLean packaged in gelatin capsules has been tested in our laboratory. When placed either in an aqueous (tap water), acidic, or alkaline solution under constant agitation, the capsules filled with PediaLean softened but retained their full integrity (original shape and volume) for at least 15 minutes before they started to wrinkle and disintegrate. Following the disintegration of the capsule, its content slowly swelled to form a soft, gelatinous mass. The fact that the capsules retained their original volume in all of the mediums is crucial to prove that the capsules, if temporarily lodged in a child's throat, will not cause choking by sudden expansion should the child continue drinking water or other fluid. The capsules are the preferred mode of delivery compared to the hard compacted Konjac fiber tablets of the past, which were associated with choking and death²⁸. The hard tablets contained fillers and accelerated expansion excipients that caused the tablets to instantly burst upon contact with water when being swallowed and to yield a hard, expanded mass that caused choking.

B4. Prescription medications for the treatment of childhood obesity

There are NO drugs that currently are approved by FDA for treatment of obesity in children. There are only two FDA-approved drugs for treatment of obesity in adults: Orlistat²⁹ (trade name Xenical), which works by reducing the ability of the gut to absorb dietary fat, and Sibutramine³⁰ (trade name Meridia), which is an appetite suppressant and works by increasing the amount of certain brain chemicals affecting mood and appetite. They have been approved for longer-term use in significantly obese adults. However, because FDA regulations do not restrict a doctor's ability to prescribe medications to children in different doses than those approved for adults and/or for different lengths of time, some morbidly obese adolescents have been treated with these drugs. Another drug called Metformin (trade name Glucophage), the original purpose of which was to help treat Type 2 diabetes, has been used to treat children's obesity. Metformin lowers blood sugar by influencing the liver, and helps lower blood lipids (triglycerides and cholesterol). Metformin also has been shown to decrease appetite and lead to a small amount of weight loss at the start of treatment³¹.

The above drugs have been used in some adolescents, although not in preteens. This is why it is so important to demonstrate in this Phase I trial the efficacy and effectiveness of this highly, micronized fiber formula supplement in preteens—so that an early treatment option exists for that population.

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Using the Trim Kids™ home-based program for all children will add rigor to the testing of the micronized fiber formula.

C. Preliminary Studies and Expertise of the Investigative Team

Dr. Nathalie Chevreau will be the Principal Investigator of this study. She received a Ph.D in chemistry from the University of Bordeaux in France in 1982 and a Masters in Foods and Nutrition from the University of Utah in 1993. She is fluent in French, reads and is *conversant in Spanish*. She served as the nutritionist in the Salt Lake City site of the Phase III clinical trial for Sibutramine as a weight loss agent in adults in 1992-1993. At Basic Research where she is currently the Nutrition Research Director, she has been the driving force behind the development of the www.weightlossforchildren.com Website for Klein-Becker usa, LLC, for which Basic Research provides marketing, sales and fulfillment services. Dr. Chevreau recruited experts in childhood obesity from around the United States to serve as experienced advisory board members for the site. She continuously interacts with them to keep the site current and resourceful to the parents. She was a driving force in bringing the micronized fiber formula (PediaLean®) to the US where it is sold in GNC stores, on the www.PediaLean.com and www.weightlossforchildren.com Websites. Some parents have purchased the formula for their children and a few have volunteered success stories via the site message board. A compilation of the 15 testimonials (that can be read on the site) is presented in Table 1.

Table 1:

Posting Date	Parent's report
March 11, 2002	Daughter lost 5 pounds in 3 weeks
March 30, 2002	Son lost 6 pounds in 2 weeks
April 8, 2002	Daughter lost 13 pounds in 3 months
April 8, 2002	12-year-old lost 10 pounds from 219 to 209 pounds
April 18, 2002	Daughter lost 14 pounds in 2 months
April 29, 2002	Son lost 10 pounds
April 29, 2002	11-year-old son lost 5 pounds in one month
April 29, 2002	Son lost 10 pounds
May 24, 2002	Daughter went from a size 22 to a 14/16 between February and May
June 27, 2002	11-year-old daughter lost 16 pounds
July 29, 2002	16-year-old daughter lost 10 pounds
July 31, 2002	Son lost 15 pounds
July 31, 2002	Daughter lost 15 pounds
Sept 1, 2002	Daughter lost 28 pounds in 7 months
Oct 18, 2002	15-year-old son lost 15 pounds in 5 months

Three testimonials were directly sent to the experts. They included an 8-year-old boy who lost 4-1/2 pounds in the first week, a boy who lost 6 pounds in 2 weeks and a 12-year-old girl who lost 11 pounds in one month. Most parents stated that their children have experienced a decrease of appetite and eat less as a result. Parents report that their children are thrilled with the weight loss and are being more physically active. No side effects have been reported. Additional anecdotal reports come from Rebecca Murray, pediatric nurse practitioner and Certified Diabetes Educator in a Connecticut middle school with mostly low-income students. During the school year 2002-2003, she treated seven overweight girls, age 13-14, who were gaining an average of 1 pound a week and were at high risk for diabetes. In the last 4 months she treated the girls with 3 capsules of PediaLean® 40 minutes prior to lunch and gave them a modified lunch. The school lunch the girls had typically consumed was a high fat, 900-calorie lunch. She reported "because of PediaLean, the girls did not come to the cafeteria ravenous and were satisfied with a 450 calories lunch consisting of a large salad with 3 oz of

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tuna". Those girls have experienced a 1 to 2 pounds weight loss per week rather than their weekly weight gain; "the girls are thrilled to be losing weight." *At the end of the school year, one of the girls had lost 30 pounds. When the school year resumes at the end of the summer, the Nurse Practitioner intends to prescribe an evening dose of PediaLean[®] to the girls to help prevent over consumption during their large family dinners to further their weight loss.*

Outside of Basic Research, LLC, Dr. Chevreau maintains a private clinical practice where she counsels overweight women and cancer patients. In 1993, Dr. Chevreau, as the PI, was awarded a 6 month SBIR Phase I grant to study protective effects of protein on chemotherapy. She is currently an adjunct faculty member for the Foods and Nutrition Division at the University of Utah where she guest lectures to graduate students on weight management. She will sponsor and mentor a graduate student who will be involved in the study as part of her master's thesis project. During the proposed study, she will also draw on the expertise of Dr. Melinda Sothorn, Dr. Myles Faith, and Dr. Michael Goran.

Debbie Sandt, PNP, will be medical consultant to this project. She will perform all medical and physical exams at each visit (including at screening) to ensure safety of the formula, and monitor growth, and monitor health status of the subjects during the study. She will prescribe and review the lab tests to be run for the study. Debbie has worked in a pediatric setting for over twenty years and is highly skilled to examine, assess, and monitor the children. She was the nurse coordinator for 3 years at the Pediatric Gastroenterology and Nutrition Clinic at Primary Children's Medical Center working with Dr. Daniel Jackson who is specialized in nutrition and in liver transplants. She currently is working in the department of pediatric nephrology at the University of Utah Medical Center. She will be on site 2 to 3 days a week to examine the subjects. She also will be available around the clock, by pager, should an adverse event arise and will be in contact with the DSMB when needed.

Ms. Shala West will be Dr. Chevreau's research assistant and will act as the study coordinator. She completed her Masters in Foods and Nutrition at the University of Utah in December 2002. Her Master's project consisted of coordinating a 3-month study involving 32 overweight children from age 5 and 12 with BMI over the 95th percentile. The study's goal was to determine the feasibility of a Low Glycemic index diet taught by pediatricians in the department of Pediatrics at the University of Utah Medical Center. She understands how to set up a study, maintain confidentiality, counsel parents and children, and manage data. In addition, she has been employed by IHC's Primary Children's Medical Center for 4 years as a Diet Technician. She is responsible for the calorie counts for children of all ages throughout the hospital and for doing the skin fold measurements. She also performs all initial nutrition screening for newly admitted patients, following up with the patients who are of a high nutrition risk. Shala performs various data entry for calorie counting, medical nutrition therapy charging, and TPN orders. She will join Basic Research, LLC at the end of 2003 to work on the www.weightlossforchildren.com Website.

Tiffany Strobel, a certified pediatric and adult exercise trainer will instruct each subject and his or her family on exercise. She will teach and demonstrate the proper techniques of the exercise described in the Trim Kids™ book and provide support to the parents and the subjects. She has been writing all the exercise-related sections for both www.myfreediet.com and www.weightlossforchildren.com sites for the last 3 years, including topics on motivation, reinforcement, and creating success. She regularly interacts with Dr. Melinda Sothorn, our Advisory Board member, to bring current and valid information to the site. She is a former competitor in the bodybuilding arena.

Dr. Daniel Mowrey, *Director of Scientific Affairs at Basic Research*, has a Ph.D in Experimental Psychology with an emphasis in psychopharmacology. He initially will teach the principles of behavior

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 modification as described in the Trim Kids™ book to the subjects and families. He will meet with each family at mid-study to review progress and discuss success and battles. His work has included the development of behavioral modification programs for counselors, host families, and teenagers in foster homes in the State of Washington. He also contributes to the content of both www.myfreediet.com and the www.weightlossforchildren.com Website, as a behaviorist.

Dr. Melinda Sothem will be a consultant to this project. She will come to Salt Lake City at the beginning of the study to train the staff on the Trim Kids™ program. A Spanish version of her book currently is being completed. She will orient the research staff on the program and the forms that the parents and children need to fill out at home and bring to the coordinator at their visits. A complimentary copy of the book will be given to the parents of both groups at the beginning of the study. Dr. Sothem will be available to the staff for phone consultation as the study progresses.

Dr. Myles Faith will be a consultant on this project. He will come to Salt Lake city at the beginning of the study to help train the staff on teaching and implementing behavioral changes. He also will train the staff on the use of the satiety scale that he has developed and validated^{32,21}. He also will be available for phone consultation to the staff as the study progresses.

Dr. Michael Goran will be a consultant on this project. He has advised the PI on the study's experimental design and outcome measures based on his experience on clinical studies involving children. He will advise on data analysis and interpretation, and will assist in writing the technical paper for publication.

Dr. Julia Steinberger, one of the advisors on the www.weightlossforchildren.com Web site will lead the Data Safety Monitoring Board (DSMB). She is a pediatric cardiologist in the Division of Cardiology at the University of Minnesota. Her research focuses on identifying risk factors for heart disease and diabetes in children and young adults. She and two local practitioners (one pediatric gastroenterologist and a general pediatrician) will review all toxicity data at the end of the 8-week safety study and throughout the trial. Any of them will have the authority to stop the study at any time should they find the safety of the children is in question.

Dr. Daniel Jackson, pediatric gastroenterologist will be part of the DSMB. He is the director of the Nutrition Clinic at Primary Children's Medical Center. He sees many overweight children in his practice and has expressed an interest in our study.

D. Research Design and Methods:

We will conduct a double blind, prospective trial involving 80 prepubertal, overweight children from 7 to 10 years of age to be randomized into 2 groups (one treatment and one control). The treatment group will receive the oral micronized fiber formula in the form of 2 capsules of 500 mg each to be taken twice a day for a total of 2 grams of micronized fiber per day. The placebo control group will get identical capsules filled with maltodextrin. Each 2-capsule dose will be taken 60 minutes before lunch and dinner. *The capsules will be swallowed whole with an 8-oz. glass of water. Subjects who have difficulty swallowing capsules will be advised to open the capsules, pour the content on a spoonful of yogurt or applesauce and consume it immediately. They will drink 8 oz of water right after having swallowed the spoonful. The study will last 16 weeks. During the first 8 weeks, a safety evaluation of the formula will be conducted with a subgroup of subjects as described below in the Safety Evaluation section.*

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Behavioral treatment is currently seen as the treatment of choice for childhood obesity. Therefore, rather than merely giving a placebo to the control group and PediaLean to the treatment group, we will provide to both groups a behavioral intervention as described in the Trim Kids™ book. By offering an intervention to the control group, we hope to decrease the probability of attrition. If the control group were to receive only a placebo and no other intervention, we are almost certain that the attrition from that group would make it more difficult to establish the validity of the study.

Randomization process, Sample Estimation and Power analysis:

Eligible subjects will be randomly assigned to the treatment or placebo control group. Uniform, fixed randomization ($P = 0.50$) will be used with all enrolled subjects and parents consisting of single stratum, enrollment blocks of 4 subjects, and random numbers for blocked assignment generated using the Excel XP pseudo-random number generator³³.

Our main study outcome variable is body mass index. In the Italian study cited in the introduction and background, there was a reduction of 20% of the excess weight that may be translated into a reduction of one BMI unit in the treated group of children between ages 6 and 18. Our goal is to demonstrate a similar or greater effect in the reduction of BMI in our prepubertal sample. Based on growth charts for that age group and assuming that the subjects will gain no more than one vertical inch during our 4 month trial (children of that age gain about 2 vertical inches per year), we are extrapolating that the children on PediaLean could lose between 5 to 10 pounds above and beyond what the placebo group will lose on the Trim Kids™ Program). A sample size of 29 in each group will have 80 percent power to detect a moderate effect size of 0.667 (a reduction in 1 BMI unit assuming a standard deviation of 1.50) using a two-group t-test with a 0.050 one-sided significance level. Assuming a 30% attrition rate, we plan to enroll 40 subjects per group to compensate for the dropouts.

Methods

1. Safety Evaluation:

A data safety monitoring plan has been developed for this study and is described in details in section E (Protection of Human Subjects). As part of the plan, a Data Safety Monitoring Board (DSMB) will be selected prior to study initiation. It will consist of 3 outside independent pediatric experts (Dr. Steinberger, Dr. Jackson, and a pediatrician). This Board will be charged with the evaluation of interim data, as described below. It will conduct a thorough toxicity review on a 2-month basis. The Board will be informed of all adverse events in a timely manner (see below). It will have the power to place the study on hold, require stat safety amendments, and ask for medical intervention when needed, should PediaLean® or the placebo have significant adverse effects.

The study will begin with enrollment and blinded randomization of 12 patients from 7 to 10 years of age to one of the two groups (6 in the PediaLean® treatment and 6 in the placebo control groups). At each visit the PNP will monitor the subjects for toxicity using the NCI toxicity criteria. She will fill the pertinent cells of the Gastrointestinal and Pain sections of the NCI toxicity document³⁴ and the results will be compiled in a data toxicity report by the coordinator for each patient. After the 12 patients have been enrolled and have completed 8 weeks of participation, further enrollment will be temporarily put on hold for 2 weeks. Copy of the data toxicity report will be sent to the DSMB for interim analysis. Only if the treatment is considered reasonably safe by the DSMB will additional patients be permitted to enroll.

Even if the treatment is deemed safe with the initial subgroup of patients, toxicity evaluation will continue for all subjects throughout the study. Every 2 months, the study coordinator will compile the toxicity report of all subjects so the PI may submit it to the DSMB. The DSMB will evaluate this report

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and respond to the PI within 30 days. The PNP or the coordinator immediately will report any adverse event graded 2 or greater to the PI, who will inform the DSMB. The DSMB will have the power to place the study on hold or take other appropriate measures to ensure the safety of the participating children.

2. Subject Recruitment and Eligibility:

Participants will be recruited via advertisements placed in pediatricians' offices, family practices, and clinics serving minorities around the Salt Lake valley. Our goal is to enroll 80 overweight children (50% girls, 50% boys, 60% of them from an ethnic minority [principally Hispanics] and 40% Caucasians). The child and one parent will be phone-screened by the coordinator. After they pass the phone screen, the child accompanied by one parent will be invited to our facilities and meet with Shala West and with Dr. Nathalie Chevreau. Families who live 25 miles or more (one way) from the Center will be reimbursed for the exact mileage at 35 cents per mile.

Ms. West will lead the orientation procedure and prepare the families for the screening session. The orientation will consist of a brief description of the study, its importance and risk factors. Parent and subject will complete a medical history and a physical activity questionnaire. This will be followed by a screening procedure where the child will undergo a physical examination and be interviewed by Debbie Sandt (PNP) to determine eligibility. If eligible, the parent(s) and subject then will participate in the IRB approved consent procedures. At the conclusion of the testing, the parents will be given a \$15.00 testing incentive payment. The schedule confirming the first day of intervention class and the next testing visit will be distributed to the parents. They also will be given the phone number of the study coordinator should they experience any problems or have any questions. The study coordinator will perform a follow-up call to the parents to answer any questions and remind them of the next visit (Visit 1 – baseline). The subject will be randomized to be either in the treatment group (PediaLean®) or the control group (placebo).

a. Screening Visit (approximately 1-1/2 hours):

- Orientation, screening and consent procedures (approximately 30 minutes)
- Family and subject medical history and physical activity questionnaire (approximately 15 minutes)
- Measurement of weight, height, for body mass index (BMI) calculation (approximately 5 minutes)
- Measurement of waist and hip circumference (approximately 5 minutes)
- Physical (Approximately 20 minutes)
- Tanner maturation self assessment (approximately 15 minutes)

Inclusion criteria:

- Subjects must be prepubertal (Tanner score less than 3) and between 7 and 10 years with a BMI greater than the 85th percentile for age and gender.
- Only one child per family may be included.
- Subjects of any ethnicity may be included. However, parent and child must be able to communicate in English, Spanish or French.
- Subjects' parent must have a home or work phone number.

Exclusion criteria:

Based on the medical and family history questionnaire, children who had a low birth weight (<2.5 kg) or from mothers who had gestational diabetes will be excluded. Subjects with evidence or history of irregular heart beat; heart palpitation or syncope, liver disease, viral

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disease, lung disease, or nervous system disease will be excluded. Individuals currently taking medications including diuretics, steroids, or other drugs that stimulate the adrenal gland also will be excluded. Individuals with significant emotional problems or who currently are taking medication for clinical depression or other diagnosed psychological conditions will not be eligible for this study.

3. Intervention:

After the subjects have been determined to be eligible, they will come for a total of 6 visits to our facility over the 4 months period. The variables to be measured or calculated at each visit are summarized in Table 2:

Table 2:

Variables/Time	Week 1 (baseline)	Week 2	Week 4	Week 8	Week 12	Week 16
Medical/Physical evaluation	X	X	X	X	X	X
Toxicity Evaluation (Adverse events report)	X	X	X	X	X	X
Weight	X	X	X	X	X	X
Height (to calculate BMI and growth over the 4 months)	X	X	X	X	X	X
BMI calculation	X	X	X	X	X	X
Waist and hip circumference	X		X	X	X	X
Body composition by Bioelectrical impedance	X			X		X
Treatment compliance		X	X	X	X	X
Safety questionnaire	X	X	X	X	X	X
Fasting blood Lipids (total cholesterol, HDL, LDL, TG)	X					X
Fasting blood glucose	X					X
Fasting blood insulin	X					X
Food frequency questionnaire	X			X		X
3-day dietary records		X		X		X
Physical activity questionnaire/ exercise log		X	X	X		X

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- a. **Week 1 visit – baseline (about 2 hours):** Subjects and at least one parent will come to the Center for group education and testing. The families will receive a free Trim Kids™ book and will attend a two-part orientation on the different aspects of the program.
- i. **Group orientation Part 1:**
 - Commitment: a 10-minute session on internal and external motivators and willingness to change.
 - Nutrition: a 30-minute session on the basic principles of nutrition, food type and portion size, and building their own menus. Subjects will be instructed on appropriate serving sizes using plastic food models.
 - Goal setting and compliance: a 20-minute session action plan, self-monitoring, and log keeping.
 - ii. **Testing:** Each subject's weight, height, waist circumference and body fat will be measured. Growth curves will be plotted. The subjects with the help of the family member will complete a food frequency questionnaire. For details on the testing procedures, please refer to section 7 below on Testing and Measurements.
 - iii. **Medical Evaluation:** *Each subject and family will meet the PNP for a medical evaluation, and a review of growth and potential adverse events.*
 - iv. **Meeting with the study coordinator:** The subjects will be given a one-week supply of the placebo or PediaLean capsules based on the study randomization. They will be instructed on how to fill the capsule compliance log. They will be scheduled to come back the following week and bring the first Trim Kids™ Weekly Checklist, a 3-day diet-log, the capsule compliance log and the bottle with any remaining pills.
- b. **Week 2 visit (90 minutes):** One week later, parent and child will come back to our facilities for part 2 of the orientation of the Trim Kids™ program.
- i. **Group orientation Part 2:**
 - Exercise: a 30-minute session on proper techniques on exercises (choosing an exercise, resting, stretching, taking heart rate).
 - Behavior modifications: 20 minutes on modeling, role-playing, problem solving, limit setting, habit formation.
 - ii. **Testing:** Weight, height, waist and hip circumference will be measured (see section IV for details on the procedure).
 - iii. **Medical Evaluation:** *Each subject and family will meet the PNP for a medical evaluation, review of growth rate, and review of adverse events, if any.*

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- iv. **Meeting with the study coordinator:** Each subject and family member will meet with the coordinator and turn in his or her 3-day food diary and capsule compliance log. The coordinator will count the capsules left in the bottle and review with them the process of paper work and expectations of the study. She will record any side effects or adverse reactions reported by the parents.

The subjects – with the help of the family member present – will be asked to complete a food frequency questionnaire, an activity questionnaire, and a satiety scale.

Subjects will be dispensed 2 weeks regimen of capsules and will be scheduled to return to the center in two week's time with their exercise log and their weekly checklists.

- c. **Week 4 visit:** Subjects' weight, height, waist and hip circumference will be measured. *Subject and family member will meet the PNP for a medical assessment and report any side effects.* They will meet with the exercise specialist to review the exercise log and discuss success and barriers. Prior to meeting with the coordinator, they will fill in the satiety scale. The coordinator will review it along with their capsule log and weekly checklist. Subjects will be asked to fill in a 3-day food record prior to the next visit.
- d. **Week 8 visit:** Subjects' weight, height, waist and hip circumference, and body fat will be measured. *The PNP will examine the subjects and assess growth. Any adverse events reported by the parents will be documented.* Subjects and parents will meet with the exercise specialist, who will review the exercise log, and with the psychologist, who will review the Trim Kids™ Checklist. The specialists will identify the areas of success, perceived weakness and failure, and instruct the subject accordingly. The coordinator will review the subjects' 3-day food record and the satiety scale. Upon review of the capsule log, the coordinator will give a small reward in the form of sports equipment to the subjects who report to be at least 90% compliant with taking the capsule. She will remind them to bring another activity log for the next visit and dispense another 4 weeks' worth of capsules. The subjects will be scheduled to return back in 4 weeks.
- e. **Week 12 visit:** Subjects' weight, height, waist and hip circumference will be measured. *The PNP will examine the subjects, assess growth, and record adverse effects. She will give a prescription for blood to be drawn so parents can take the subjects to have their fasting insulin, glucose and lipid profile testing before the last visit.* Subjects will meet with the coordinator and review the capsule log, weekly checklist, and satiety scale. Subjects will be asked to fill in a 3-day food record prior to the next visit.
- f. **Week 16 (Final visit):** Subjects' final weight, height, waist and hip circumference, and body fat will be measured. Subjects will meet with the coordinator and review the capsule log, weekly checklist, 3-day food diary and exercise log. Subjects and family will complete the satiety scale and the food frequency questionnaire. A small reward in the form of sports equipment will be given if the subject is at least 90% compliant with taking the capsule. If the parents have not missed a visit, they will be given a \$20.00 cash reward. The PNP will administer an exit physical examination and review the results of the *insulin, glucose* and lipid profiles with them.

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4. Nutrition Education and Diet Supervision:

Nathalie Chevreau PhD, RD, and Shala West, RD will instruct both groups on nutrition as presented in the Trim Kids™ book.

Education will continue via feedback on the 3-day dietary record (weeks 8 and 16), and the findings of the food frequency questionnaire.

Subjects and parents will evaluate the subject's compliance to the plan by filling out and submitting the Trim Kids™ weekly Checklist and the 3-day food diaries, at weeks 8 and 16.

5. Exercise Instruction:

Tiffany Strobel will instruct both groups on physical activities and exercises as described in the Trim Kids™ book. The exercise activities will correspond with the child's physiological condition of obesity and ability to comprehend, and apply health and fitness information to daily life situations. Exercise duration and intensity will be tailored to fit the progress that subjects make during the study. All subjects will receive examples of the routine to follow at home, and will be instructed on proper use of the log form.

Subjects and parents will evaluate compliance to the exercise plan by completing and submitting the self-reported activity log forms.

6. Family Behavioral Counseling

Shala West, assisted by Dr. Daniel Mowrey, will instruct the family on behavior modifications skills as described in the Trim Kids™ book. She will teach how to use discussion, modeling, role-playing, and guided problem solving to achieve desired habits. Topics such as self-monitoring, commitment, limit setting, habit formation, goal setting and action plans, decision-making skills, attitudes, and assertiveness training will be discussed.

7. Testing & Measurements:

Every child will be tested for the outcome variables according to schedule shown in Table 2.

- **Toxicity Evaluation:** Any adverse events reported by the parents or assessed by the PNP during medical examination will be scored using the NCI toxicity criteria. A toxicity report will be recorded for each subject and submitted to the DSMB for evaluation. If the subject drops out of the study, every effort will be made to contact the family in order to assess whether the dropping out was due to adverse events or other reasons (i.e. time constraints, etc.).
- **Measurement of Weight:** The subject will be asked to arrive close to the same time for each visit. A calibrated Health O Meter 402KSL Physician Balance Beam Scale will be used to obtain the weight in kilograms of each subject. Subjects will be weighted without their shoes and the result will be recorded on the data statistical form.
- **Measurement of Height:** A calibrated Health O Meter 402KSL stadiometer will be used to obtain the height in centimeters of each subject. The subject will be measured without their shoes. Height will be recorded to the nearest tenth of a centimeter (0.1 cm).
- **Growth:** *Growth will be measured as a change in height over the 4-month period. Height will be measured as a function of age and gender. It will be plotted on the 2000 CDC growth charts at each visit. The dietitian and the PNP will review the data to ensure that the increase in height over the 4-month period is appropriate and that height increments are normal for the subjects' respective chronological ages.*

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- **BMI calculation:** Body Mass Index will be determined using the following formula: Weight in kilograms/height in meters².
- **Measurement of Waist and Hip Circumference:** A measuring tape with metric scale will be used. *Waist:* Subject will be undressed or wear light clothing for this measurement. The subject will stand erect with abdomen relaxed, arms at sides and feet together. The measurement will be taken at the narrowest part of the torso, above the level of the navel. *Hips:* Subject will stand erect with arms at sides and feet together. The tape will be positioned at the maximum circumference of the buttocks.
- **Measurement of body composition by Bioelectrical Impedance:** A *Tanita TBF-551 fat monitor* will be used to measure body composition. It uses a simplified version of BIA that uses leg-to-leg bioelectrical impedance analysis. The subject will step barefoot on the unit to allow contact between the footpad electrodes and the bare feet. The footpad sends a safe, low-level electrical signal through the body. A computer software in the microprocessor imbedded in the unit measures the electrical resistance, and based on the subject's gender, height, weight and age, determine the body fat percentage. The process will be repeated two additional times. The average from the 3 measures will be calculated and recorded on the data statistical form.
- **Treatment Compliance:** Compliance will be measured by subtracting the number of capsules brought back by the subject at a subsequent visit from the number of dispensed capsules at the preceding visit. A ratio of compliance will be calculated.
- **Satiety:** Subject's satiety will be measured using the ordinal silhouette scale developed by Dr. Myles Faith et al designed to quantify feeling of fullness (satiety) in children at every visit (see attached pictures on Figure 1).

Figure 1: satiety scale for boys and girls



- **Lipid Profile Testing:** in this Phase I trial, the most economical and practical way to have the subjects' fasting blood lipids levels measured is to use an outside blood center. Parents will take the child to any of the designated blood draw centers before the subjects go to school. Prior to the study, we will have secured agreements with at least 5 centers that will be able to draw blood samples for the study and we will use *Lab Corp to conduct the analyses*. Subjects will be required to fast for 12 hours prior to the test. 1.8 cc of whole blood will be obtained by venous puncture, collected in serum separator tubes (containing 1.5 mg/ml EDTA), centrifuged immediately to separate cells from serum and refrigerated for transport. Total cholesterol, triglycerides, and high density lipoproteins will be measured on a Beckman Synchron CX5 automated chemistry analyzer and the LDL cholesterol will be calculated using the Friedewald equation.

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- **Fasting serum glucose level:** Fasting serum glucose level will be measured by an enzymatic method.
- **Fasting serum insulin level:** Fasting plasma insulin level will be measured by chemiluminescent immunoassay.
- **Nutritional Intake**
Food intake will be recorded on weekly diaries found in the Trim Kids™ book. Subjects will be instructed to review the diaries every week with their parents and assess how well they met their goals. In addition, the children in both groups will be required to bring a 3-day food diary at weeks 2, 8 and 16 to the coordinator. Calorie, grams of carbohydrates, protein and fat, number of serving of fruits, vegetables and milk products will be calculated using the Food Processor software and compared with the diet goal. For each time the subjects bring their diaries and meet their diet goal, they will earn points that will be converted into lottery tickets (i.e. the more points they earn, the greater chances of winning). Three participants will have a chance to win \$20 at the lottery drawn every 4 weeks (points for activities will be included – see below). At weeks 8 and 16, they will fill in a food frequency questionnaire for an additional measurement of compliance with the week meal plan, at our facility.
- **Physical Activity Report**
The subjects will record the number of minutes of exercise per day on a self-report exercise log. Like the food record, the subjects will be required to bring their logs on weeks 4, 8, and 16. The coordinator will give feedback at those times. Similarly, for each time they bring their activity log and meet their goal, they will earn points to be converted into tickets and added to the pool for that week's prize lottery.

8. Statistical Analysis:

The coordinator will enter the data into the Microsoft Access XP relational database for data management. Data analysis will be conducted using STATA 7.0 and SPSS 11.0 and performed by Dr. Stephen Alder, biostatistician and director of the Research and Statistical Consulting Service in the University of Utah Department of Family and Preventive Medicine.

The primary statistical analysis will focus on differences in BMI between treatment and control group subjects at the conclusion of the trial (week 16). Secondary statistical analyses will focus on differences in *body composition, waist and hip circumference, satiety, nutrient intake, blood lipids, glucose and insulin level and compliance with the treatment*, and longitudinal trend analyses of outcome variables during the duration of the study. Baseline comparisons between study groups will be conducted to determine whether meaningful differences exist between subjects assigned to the treatment and control conditions. Differences observed between the two groups will be assessed for inclusion as covariates for outcome comparisons. Analyses also will be conducted to determine whether adjustments are needed in the final analyses due to systematic attrition associated with pre-randomization measures or group assignment. Assessments of these analyses will be used to determine whether the missing values can be considered missing completely at random (MCAR), missing at random (MAR), or informative. Descriptive statistics will be calculated to characterize the sample in order to assess generalizability and subject/parent use of treatment or control intervention resources. Fidelity analyses will also be included that compares each subject's: 1) nutritional plan with responses to the food frequency questionnaire and the 3-day dietary records, and 2) exercise logs with exercise instruction received.

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Two types of statistical analyses will be considered for the primary and secondary analyses. The first type, a post-intervention analysis of week 16 measurements using independent samples *t*-tests, does not account for differences in baseline measures between study groups and assumes that endpoint differences in the absence of a treatment effect will be zero. The second type, analysis of covariance (ANCOVA), allows for the accounting of baseline measures when comparing week 16 measurements³⁵. For some variables, multiple measures will be available (e.g., BMI, body composition etc.). Likelihood-based inferential methods, available to address longitudinal analyses with missing data, will be evaluated for use (using SAS PROC MIXED). Repeated-measures analysis of variance and methods for trend analyses will be assessed to further analyze the nature of the difference between groups over the course of the study. All analyses will use an alpha-level of 0.05.

All statistical tests will be evaluated to determine if assumptions are sufficiently met. If meaningful violations are observed, attempts will be made either to make adjustments (e.g., transforming variables) or use alternative statistical methods more suitable to the data, including non-parametric tests. The primary analysis will follow an *intent-to-treat* approach, with original group assignment maintained throughout the analysis regardless of the actual treatment received. *On-protocol* analyses will also be conducted based on fidelity analysis assessments of compliance and will be considered as secondary.

E. HUMAN SUBJECTS RESEARCH

PROTECTION OF HUMAN SUBJECTS

The following data and safety plan has been developed for the study and a DSM board is described in details in the Method section on page 37.

1. Risks to the Subjects:

a. Human Subjects involvement and characteristics:

Eighty prepubertal children between ages 7 and 10 will be enrolled in the study. They will all be overweight with a BMI-for-age greater than the 85th percentile. They will be split into 2 groups of 40: the treatment group will receive gelatin capsules filled with a micronized fiber (PediaLean) and be instructed to take 2 capsules twice a day with at least 8 oz water 60 min before lunch and dinner (for a total of 2 grams of micronized fiber per day). The control group will receive similar looking capsules filled with Maltodextrin as the placebo. They will also take 2 capsules twice a day before meals as indicated above. We plan to enroll 50% boys and 50% girls. Because minority experiences a higher rate of obesity than Caucasian, we will aim to enroll between 50% and 60% minority children. Children who enter the study will pass the inclusion and exclusion criteria described in the Research and Design Section (page 38). Participation will be totally voluntary.

b. Sources of Materials:

Data that include demographic, medical history, anthropometrics, age, gender, body composition, waist and hip measurements, food intakes, activity logs will be obtained solely for the purpose of the study and kept confidential for any purpose other than for the study. Parent and child confidentiality will be upheld at all times. Parent and child will have the right to withdraw at any time. Parent(s) will be present during all screening and testing procedures.

John Stillman, director of The Investigational Review Board of the University of Utah has confirmed that his board will review, approve, and monitor the study.

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c. **Potential Risks:**

Most of the testing and measurements will be non-invasive and not physically demanding. The intervention includes taking a fiber-based formula orally and receiving nutrition, fitness education and family counseling. The risk of taking the capsules is minimal. The capsule is soft and will disintegrate easily in the stomach, releasing the powder. Those subjects who have difficulty swallowing pills will be able to open the capsule, pour the contents in a spoonful of applesauce or yogurt, and drink water afterward. *Potential risk, also referred to as Adverse Events, may include bloating and cramping associated with an increase in fiber that can be resolved by decreasing or stopping the dose until resolution of the symptoms and gradually restarting the formula. Other complications that are associated with a typical fitness regime may arise. The two blood drawings to measure lipid profiles, insulin and glucose levels which are minimally invasive, will be done by certified phlebotomists at selected blood centers.*

2. **Adequacy of Protection against Risks:**

a. **Recruitment and informed consent:**

Children will be recruited by advertisements in local pediatricians' offices, and family clinics, especially from those that serve the minority population. We plan to enroll 80 children from 80 families (one child per family) with no exclusion of specific ethnic groups.

After the eligibility criteria have been met (see page 36) and the parent and child choose to participate, the intervention team will individually meet with each family. An explanation of all procedures, potential risks, temporary side effects, anticipated benefits, and alternative methods will be given to both the child and parent(s). Assurance that all questions have been answered will be obtained. Names and telephone numbers of the coordinator, the PI and the PNP will be given to each study subject for use if future questions arise. Signatures of both parent and child will be obtained on the consent form. No money or gift will be offered to the parent as an incentive to enroll their children.

b. **Protection against Risk**

A PNP will be available to monitor any adverse events that may arise from testing or intervention recommendations. She will examine the child at each visit and fill in the toxicity report for that period. Occurrence and severity of adverse events will be graded according to the NCI Common Terminology Criteria for Adverse Events version 3.0³³. Following the visit, the coordinator will compile the toxicity data for each child. When the first twelve children have completed the first 8 weeks of study, she will give the toxicity report to the PI who will send it to the DSMB. Any adverse event graded 2 or greater immediately will be reported to the DSMB. The DSMB will have the power to place the study on hold or take other appropriate measures to ensure the safety of the participating children. Enrollment of an additional 68 subjects will complete our study sample, and toxicity data will be collected at each visit. Every 2 months, the coordinator will give the compilation of the toxicity data to the PI who will send it to the DSMB for review.

i. **ADVERSE EVENTS definitions**

An Adverse Event (AE) is any untoward medical occurrence in a patient or clinical investigation subject who was administered a pharmaceutical or nutraceutical product and that does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a investigational product, whether or not related to the investigational product. Signs

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and symptoms related to lack of efficacy of the product (in this case, subjects' BMI increases more in the PediaLean group than in the placebo) should not be considered adverse events. Also planned surgical interventions should not be considered adverse events.

A SERIOUS ADVERSE EVENT (SAE) is any event that suggests a significant hazard, contraindication, side effect, or precaution, whether or not it is considered to be associated with the trial product. An SAE is one that meets any of the following criteria:

- i.1 Results in death.*
- i.2 Is life-threatening*
- i.3 Requires inpatient hospitalization or prolongation of existing hospitalization.*
- i.4 Results in persistent or significant disability/incapacity.*
- i.5 Other important medical events that based upon appropriate medical judgment are thought to jeopardize the patient or subject and/or require medical or surgical intervention to prevent one of the outcomes defining a serious adverse event.*

AN UNEXPECTED ADVERSE EVENT is any experience not previously reported for PediaLean®

ii. *Classification of Adverse Events*

Severity

For this study, the severity of an adverse event will be rated according to the following definitions:

Mild:

- Symptom barely noticeable to subject; does not influence performance or functioning. Prescription drug not ordinarily needed for relief of symptom but may be given because of personality of subject.*

Moderate:

- Symptom of a sufficient severity to make subject uncomfortable; performance of daily activities influenced; subject is able to continue in study; treatment for symptom may be needed.*

Severe:

- Symptom causes severe discomfort. May be of such severity that subject cannot continue in study. Severity may cause cessation of treatment with test product; treatment for symptom may be given and/or subject hospitalized.*

Relationship to Study Formula

For this study, the adverse event cause and effect relationship with the study drug will be classified as follows:

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Definite: When the event:

- follows, in a reasonable temporal sequence, the administration of the drug or in which the drug level has been established in body fluids or tissues.
- follows a known or expected response pattern of the suspected formula.
- is confirmed by improvement after de-challenge or dosage reduction of the formula.
- reappears after repeated exposure (re-challenge).

Probable: When the event:

- follows, in a reasonable temporal sequence, the administration of the formula.
- follows a known or expected response pattern of the suspected formula.
- is confirmed by improvement after de-challenge or dosage reduction of the formula.
- cannot be reasonably explained by the known characteristics of the patient's clinical state.
- no re-challenge test or laboratory confirmation is available.

Possible: When the event:

- follows, in a reasonable temporal sequence, the administration of the formula.
- follows a known or expected response pattern of the suspected formula but could have been easily produced by a number of other etiologies.

Unlikely: When there is no reasonable temporal association between the study drug and the suspected adverse event. The event could have been related to the patient's clinical state or concomitant treatment(s).

Not related: When sufficient information exists to indicate that the etiology is unrelated to the study formula

Unknown or unassessable: When causality is not assessable, e.g., because of insufficient evidence, conflicting data, or poor documentation.

iii. Reporting Adverse Events

All AEs, irrespective of the relatedness to the study formula, reported in interviews or found by medical examination will be recorded on the toxicity report. The coordinator will submit the report to the PI. The PI will be responsible for ensuring that all information concerning AEs is reported to the DSMB and the IRB.

iv. Reporting Serious Adverse Events

Parents must report immediately any SAEs occurring within 7 days post study to the PI and the DSMB. The PI or study coordinator will call as well as fax the toxicity report to the DSMB within 24 hours of observation or notification of an SAE (phone and fax numbers will be determined at the beginning of the study). The IRB will also be notified of any serious adverse event which is unexpected and at least possibly related to the study formula according to the policies of the respective institution's IRB.

The DSMB will review all incoming toxicity reports for accuracy and completeness and will decide whether to place the study on hold. SAEs will be reported to the FDA by the DSMB.

v. Follow-Up Period for Serious Adverse Events and Non-Serious Adverse Events

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Follow-ups of all SAEs will be done until the outcome is resolved, or, in the PNP's opinion, a stable condition is reached, or until the patient is unavailable for follow-up.

Based on the medical judgment of the PNP, all non-serious AEs (including any abnormal laboratory values identified as AEs by the PNP) will be followed up to 4 weeks after the patient completes the study. All non-resolved, non-serious AEs beyond such date will be recorded as "ongoing" without further follow-up.

vi. *Interim Analyses*

In this study interim analyses of data obtained from the first 12 randomized patients for safety will be evaluated. The interim analyses will be performed as soon as possible after the 12th patient has completed 8 weeks of the study. However, approval for continuation of the study by the DSMB will be given not earlier than 15 days after the 12th patient has completed the 8 weeks of the study, because serious adverse events occurring within 15 days post study formula administration should be considered for the decision of the DSMB. For statistical issues and methods refer to following sections.

For the interim analysis of the data from this double-blind treatment arm only the statistician performing the analysis and the DSMB will be unblinded. All other members of the study team will remain blinded until final analysis.

vii. *Safety Analysis*

Descriptive statistics (and 95% Confidence Intervals) will be provided for the incidence of adverse events. In addition, all adverse events will be listed. The laboratory data will be analyzed and described as follows: listing, counting of values out of the reference value range, counting of marked abnormalities. "Shift tables" will be used to evaluate categorical changes in clinical laboratory parameters by examining the proportion of patients whose test values are outside the specific ranges at their final visit or changed at the final assessment. Summary value will be generated for quantitative variables and observed abnormalities will be documented.

3. Potential Benefits of the Proposed Research to the Subjects and Others

Participation in this research will benefit the parents and the subjects by providing information on the subject's health status and disease risk related to obesity. Children (with their parents) will be enrolled in a non-invasive treatment program at no cost. Parents will be able to use the knowledge and strategies with other members of the family. Weight loss of already overweight children in that age group will benefit these children by decreasing the likelihood of diabetes or any other complications related to obesity and decreasing the teasing and chastising that often occurs in schools and public places.

4. Importance of the knowledge to be gained

Children in the United States probably are the heaviest on the planet and the need for a safe, pharmacologic, treatment is needed especially for youngsters. This research will demonstrate efficacy of a fiber-based formula in potentiating the decrease in BMI achieved with behavioral treatment alone. Regardless of whether weight loss occurs (Subjects who maintain weight while growing in stature will see their BMI decreased), this fiber-based formula will, without doubt, help improve lipid profiles and blood glucose control while having a very low probability of minimal side effects.

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Principal Investigator: Chevreau, Nathalie

INCLUSION OF WOMEN

We intend to enroll 50% boys and 50% girls in all ethnic groups. There is a higher degree of overweight children among minority children, but the proportion between the 2 genders is relatively the same. An obesity study of 7208 children from 5 to 17 years old in Texas by Parker et al (International J. of Obesity, March 2001) showed 23% of Mexican females, age 6-11 were overweight (BMI > 95thile) as well as 26% of Mexican boys of same age. Therefore a 50/50 split is appropriate for this study.

INCLUSION OF MINORITIES

Based on the National Longitudinal Survey of Youth conducted from 1096 to 1998 on 8270 children (ages 4 to 12 years old), overweight prevalence (BMI greater than 95thile) was 21.5% among African Americans, 21.6% among Hispanics, and 12.3% among non-Hispanic Caucasians (Strauss et al., JAMA 2001). This shows that there is roughly twice the occurrence of obesity in Hispanic children than non-Hispanic Caucasians. We would like to enroll subjects close to this ratio, or between 45 to 55 Hispanic or black American children and 30 to 35 Caucasians.

INCLUSION OF CHILDREN

This study targets overweight children. We are including prepubertal children from ages 7 to 10 to avoid the variability of weight associated with puberty and to treat the child before any weight increase linked to maturation occurs.

DATA AND SAFETY MONITORING PLAN

The data and safety plan has been described in detail under the heading "Protection of Human Subjects". Please refer to pages 45 to 49. In summary, the plan includes a Data Safety Monitoring Board comprised of 3 pediatric experts who will review all toxicity reports submitted by the PI on an ongoing basis. A PNP will conduct all medical examinations and assess whether the subjects experience any adverse events due to the treatment or other reasons. The DSMB will have the authority to stop the study if the safety of the children is in question, and may request amendments to the protocol and/or request medical treatment for the children. The team will follow the plan thoroughly to ensure the well being of the children at all times.

F. Vertebrate Animals: N/A

G. Literature Cited:

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 INFORMATION

Principal Investigator: Chevreau, Nathalie

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INFORMATION

Principal Investigator: Chevreau, Nathalie

H. Consortium/Contractual Arrangements

None

I. Consultants

Tab 53

SUMMARY STATEMENT
(Privileged Communication)

Release Date: 03/28/2003

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Application Number: 1 R43 HD045097-01

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SALT LAKE CITY, UT 84116Review Group: ZRG1 SSS-T (10)
Center for Scientific Review Special Emphasis PanelMeeting Date: 02/27/2003
Council: MAY 2003
Requested Start: 07/01/2003
PCC: ENG -GG
Dual IC(s): DK

Project Title: Micronized fiber, natural weight loss agent for preteens

SRG Action: Priority Score: 306

Human Subjects: 44-Human subjects involved - SRG concerns

Animal Subjects: 10-No live vertebrate animals involved for competing appl.

Gender: 1A-Both genders, scientifically acceptable

Minority: 1U-Minorities and non-minorities, scientifically unacceptable

Children: 2A-Only Children, scientifically acceptable

Clinical Research - not NIH-defined Phase III Trial

Project Year	Direct Costs Requested	Estimated Total Cost
1	100,000	100,000
TOTAL	100,000	100,000

ADMINISTRATIVE BUDGET NOTE: The budget shown is the requested budget and has not been adjusted to reflect any recommendations made by reviewers. If an award is planned, the costs will be calculated by Institute grants management staff based on the recommendations outlined below in the COMMITTEE BUDGET RECOMMENDATIONS section.

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06/30/03

PL003083

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CHEVREAU R43HD045097-01**INCLUSION OF MINORITIES PLAN UNACCEPTABLE****PROTECTION OF HUMAN SUBJECTS UNACCEPTABLE**

RESUME AND SUMMARY OF DISCUSSION: The Phase I SBIR application is from a team of experienced investigators. This study proposes a 4-month double blind, randomized prospective trial of 104 pre-pubertal, overweight children between the ages of 7-10 years who will be randomized into 2 groups, one treatment (receiving Pedialean) and one control. Other strengths include potential for an early treatment of childhood obesity; and the innovation in usage of micronized fiber in children as a weight loss agent. These issues and the identified weaknesses of the clinical trial were the focus of discussion at the study section meeting. Major weaknesses identified are all in respect to the experimental design of the clinical trial. There is a general lack of quantitative criteria to measure success. In addition, there is lack of sufficient pediatric medical expertise to monitor safety and efficacy in this trial. Further, it is proposed that the laboratory work will be carried out in five different sites and the study section is of the opinion that this may lead to errors. These issues and the lack of data safety monitoring plans for the randomized trial and the lack of attention to higher degree of prevalence of overweight in minority children have weakened the application.

DESCRIPTION (provided by applicant): The objective of this research is to demonstrate the efficacy and effectiveness of the first and only weight loss agent for preteens in the United States paving the way for its widespread marketing and distribution. This would serve as an early treatment and/or prevention of childhood obesity that is critical in preventing related complications and in stemming the tide of pediatric obesity in the US.

The experimental compound (Pedialean™) is a highly purified, micronized fiber extract from a Japanese tuber. We will conduct a rigorously controlled, double-blind, randomized, 4-month trial in overweight 7-10 year old children. The major outcomes to be assessed in this intervention will include body mass index (BMI), body fat, hunger/satiety and lipid profile. One hundred and four prepubertal, overweight children will be randomized into 2 groups (one treatment and one control). The treatment group will receive the oral micronized fiber as 2-500 mg capsules taken twice a day (2 grams of fiber per day) 60 minutes before meals. The placebo group will get maltodextrin-filled capsules. Both treatment and control children will follow the Trim Kids TM program, shown to be an effective family-based weight loss management tool based on the Social Cognitive Theory (SCT). This will minimize or eliminate family differences and allow better detection of the effect of Pedialean™. Differences between treatment and control groups at the conclusion of the trial (week 16) will be measured by independent sample t-tests. Analysis of covariance (ANCOVA) will allow for the accounting of difference in baseline measures when comparing week 16 measurements. Repeated-measures analysis of variance methods will be used to further analyze differences between groups over the course of the study.

CRITIQUE 1:

SIGNIFICANCE: This proposal addresses the need for a safe and efficacious approach to treating pediatric obesity. The proposal provides a background regarding the development of Pedialean, which is a micronized fiber capsule derived from Japanese konjac root - a traditional as a thickening agent. The advantages of this product over other fiber sources and medications are carefully described but most statements do not included citations from the scientific literature as evidence.

APPROACH: The aims and hypotheses to be tested appear to be logical, but more issues may need to be addressed. Case reports and testimonial are included as preliminary evidence of the acceptability and potential efficacy of using Pedialean in the treatment of severely overweight children, but these data do not address issues such as those who do not do well or problems encountered. Pedialean is produced commercially by a Japanese company, and Dr. Chevreau was instrumental getting the

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General Nutrition Centers as the American distributor. The product can currently be purchased in the United States from a website.

The study design is simple and will determine if the addition of Pedialean increases weight loss in the Trim Kids program. However, a number of dependent variables are listed, but insulin resistance and nutritional status (intake or biomarkers) are not addressed. A total of 100 children will be enrolled in the study, but there is no power calculation indicating how many children will be needed to determine weight change or any other dependent variable. The analysis of covariance seems to be naive and does not address the importance of each variable included. While fiber supplements are widely used by adults, there are no measures of nutrition status or monitoring of potential problems in the growing children who will be in the study. The use of fiber supplements as a strategy to address the emerging pediatric weight problems is appealing, but more information is needed regarding methods for the study.

INNOVATION: This approach is highly innovative as a strategy for treating overweight youth. While fiber supplements have been used with adults, their use in pediatric weight control is limited. Therefore, a study of this type is timely. However, the fact that the product being evaluated is currently on the retail market raises questions about the role of the funding with respect to product development etc.

INVESTIGATORS: This is a strong research team lead by Natalie Chevreau, PhD, who is PI and who became the Nutrition Research Director at American Phytotherapy Research Laboratory in 2001. Dr. Chevreau has a number of research publications and is experienced in obesity research. Her work has been largely in the area of adult obesity, but other members of her team have considerable experience in weight control in children from a clinical and research perspective. A nurse practitioner will be responsible for the clinical trial, but the study participants who are likely to be a high risk may need physician oversight.

ENVIRONMENT: The resources needed to conduct the study are readily available to the investigators. This project will effectively use consultants to expand the resources and expertise of the research team. Pedialean is currently available for retail sales in the United States. Thus, product development per se will not be needed.

PROTECTION OF HUMAN SUBJECTS: The proposal outlines potential risks and benefits and addresses how human subjects will be protected. More attention to the health status of growing children should be included. A little more attention to privacy and the role of parents and children in the consent process will be needed. The University of Utah will provide IRB review for the study.

INCLUSION OF WOMEN: The proposal does not address the distribution of study sample with respect to gender and ethnicity as a separate section in the proposal.

INCLUSION OF MINORITIES: The demographics of the population in Utah are included in the proposal in included. With 90% of the community being Caucasian, the investigators need to consider issues regarding the higher degree prevalence of overweight in minority children.

INCLUSION OF CHILDREN: All study participants will be overweight children who are 7-10 years of age.

CRITIQUE 2:

SIGNIFICANCE: There is a significant rise in childhood obesity along with an increased occurrence of type 2 diabetes in youth. Thus, it is imperative that interventions be developed that focus on safe and effective weight loss for overweight children.

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APPROACH: This study proposes a 4-month double blind, randomized prospective trial of 104 pre-pubertal, overweight children between the ages of 7-10 years who will be randomized into 2 groups, one treatment and one control.

The treatment group will receive an over-the-counter experimental compound, called Pedialean, which is a highly purified micronized fiber extract from a Japanese tuber. The control group will receive placebo. The intervention group will receive this therapy as two 500 mg capsules taken twice-daily 60 minutes before meals while the control group will receive placebo at the same schedule. This study will also incorporate a behavioral, family-based intervention entitled TrimKids, which will be provided to both the treatment and control groups. This program has been shown to be an effective family-based weight loss intervention based on social cognitive theory.

While the study design appears rigorous with the inclusion of a placebo control group, there are no clear expectations for differences between groups. Primary outcomes include BMI, waist/hip circumference, body fat, satiety, blood lipid changes, and compliance with treatment or placebo. However, there are no power calculations or criteria for assessing success. For example, there is no estimation of an expected difference between the treatment and control groups. There is no presentation of statistical power.

In addition, the investigators may consider measuring markers of insulin resistance such as fasting insulin and blood glucose levels. Also, the physical assessments of the study patients omitted signs of insulin resistance such as acanthosis nigricans and hirsutism. While the investigators plan to study pre-pubertal or early pubertal (Tanner stages 1-2) children, it is possible that some of these overweight or obese (BMI >85th %tile) children will display such findings, especially with the association of an earlier onset of puberty with childhood obesity.

There are potential concerns about this oral compound as the background data only include a single 4-month study involving 53 obese, Italian children. There are no data presented to ensure safety with respect to absorption of nutrients or GI motility with the use of this experimental treatment. Therefore, there appears to be inadequate monitoring of safety issues, particularly in a group of healthy, growing, and developing youth.

INNOVATION: The use of a safe and effective weight loss agent for management of overweight and obese youths would be a welcomed innovation.

INVESTIGATORS: The study team is highly qualified to carry out this proposal. In addition to the Principal Investigator, Dr. Chevreau who is an RD with training in organic and inorganic chemistry, the team includes a behavioral psychologist, exercise physiologist, pediatric trainer, and biostatistician. However, medical expertise appears to be deficient as the proposal only includes a pediatric nurse practitioner.

ENVIRONMENT: The study will recruit patients and families from many different offices/areas. The main study site will be at the office of the PI. It is proposed that the lab work will be obtained at 5 different sites, which may lead to potential errors due to the large numbers of labs to be utilized in this clinical trial.

OVERALL EVALUATION: Overall enthusiasm for this proposal is tempered due to the lack of quantitative criteria to measure success. In addition, there is lack of sufficient pediatric medical expertise to monitor safety and efficacy in this trial.

PROTECTION OF HUMAN SUBJECTS: There is no data safety-monitoring plan. This trial involves overweight, healthy youths without appropriate medical monitoring. In addition, an external data safety monitoring board or monitoring plan may be necessary due to the recruitment and inclusion of children from many different sites.

INCLUSION OF WOMEN PLAN: Acceptable. Adequate numbers of female children are recruited.

INCLUSION OF MINORITY PLAN: Unacceptable. The investigators should consider issues of higher degree of prevalence of overweight in minority children, rather than explaining the issue of lack of minorities on basis of local demographics.

INCLUSION OF CHILDREN PLAN: Acceptable. The entire cohort will consist of pre-teen children.

CRITIQUE 3:

SIGNIFICANCE: The rise in childhood obesity continues unabated in U.S. At the present time, there are no currently approved drugs for the treatment of obesity in children. The discoveries of safe and effective treatments for childhood obesity are of extreme importance and will help reduce the complications associated with complex nutritional disorder.

APPROACH: The applicant proposes to use soluble fibers as a weight loss agent in obese children. The approach is a double blind, randomized, prospective trial of 104 prepubertal overweight children from 7 to 10 years. The study is well designed and she added a behavioral intervention to both arms, which justifies the use of a placebo. Moreover, she is using one of the better behavioral intervention programs available for children: Trim Kids, by Dr Sothorn. The study is hypothesis driven and the preliminary data provided are supportive of the hypothesis. The proposed fiber to be used is an extract from a Japanese tuber called Konjac root that has been used as a thickening agent and additives in many foods. A small trial of 4 month has been done in Italy in obese children, which was accompanied, by 20% weight loss, improvement of lipid profile and no side effects.

INNOVATION: The use of micronized fiber is a novel modality for reducing weight in children.

INVESTIGATOR: The applicant is well qualified for performing such a study. In addition she has assembled a number of experts in the field of Childhood Obesity that will help in performing and analyzing this important clinical trial. Letters of support are provided in the grant.

ENVIRONMENT: The environment is excellent.

OVERALL EVALUATION: This is a very well designed trial and the enthusiasm is high for this application.

PROTECTION OF HUMAN SUBJECTS: Unacceptable. Data safety monitoring plans are inadequately addressed.

INCLUSION OF WOMEN PLAN: Acceptable. Female children are adequately represented in the clinical trial.

INCLUSION OF MINORITY PLAN: Unacceptable. Minority children are not adequately represented, even though there is a higher degree of overweight children among minorities.

INCLUSION OF CHILDREN PLAN: Acceptable. Only children of age 7-10 will be recruited.

THE FOLLOWING RESUME SECTIONS WERE PREPARED BY THE SCIENTIFIC REVIEW ADMINISTRATOR TO SUMMARIZE THE OUTCOME OF DISCUSSIONS OF THE REVIEW COMMITTEE ON THE FOLLOWING ISSUES:

PROTECTION OF HUMAN SUBJECTS (Resume): UNACCEPTABLE

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Data safety monitoring plans are inadequately addressed for the proposed randomized clinical trial; this study involves recruitment of overweight and healthy youths without appropriate medical monitoring. It is also necessary to have an external data safety monitoring board or monitoring plan due to the recruitment and inclusion of children from different sites.

INCLUSION OF WOMEN PLAN (Resume): ACCEPTABLE

The targeted recruitment table on page 46 shows that 62% of children recruited will be females.

INCLUSION OF MINORITIES PLAN (Resume): UNACCEPTABLE

Minorities are not adequately represented. The investigators should redesign their studies so as to address issues of higher degree of prevalence of overweight among minority children. An explanation on basis of local demographics to account for inadequate recruitment of minorities is not acceptable.

INCLUSION OF CHILDREN PLAN (Resume): ACCEPTABLE

The entire cohort will consist of children of age between 7 to 10.

COMMITTEE BUDGET RECOMMENDATIONS: The budget was recommended as requested.

MEETING ROSTER

Center for Scientific Review Special Emphasis Panel
CENTER FOR SCIENTIFIC REVIEW
ZRG1 SSS-T (10) B
 February 27, 2003 - February 28, 2003

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Consultants are required to absent themselves from the room during the review of any application if their presence would constitute or appear to constitute a conflict of interest.

Produced to the Committee
on Energy and Commerce
06/30/03

PL003090

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PediaLean

From: Jennifer Collard
Sent: Thursday, June 05, 2003 1:25 PM **Tab 54**
To: Kimm Humpherys
Subject: RE: Pedialean question from Hong Kong

I haven't heard or seen anything...did they send it to Nathan or directly to Japan?

-----Original Message-----

From: Kimm Humpherys
Sent: Thursday, June 05, 2003 1:14 PM
To: Jennifer Collard
Subject: RE: Pedialean question from Hong Kong

do you know if this was taken care of? I recieved a note from carla saying that it had been taken care of.

-----Original Message-----

From: Jennifer Collard
Sent: Thursday, June 05, 2003 7:20 AM
To: Kimm Humpherys
Subject: Pedialean question from Hong Kong

I sent you a customer inquiry log on Pedialean yesterday from Hong Kong, they were inquiring about the safety of the product because some organizations were questioning the product here in the US. You asked for more info. about these organizations and this is what I was sent from Hong Kong:

Dear Jen,

Please visit the following Web page for those are the government body who send out the quires and complaints.

http://www.house.gov/commerce_democrats/press/108ltr19.htm

Or, use the key word, pediatropin, to search the Website: www.yahoo.com. You can find more relevant news.

Thanks, Shirley

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PL002353

6/17/2003

PediaLean

From: Jennifer Collard
Sent: Tuesday, June 10, 2003 9:26 AM
To: Kimm Humpherys
Subject: RE: asia100

Tab 55

Thanks...I will let the customer know.

-----Original Message-----

From: Kimm Humpherys
Sent: Tuesday, June 10, 2003 9:26 AM
To: Jennifer Collard
Subject: asia100

The issue has been resolved with the organization questioning pedialean. We have provided the safety and efficacy data to the organization.

PL002342

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INFORMATION

6/17/2003

PediaLean

From: Jennifer Collard
Sent: Friday, June 13, 2003 11:32 AM
To: Don Atkinson
Subject: FW: Safety issue of Pedilean

Tab 56

Our Distributor in Hong Kong is trying to get Pedialean approved, however, the Taiwan government heard that pedialean was not safe and that agencies in the U.S were questioning the product. We'll Carla has some information that she sent to this agency in the U.S and cleared everything up. Taiwan is now asking for documentation (proof) that is issue was resolved before they will approve the product to be imported.

Carla said that we need to get Dennis's approval on this issue before she will release the documents that were sent to this agency. Can you help me get approval from Dennis so we can get Pedialean approved for Hong Kong to order.

Jenn

-----Original Message-----
From: Carla Fobbs
Sent: Friday, June 13, 2003 11:22 AM
To: Jennifer Collard
Subject: RE: Safety issue of Pedilean

I AM NOT DOING ANYTHING ON THIS TO GET AN ANSWER. I WOULD LIKE SALES TO GO TO DENNIS FOR HIS APPROVAL AND THEN HE CAN LET ME KNOW WHETHER AND WHAT HE WOULD LIKE TO PROVIDE TO YOU.

-----Original Message-----
From: Jennifer Collard
Sent: Friday, June 13, 2003 11:07 AM
To: Carla Fobbs
Subject: RE: Safety issue of Pedilean

Thanks for letting me know. I will just hang tight until we have an answer.

Thanks Carla

-----Original Message-----
From: Carla Fobbs
Sent: Friday, June 13, 2003 11:03 AM
To: Jennifer Collard
Cc: Kimm Humpherys
Subject: RE: Safety issue of Pedilean

Jenn,

I forwarded Kimm's e-mail to Dennis yesterday and cc Kimm so she would know that I cannot give this information out without Dennis' approval. So, the answer is "no" you cannot get what we sent to the agency until Dennis gives his approval!

Carla

-----Original Message-----
From: Jennifer Collard
Sent: Friday, June 13, 2003 11:01 AM
To: Carla Fobbs
Subject: FW: Safety issue of Pedilean

Can I get a copy of the pedialean studies that were send to the agency who was questioning Pedialean. The Taiwan government wants to see proof that Pedialean is safe before they will approve it to be imported into their area.

PL002145

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-----Original Message-----
From: Kimm Humpherys
Sent: Friday, June 13, 2003 10:56 AM
To: Jennifer Collard
Subject: RE: Safety issue of Pedilea n

Can you send them a copy of the studies? That is really all we sent to the agency who was questioning pedialean

-----Original Message-----
From: Jennifer Collard
Sent: Thursday, June 12, 2003 9:41 AM
To: Kimm Humpherys
Subject: FW: Safety issue of Pedilea n

Do we have any documents that prove we have contact the organizations here in the states that were questioning Pedialean. Before Hong Kong can bring the product in the Taiwan government wants proof.

(This is regarding the customer response I sent you last week).

Jenn

-----Original Message-----
From: Shirley Cheung at Health Supp Asia
Sent: Thursday, June 12, 2003 2:31 AM
To: Jennifer Collard
Subject: Re: Safety issue of Pedilea n

Hi Jen,

Any related doucement you can send to me for this issue? 'cos Taiwan Government send these doucement back and we need some doucement to ssupport this issue have been resolved.

Tks, Shirley

Kristen Jones

From: CstSrv
Sent: Friday, November 22, 2002 6:30 AM
To: [REDACTED]
Subject: RE: Pediatric wt. loss

Tab 57

Dear customer,

Thank you for taking the time to email us. Here is where you may find the published studies for Pedialean:

Denmark. Study was completed independently of Klein-Becker usa and its holding company, Basic Research. It was published in "Ped. Med. Chir., 1992."

To reach Dr. Natalie Chevreau, call 801-517-7000 which is our corporate office and they may assist you.

If you have any further questions, please let us know.

Athena
customer service representative
1-800-898-5153

-----Original Message-----

From: [REDACTED]
Sent: Thursday, November 21, 2002 9:54 PM
To: customerservice@basicresearch.org
Subject: Pediatric wt. loss

Where were the studies published for your products that take weight off childrens?

How do I reach Nathalie Chevreau, Ph.D?

Thanks

--
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

PL000344

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INFORMATION

Kristen Jones

From: CstSrv
Sent: Thursday, August 15, 2002 8:16 AM
To: [REDACTED]
Subject: RE: PediaLean Studies

Tab 58

[REDACTED]

Thank you for inquiring about the PediaLean. It is wonderful to see that you and your patients are interested in the PediaLean. The study was completed independently of Klein-Becker usa and its holding company, Basic Research. It was published in "Ped. Med. Chir., 1992." It was studied in Denmark. If you have any further questions, please let us know.

Thank you,
Melanee Jensen
Customer Service
1-800-898-5153

-----Original Message-----

From: [REDACTED]
Sent: Tuesday, August 13, 2002 2:06 PM
To: customerservice@basicresearch.org
Subject: PediaLean Studies

I am a practicing Pediatrician. One of my parents asked me to look into the safety & efficacy of PediaLean.

I have read reports of a "well-controlled, double-blind study" of PediaLean, but cannot find references to the source Journal.

Please e-mail me or provide links/details as to any such studies that have been published in the U.S. or overseas.

Many thanks in advance.

[REDACTED]

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PL000329

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PediaLean

From: Carla Fobbs
Sent: Friday, March 07, 2003 3:08 PM
To: 'Stephen Nagin'
Subject: RE: www.pedialean.com

I have my days! :)

Tab 59

-----Original Message-----
From: Stephen Nagin
Sent: Friday, March 07, 2003 3:08 PM
To: Carla Fobbs
Subject: RE: www.pedialean.com

Gosh. Can't your magic wand wave faster?????????

-----Original Message-----
From: Carla Fobbs
Sent: Friday, March 07, 2003 4:58 PM
To: Stephen Nagin
Cc: Kristen Jones; Dennis Gay
Subject: FW: www.pedialean.com
Importance: High

FYI!!!

-----Original Message-----
From: Pam Hiatt
Sent: Friday, March 07, 2003 2:56 PM
To: Carla Fobbs
Cc: Michael Meade
Subject: RE: www.pedialean.com

It's been removed!

-----Original Message-----
From: Carla Fobbs
To: Pam Hiatt
Cc: [REDACTED]
Sent: 3/7/2003 2:37 PM
Subject: www.pedialean.com
Importance: High

I need the BBOnline membership logo deleted from this website immediately! Please confirm by e-mail once this is done.

Thank you!

PL001742

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Kristen Jones

From: CstSrv
Sent: Tuesday, September 24, 2002 7:27 AM
To: [REDACTED]
Subject: RE: Question

Tab 60

Dear Tashia,

Thank you for taking the time to email us. Below the ages of 18, we recommend one of our greatest products called the Pedialean. Basically, what pedialean does for is restrict your caloric intake to the point where you will not eat and snack as you normally would. We have received an overwhelming response from our customers who have seen great and safe results, and you could experience them too

If you have any further questions, please let us know.

Athena
customer service representative
1-800-898-5153

-----Original Message-----

From: [REDACTED]
Sent: Wednesday, September 18, 2002 9:18 AM
To: customerservice@basicresearch.org
Subject: Question

<PRE>I wanted to know what to take at all most being 18 years of age i would like to lose at least 10 to 15 pounds maby 20 I would like to know what kind of your medaction to use Thank you [REDACTED]

PL000335

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Kristen Jones

From: CstSrv
Sent: Monday, September 09, 2002 5:05 AM
To: [REDACTED]
Subject: RE: Taking Med. in School

Tab 61

Hello [REDACTED], thank you for taking the time to email us. The Pedialean acts kind of like a Jell-O substance. It actually expands in the child's stomach so that they fill full. It should not cause any long term problems for your child. Don't be alarmed by what it did in the water, if you let it sit a glass of water for a while it expands and kind of turns the water in a gel like substance. The Pedialean is not FDA approved (which is prescription products) but it is FDA regulated. The FDA reviews every product on the market, but will not approve unless it is a prescription. They do however monitor and regulate the Pedialean. Please let us know if you have anymore questions or concerns.

Thanks Again
Jessica
Customer Service
1-800-898-5153

-----Original Message-----

From: [REDACTED]
Sent: Sunday, September 08, 2002 9:22 AM
To: CstSrv
Subject: Re: Taking Med. in School

I also wanted to let you know that I put this product in a bottle of water and I didn't like what I found out. How does this work though the body? It looks like it would stay in the body and congest the child. Would this cause the child to have problems in the future. I also called our family doctor and she said that because Pedialean is not FDA regulated that she would not recommend this product to my child. How can I find out if this is safe for my child?

----- Original Message -----

From: CstSrv
Sent: Thursday, September 05, 2002 8:04 PM
To: [REDACTED]
Subject: RE: Taking Med. in School

Thank you for taking the time to email us. Some of our customers who are in the same situation have their children take the Pedialean at breakfast and then at dinner. Try and see if that works better for you.

Thanks again,
Tanna Shumard

PL000332

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Customer Service dept.

-----Original Message-----

From: [REDACTED]
Sent: Thursday, September 05, 2002 6:23 AM
To: customerservice@kleinbecker.com
Subject: Taking Med. in School

My daughter is not able to take this med. in school. Our family doctor will not sign for it because it is not fda regulated. What can I do? I want her to have it be for lunch. I tried to put it in water but it did not look right and my daughter was afraid she would get in trouble.

[REDACTED]

PL000333

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Kristen Jones

From: Daniel Mowrey
Sent: Wednesday, February 13, 2002 11:46 AM
To: 'Kramer, Robert'
Subject: RE: PediaLean

Tab 62

Dear Dr. Kramer,

Please excuse my tardiness in replying to your request. Normally, the request would be handled by our Dr. Nathalie Chevreau, but she has been called up to serve as a liaison with some of the French delegates involved in the Olympics (Dr. Chevreau is French, and we are located near Salt Lake City).

Anyway, in response to your questions, you should be able to download the study on the Pedialean active constituent from the website (weightlossforchildren.com). This material is produced in Japan, and has been used in foodstuffs in this country and around the world for at least 25 years. It comes from the tuber of a cultivated cash crop, *P. rivieri*. The material is highly purified and concentrated. It doesn't work as a dietary aid when processed in foodstuffs because it is fully hydrated during processing. As a raw material, however, it was useful in the study to help the youngsters reduce weight.

As you can determine from the website, PediaLean is meant as an adjunct, not as a primary weight loss agent. We see it as tool parents can use to help maximize other weight management techniques they are using to reduce obesity in their own children, such as diet, exercise and behavior management.

Basic Research has a reputation as the weight loss experts. The website was born from a desire to provide support for overweight children. There has been virtually nothing available for kids from a supplement point of view and as the experts on the Advisory panel will attest, managing weight in this age group is extremely difficult. Parents need all the help they can get. Hence the website.

Basic Research has worked out an agreement with American Phytotherapy Research Laboratory to donate 10% of the profits from the sale of PediaLean to a research fund that will be used to finance research on childhood obesity. The first project will probably be a replication of the Italian study on American soil.

That is somewhat of an introduction to weightlossforchildren.com and PediaLean. If you have further questions or would simply like to discuss this project, please call me on my personal cell phone: 801.921.6004, or office phone: 801.234.7012.

Sincerely,

Daniel Mowrey, Ph.D.
 Director of Scientific Affairs
 Klein-Becker usa
dmowrey@apri.ws

-----Original Message-----

From: Kramer, Robert
Sent: Friday, February 08, 2002 2:22 PM
To: 'customerservice@weightlossforchildren.com'
Subject: PediaLean

I was wondering if you could provide the reference to the study that you mention in your website, it seems you overlooked providing the details of the publication. I was also wondering if you could provide me with some kind of rationale of why you feel this fiber supplement is effective in weight-loss, and what kind of safety trials it has undergone. Thanks.

Robert E. Kramer, MD
 Division of Pediatric Gastroenterology
 University of Miami School of Medicine

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PL000350

6/11/2003

Carla Fobbs

From: MKF555 [REDACTED]
Sent: Monday, June 16, 2003 12:39 PM
To: Carla Fobbs
Subject: Fw: kidde instructions

Tab 63

----- Original Message -----
From: Ralph Order
To: [REDACTED]
Sent: Tuesday, December 18, 2001 11:49 AM
Subject: kidde instructions

DIRECTIONS:

PediaLean is easy to use – there are no special restrictions, no harmful side effects.

Children age 6 – 9: two (2) capsules, twice a day – 30 to 60 minutes before lunch and dinner.

Children and adolescents age 10 or older: three (3) capsules, twice a day – 30 to 60 minutes before lunch and dinner.

Note: It is recommended that the capsules be taken with 8 ounces of water, juice or other liquid.

To Parents: Before your child begins using the PediaLean compound, we strongly suggest that you visit www.WeightLossForChildren.com -- Klein Becker's online information and support site for PediaLean parents. Along with expert advice and information, you'll get a personalized, easy-to-follow eating and exercise plan for your child, that takes into account your child's gender, height, weight and age.

For additional information call 1-800-xxx-xxxx

Carla Fobbs

From: MKF555 [REDACTED]
Sent: Monday, June 16, 2003 12:39 PM **Tab 64**
To: Carla Fobbs
Subject: Fw: Contact Us email message from: Mary Varrone

----- Original Message -----

From: [Mitch Friedlander](#)
To: [Tneah Strobel](#)
Sent: Wednesday, May 01, 2002 7:41 AM
Subject: Fw: Contact Us email message from: Mary Varrone

----- Original Message -----

From: [REDACTED]
To: customerservice@weightlossforchildren.com
Sent: Wednesday, May 01, 2002 7:35 AM
Subject: Contact Us email message from: Mary Varrone

My 9 year old daughter has been on PediaLean for four weeks. The first two weeks she gained a pound each week. The next week she lost 1/2 a pound. The fourth week she gained 1 1/2 pounds. Is this normal? Should I purchase another month's supply and keep going on with the program? I left a message on the support board and received one response from another parent that is having the same problem but didn't get any help either. His daughter is becoming frustrated. Mine isn't yet but I'm sure it's only a matter of time! I remain supportive and try to encourage her but I can tell she is starting to get disappointed. Any suggestions would be greatly appreciated. Mary Varrone

PL001578

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6/16/2003

Carla Fobbs

From: MKF555 [REDACTED]
Sent: Monday, June 16, 2003 12:36 PM
To: Carla Fobbs
Subject: Fw: It made it to Yahoo

Tab 65

----- Original Message -----

From: [REDACTED]
To: Mitch Friedlander
Sent: Saturday, December 07, 2002 10:59 AM
Subject: Re: It made it to Yahoo

DIDN'T I TELL YOU SATURDAY WAS BETTER -- YOU WANTED TO WAIT TILL MONDAY!!!! WHEN WILL YOU START LISTENING TO ME!!!!

I CAN'T BELIEVE IT!!!! NOW I GUESS WE AWAIT NOTICE FROM EDITA!!!

----- Original Message -----

From: Mitch Friedlander
To: Nick at Vertical ; Dennis Gay ; Daniel Mowrey
Sent: Saturday, December 07, 2002 8:31 AM
Subject: It made it to Yahoo

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Press Release

Source: Basic Research

Taking Advantage of Overweight Children? 'Skinny Pill for Kids' May End Up in Court Before It Hits the Shelves

Saturday December 7, 5:00 am ET

SALT LAKE CITY, Dec. 7 /PRNewswire/ -- Basic Research®, manufacturer of PediaLean(TM) – the first and only weight loss formula for children supported by a published, peer-reviewed clinical trial – and developer of www.WeightLossForChildren.com is considering legal options to counter the outrageous claims made by Florida-based, self-proclaimed "America's favorite nutritionist" Edita Kaye about her so-called "Skinny Pill for Kids."

"On her web site (www.skinny.com) Ms. Kaye claims that her 'Skinny Pill for Kids' is a '... safe, effective weight loss formula for children ages 6 -12,'" explained Dr. Daniel Mowrey, Director of Scientific Affairs for Klein-Becker, PediaLean's exclusive North American distributor. "However, a review of the National Institutes of Health (NIH)

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PL001595

6/16/2003

database (PubMed) reveals not one single published clinical trial that has been conducted with anything called the 'Skinny Pill for Kids' or the combination and amount of active ingredients that make up the formula related to weight loss in children ages 6 to 12."

Find out your credit score instantly

"As Americans become more aware of the obesity epidemic plaguing our children," said Dennis Gay, President of Basic Research, "it's to be expected that diet pills and weight loss plans aimed at overweight children will begin to enter the market. But those who offer pills, products and diets lacking any scientific substantiation to guarantee safety and effectiveness may be doing more harm than good - confusing parents with sales jargon and false promises, while, in my opinion, potentially compromising the credibility of effective compounds that have been clinically shown to help children lose weight."

Basic Research's PediaLean formula and www.WeightLossForChildren.com, an integral support and information component of the PediaLean program, were developed over two years in conjunction with many of the world's leading pediatric obesity specialists. The PediaLean formula itself was clinically tested with children and proven to help kids lose weight. No other weight-loss product for children has clinical trials or such an extensive, continually updated online support program.

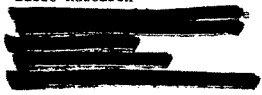
"This 'Skinny Pill for Kids' product contains, among other things, herbal diuretics (Uva Ursi and Juniper Berry), which could be problematic for some children," explained Nathalie Chevreau, PhD, RD, Director of www.WeightLossForChildren.com. "In my opinion, the unregulated use of diuretics for children and the cavalier way in which so-called natural herbs are being offered to overweight kids is not in the best interest of children or their parents."

"PediaLean remains the first and only natural formula supported by a peer-reviewed, published weight loss study involving children, not adults, and claims to the contrary are not accurate," said Gay. "We've spent an enormous amount of time and money developing a comprehensive solution for overweight children and their parents - starting in 2001 with PediaLean and building an exclusive online dietary plan that is calculated to match a child's age, weight, sex, and activity level. Suggesting, as Ms. Kaye does, that a single 'quick start' diet can work for all children ages 6 to 12 is, I have been advised, ludicrous. In response to recent developments, I am consulting with our legal team and scientific staff to determine what actions can or should be taken.

- (For the clinical study on PediaLean, please go to www.WeightLossForChildren.com)

For More Information Contact:

Nicholas J. Lester, Chief Information Office
Dr. Daniel B. Mowzey, Director of Scientific Affairs
Basic Research



Source: Basic Research

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Kristen Jones

From: Nathalie Chevreau
Sent: Wednesday, February 06, 2002 10:11 AM
To: Daniel Anderson
Cc: Mitch Friedlander
Subject: RE: invitation to become part of the advisory committee to the ww w.we ightlossforchildren.com site

Tab 66

yes, we need to sit down with Mitch. I'll ask him when it is a good time.

-----Original Message-----

From: Daniel Anderson
Sent: Wednesday, February 06, 2002 9:27 AM
To: Nathalie Chevreau
Subject: RE: invitation to become part of the advisory committee to the ww w.we ightlossforchildren.com site

Nathalie,

Who do we need to sit down and visit with on this issue, is it Mitch? Kirsten has raised some issues that are not easy to resolve. I think that this agreement may not work for her.

Dan

-----Original Message-----

From: Nathalie Chevreau
Sent: Tuesday, February 05, 2002 10:41 AM
To: Daniel Anderson
Subject: FW: invitation to become part of the advisory committee to the ww w.we ightlossforchildren.com site

Hello Dan,

Could you please look at her comments and see what we can do about them?

Thanks

Nathalie

-----Original Message-----

From: Kirsten Krahnstoever Davison
Sent: Tuesday, February 05, 2002 10:24 AM
To: Nathalie Chevreau
Subject: RE: invitation to become part of the advisory committee to the ww w.we ightlossforchildren.com site

Hello Nathalie,

I have read the contract and there are certain aspects of it that concern me.

The clauses that I have problems with are as follows:
#5 inventions. I disagree with this clause because it is very difficult to define what is my knowledge and what is the company's knowledge. Work that I publish during the time that I consult with the company is my own. I also would not put advice on the website if as a result, it is no longer defined as my work and I do not have the freedom to pursue additional research in the area independent of the "company".
#10 Articles and likeness. This clause would prohibit me from making my

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PL000407

Kristen Jones

From: [REDACTED]
Sent: Monday, May 13, 2002 10:25 PM
To: customerservice@weightlossforchildren.com
Subject: Contact Us email message from: tamar mezrahi

Tab 67

She has been taking pedialean for 5 days and she does not know what is that for, i told her,they are vitamins. The first day she could not sleep, then the third day she felt a pain in her chest so i didnt give her the pill the next day, she took it the four day and she didn't complain, today she took only one, i didn't want to give her two, and she came from school feeling the same pain in her chest. I just want to know if there is something related to Pedia-lean. She is 8 years old.

PL000612

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Kristen Jones

From: Nathalie Chevreau
Sent: Monday, May 06, 2002 3:45 PM
To: [REDACTED]
Cc: Daniel Mowrey; Tneah Strobel
Subject: RE: Contact Us email message from: Edna L. Sipaque

Dear Edna,

Tab 68

The success rate with Pedialean has been amazing and I would like to talk to you about your daughters' results and possibly make some recommendations. Please call me on my cell phone at 801.414.3356 during the day time. We are in Utah, therefore on Mountain Standard Time.

Sincerely,

Nathalie Chevreau PhD, RD

Nutritional Research Director

-----Original Message-----

From: [REDACTED]
Sent: Monday, May 06, 2002 2:02 PM
To: customerservice@weightlossforchildren.com
Subject: Contact Us email message from: Edna L. Sipaque

I brought PediaLean for my daughter she's 11 yrs. I notice some changes 3 weeks after she started to used PediaLean but now she's almost finish the 2nd bottle and she's gaining more she started with 160 pounds and now she has 170 pounds there's any way you can help me to find a way to help my daughter to losse weight and lower her colesterol? she has 240 in colesterol.Please could you help me.
Thank You. Edna

PL000591

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PediaLean

From: Carla Fobbs
Sent: Monday, February 18, 2002 3:57 PM
To: Gina Gay
Subject: [REDACTED]

Tab 69

Tracking: Recipient Read
 Gina Gay Read: 2/18/2002 4:29 PM

Here you go!

-----Original Message-----

From: Daniel Mowrey
Sent: Monday, February 18, 2002 3:52 PM
To: Carla Fobbs
Subject: PediaLean gma.doc

The history of pediatric weightloss management is replete with examples of products that have simply failed to pass tests for effectiveness and safety. They either didn't work or they posed undesirable risk for children. PediaLean is the first and only product designed specifically for childhood obesity that has proven to be both safe and effective. As such it represents a watershed in this critical area.

PediaLean (Pediatorpin) is the outgrowth of research and technology in which the fibers from the tuber of an Asian plant, *Proteinophallus rivieri*, were subjected to a rigorous extraction and purification process to yield a highly purified, concentrated, high molecular weight product. Unlike *all* other less purified and concentrated *P. rivieri* extracts, this unique product (DICOMAN 5) proved viable in a clinical trial exploring its role in reducing body weight in obese children. In this trial, the group of children that took PediaLean lost weight, while the group that didn't, did not lose weight.

No other *P. rivieri* raw material, extract or product of any description, and no other root fiber of which we are aware, indeed, no other product at all, has ever produced positive results of this kind. Furthermore, the product was shown to be perfectly safe for use by children.

After obtaining a copy of the study, Klein-Becker usa tracked down the manufacture of the fiber and learned that DICOMAN 5 represented a significant breakthrough in the processing of this particular fiber. Next, Klein Becker usa obtained the exclusive rights to DICOMAN 5, and developed the product for use as an adjunct to a reasonable pediatric diet and exercise program. (It was in discussions of what those programs should look like that the decision was made to create a website (weightlossforchildren.com) to help parents of obese children access the best advice this country's experts could provide as to what diets, menus, exercises, psychological and social support could be given to parents. Additionally, it was decided that 10% of the profits arising from the sale of PediaLean would go directly toward research in the area of pediatric obesity, the nature of which would be decided by an International Board of Advisors, several of which are now listed on the website.)

In summary, where all other attempts to provide viable weight loss products for children have failed, PediaLean has succeeded. Combined with a reasonable (normocaloric) diet and moderate exercise program, children who use this product can be assured of weight loss for the very first time.

PL002871

6/17/2003

Produced to the Committee
 on Energy and Commerce
 06/30/03

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 INFORMATION

PediaLean

From: CstSrv
Sent: Tuesday, July 02, 2002 3:01 PM
To: [REDACTED]
Subject: RE: PediaLean

Tab 70

Thank you for taking the time to email us. To our knowledge there is no common name for the micronized fiber found in the Pedialean. However, we will forward your email onto those who helped in the formulation of the product. If they have any further information regarding this, we will contact you.

Thanks again,
Tanna Shumard
Customer Service Dept.

-----Original Message-----

From: Nancy Grant [REDACTED]
Sent: Monday, July 01, 2002 4:06 PM
To: customerservice@basicresearch.org
Subject: PediaLean

I have searched for hours on herbal suppliment encyclopedia sites and always come up with nothing when looking for "P. rivieri". Just what is this ingredient's common name? I don't like giving my child herbal suppliments when I don't know anything about them.

Sincerely,

Nancy Grant
[REDACTED]

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PL002711

6/17/2003

Produced to the Committee
on Energy and Commerce
06/30/03

Kristen Jones

From: Nathalie Chevreau
Sent: Friday, December 20, 2002 9:11 AM
To: 'Robert Mendoza'
Cc: Daniel Mowrey
Subject: RE: PediaLean

Tab 71

Dear Dr. Mendoza,

Thank you for your message. I appreciate your comments about the study and they are definitely valid. I would like to emphasize that Pedialean is an adjunct to a traditional weight loss program (better nutrition, physical activity and behavioral changes). It is by no means a miracle pill. That is why we offer parents the free website www.weightlossforchildren.com for them to get help for the program. We have had also very good response from parents who have posted success stories on the web or called us for which the combination of the site and Pedialean have made a difference.

One of our goal is to be able to conduct a clinical trial in the US as 10% of the sale of Pedialean goes into a research fund. We have expert advisors such as Dr. Sothorn, Dr Goran, Dr. Steinberger to name 3 (you may see the list on the site) who contribute every month to the site.

Childhood obesity is an ongoing problem and we had and intend to continue to provide help to parents.

Feel free to call me if you have other questions. I was wondering what your line of work is and whether you work or do research on obesity. I would love to know.

Sincerely,

Nathalie Chevreau PhD, RD
 Nutritional Research Director
 801-517 7026

-----Original Message-----
From: Robert Mendoza [mailto:]
Sent: Friday, December 20, 2002 8:02 AM
To: Dr. Chevreau
Subject: RE: PediaLean

Dear Dr. Chevreau,

Thanks for pointing me to the published Italian study with PediaLean. Although the test and control groups provided results (weight loss) that were statistically different, the standard deviations are rather large for the two groups. Although, I realize that it is difficult to get smaller deviations with the type of study you are doing (weight loss) and the small number of subjects. However, what the statistics do not indicate is the change in weight for each individual, and a graph depicting this would have been quite useful. So, I don't know if 10% or 90% of the children taking PediaLean experienced weight loss, and I don't know if any children gained weight after taking PediaLean. From the paper, I did notice that the overweight range (before and after among girls) remained as high as 80%. This tells me that at least one girl was 80% overweight before taking PediaLean and she remained 80% overweight (or did another girl gain weight after taking PediaLean?). Finally, the results are a bit skewed because some children taking PediaLean did not complete the study, and your publication states that these individuals may not have experienced a change in diet (in other words, they did not feel that they were losing weight). In all, I am sure PediaLean can provide some benefit for overweight children, but it appears to be only a small benefit and a simple

PL001408

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change in diet or a little more exercise might serve children just as well.

Thanks again for taking the time to give me the information.
Robert Mendoza, Ph.D.

At 11:50 AM 12/12/2002 -0700, you wrote:

>Dear Robert,

>

>You can read the translation of the Italian clinical study on our
>www.weightlossforchildren.com site. When you revisit the site, scroll down
>the home page and you will see the "clinical Study" button toward the end of
>left navigational bar. Click on it and it will give you the study that you
>can print.

>

>Let me know if you have other questions.

>

>Sincerely,

>

>Nathalie Chevreau PhD, RD
>Nutritional Research Director

>

>-----Original Message-----

>From: Robert Mendoza [mailto:robert.mendoza@weightlossforchildren.com]
>Sent: Saturday, December 07, 2002 7:13 AM
>To: customerservice@weightlossforchildren.com
>Subject: PediaLean

>

>Dear Customer Service,

>

>I read the summary of the PediaLean study in 23 children at your web
>site. Can you provide me with a copy of the published report of this
>study? If not, can you tell me where it was published and I'll try to get
>it myself?

>

>Thanks,
>Robert Mendoza

PL001409

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BASIC
RESEARCH

5742 West Harold Gatty Drive
Salt Lake City, UT 84116

phone (801) 517-7000

fax (801) 517-7001

website www.BasicResearch.org

Tab 72

April 1, 2004

VIA ELECTRONIC SUBMISSION
(kelli.andrews@mail.house.gov)

Kelli A. Andrews
Counsel
House of Representatives
Committee on Energy & Commerce
316 Ford Building
Washington, D.C. 20515

**CONFIDENTIAL AND
PROPRIETARY
INFORMATION**

RE: PediaLean®

Dear Kelli:

Over the last couple of weeks, we have provided information to you relating to your requests contained in your February 25, 2004 letter (i.e., copies of PediaLean® inserts were forwarded to you, together with information relating to when the www.weightlossforchildren.com website was launched, a list of entities for which Basic Research distributes product, and a list of retail stores that have sold PediaLean®).

You also requested additional information in your February 25, 2004 letter, which we now provide to you as follows:


1. Document # PL005412 attached hereto details the direct sales from the Internet, the direct sales from the call center and the direct wholesale sales for PediaLean since the inception date of the project (January 1, 2002) through February 27, 2004.
2. Document # PL005413 attached hereto gives you a complete break-down of the costs related to the entire weight loss for children project through February 27, 2004. Please keep in mind that certain costs per unit would have been significantly lower if the total unit sales would have been higher (See *NOTE on Document # PL005413).
3. You requested the date when PediaLean® was last manufactured. That date is July 2003.

Kelli A. Andrews
April 1, 2004
Page 1

CONFIDENTIAL AND
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INFORMATION

If there is additional information that you have requested and you feel is left unanswered, please feel free to contact Mr. Nagin. From what I understand, he is back in his office after traveling the last couple of weeks. At any rate, I am sure he will be in contact with you within the next couple of days. Otherwise, please feel free to contact me. My direct line is: 801.517.7008.

Sincerely,



Carla R. Fobbs,
Legal Administrator

cc: Stephen E. Nagin
(via email)

/encls.

Pediatelean
 Date Range: Inception of product (Jan 1, 2002) through 2-27-04

| Year | Direct Sales from Internet | Direct Sales from Call Center | Total Direct Sales | Returns And Allowances | Direct Net Sales |
|--------------|----------------------------|-------------------------------|--------------------|------------------------|------------------|
| 2002 | 54,909 | 94,780 | 149,689 | (19,959) | 129,711 |
| 2003 | 22,060 | 50,003 | 72,063 | (10,702) | 61,361 |
| 2004 | 2,845 | 7,759 | 10,604 | - | 10,604 |
| Total | \$79,814 | \$152,522 | \$232,336 | -\$30,660 | \$201,676 |

Tab 73

| Year | Direct Net Sales | Wholesale Net Sales | Total |
|--------------|------------------|---------------------|------------------|
| 2002 | 129,711 | 294,762 | 424,473 |
| 2003 | 61,361 | 85,459 | 146,820 |
| 2004 | 10,604 | (1,627) | 8,977 |
| Total | \$201,676 | \$378,594 | \$580,270 |

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 PROPRIETARY
 INFORMATION

PL005412

Tab 74

**PediaLean Project Costs/
Program Costs Per Unit**

| <u>Description of Costs per Unit</u> | <u>\$\$</u> |
|---|------------------|
| Cost of Goods Sold (1) | \$8.10 |
| Direct Advertising | \$13.70 |
| Legal Expenses | \$1.37 |
| Advisory Board & Articles | \$4.38 |
| Nutritionist | \$0.35 |
| Conferences | \$0.42 |
| Website: Building, programming &
maintenance | \$11.62 |
| PediaLean Direct Cost per Unit | \$39.94 |
| Burden & Overhead | \$13.46 |
| Grand Total Cost per Unit | \$53.40 * |

Notes:

(1) Cost of Goods Sold \$183,655 plus the cost of units on hand \$3,736, divided by the total units (#23,148).

All other costs per unit are calculated by dividing the costs by the number of total units.

Average Sale Price is \$25.89 a unit.
Sales of \$580,270 divided by units sold (#22,409).

*NOTE: The above cost per unit is based upon current sales figures and reflects all start-up costs. Of course, certain costs per unit, such as the cost of advertising, legal expenses, advisory board, website, nutritionist, etc., would have been significantly lower if the total unit sales would have been higher.

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Tab 75

PediaLean

From: Michael Meade
Sent: Thursday, June 12, 2003 11:37 AM
To: Kristen Jones
Subject: RE: PediaLean request--product price

finished product = \$4.48

-----Original Message-----

From: Kristen Jones
Sent: Monday, June 09, 2003 4:33 PM
To: Operations
Cc: Carla Fobbs
Subject: PediaLean request--product price
Importance: High

Michael,

In the request for supplemental information on PediaLean that we received from Congress, they request the following information:

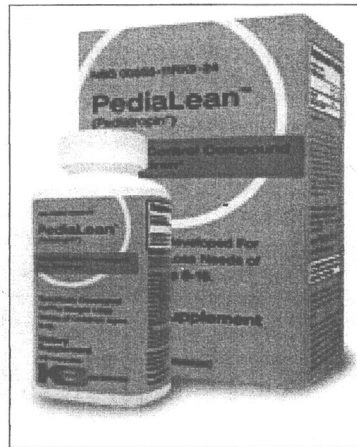
12. How much does it cost the company (whichever one) to make each Pedialean product?

Please provide this information to the Legal Department by Wednesday of this week.

Thank you,
Kristen Jones

Klein-Becker
PediaLean
 (120 Count)

Tab 76



**CONFIDENTIAL
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 INFORMATION**

| | | |
|------|-----------|-----|
| 2001 | Period 1 | |
| | Period 2 | |
| | Period 3 | |
| | Period 4 | |
| | Period 5 | |
| | Period 6 | |
| | Period 7 | |
| | Period 8 | |
| | Period 9 | |
| | Period 10 | |
| | Period 11 | |
| | Period 12 | |
| | Period 13 | NEW |
| 2001 | | |

| | | |
|------|-----------|------------|
| 2002 | Period 1 | \$ 4,477 |
| | Period 2 | \$ 250,389 |
| | Period 3 | \$ 36,907 |
| | Period 4 | \$ 23,570 |
| | Period 5 | \$ 17,880 |
| | Period 6 | \$ 11,542 |
| | Period 7 | \$ 21,187 |
| | Period 8 | \$ 4,908 |
| | Period 9 | \$ 9,577 |
| | Period 10 | \$ 10,950 |
| | Period 11 | \$ 17,786 |
| | Period 12 | \$ 6,967 |
| | Period 13 | \$ 8,332 |
| 2002 | | \$ 424,472 |

| | | |
|------|-----------|------------|
| 2003 | Period 1 | \$ 9,058 |
| | Period 2 | \$ 6,320 |
| | Period 3 | \$ 20,778 |
| | Period 4 | \$ 25,375 |
| | Period 5 | \$ 14,840 |
| | Period 6 | \$ 23,338 |
| | Period 7 | \$ 12,496 |
| | Period 8 | \$ 8,871 |
| | Period 9 | \$ 6,232 |
| | Period 10 | \$ 7,366 |
| | Period 11 | \$ 6,203 |
| | Period 12 | \$ 5,014 |
| | Period 13 | |
| 2003 | | \$ 145,891 |

PL003329

New Product Update

Testosterone: Not just for the hardcore

Androgen-Saturated Transepidermal Gel **Tab 77**

BUY ONLINE NOW!

Or Call 1-800-919-9715



Testosterone-Boosting Gel Shakes Up U.S. Fitness Market

As we all know, testosterone is responsible for increased muscle mass, increased strength, increased sex drive, aggression, confidence, reduction of body fat and the will to win. If there's ever been a substance at the core of manhood itself — it's testosterone. So how can you raise your testosterone levels without a doctor's prescription? Well, thousands upon thousands of men around the globe have turned to TestroGel®... the androgen-saturated, topically applied gel that boosts testosterone

levels... and we mean really boosts testosterone levels.

Increase Testosterone Without Raising Estradiol Levels

Unlike ordinary pills and powders, TestroGel helps raise testosterone levels without increasing estradiol (the female hormone responsible for decreased sex drive, genital weakness and the embarrassment of gynomastia — female-like breasts on men). That's why TestroGel is known as the preferred prescription alternative around the globe.

TestroGel® is Odorless and Easy to Apply

With TestroGel there are no painful applications, no uncomfortable patches to wear, and no annoying pills to take. TestroGel absorbs in seconds, leaving no greasy residue or telltale medicinal odor. No one but you will know why you've suddenly become bigger, more ripped, more powerful, and more aggressive, but everyone will see an incredible difference.

Unleash the Incredible Power of TestroGel®!

Once confined to the most radical bodybuilding elite — bent on being the biggest, strongest and most aggressive — the thirst for TestroGel has spread to that vast population of men who are tired of lifting weights month after month without realizing the significant muscle growth and definition that sets them apart from the crowd. That's why so many people are willing to pay more than \$3.00 per application just to use TestroGel.



Order Today and Take the TestroGel® Challenge!

Put TestroGel to the test! Use TestroGel for just ten days. If you don't have more muscle mass, more strength, and less body fat — if you don't feel more intense, more aggressive, and more powerful — we'll give you your money back... no questions asked. **That's right! TestroGel is guaranteed to work for you or it costs you absolutely nothing!**



"Although TestroGel has become one of the most sought-after new products in America — based on its reputation as a 'sex gel' — bodybuilders are hoarding tubes of TestroGel because it has emerged as a clinically verified alternative to prescription performance enhancers."

— Dr. Daniel B. Mowrey, Director of Scientific Affairs, Klein-Becker usa

BUY ONLINE
NOW!

Or Call 1-800-919-9715

Warning: TestroGel is not intended to cure, treat, alleviate, or mitigate in any way, symptoms or conditions related to hypogonadism. TestroGel should not be used as a substitute for medically supervised hormone replacement therapy. TestroGel should not be confused with the prescription medication AndroGel®. If you suspect you suffer from hypogonadism or clinically deficient testosterone levels, consult a licensed, qualified health-care professional. TestroGel is not intended to diagnose, treat, cure, or prevent any disease. Remember: self-diagnosis and/or self-medication is irresponsible and can be dangerous. To find a qualified health-care professional in your area, you may contact The American Medical Association (AMA) at (312) 464-5000 or visit www.ama-assn.org

"Share Your Success Story"

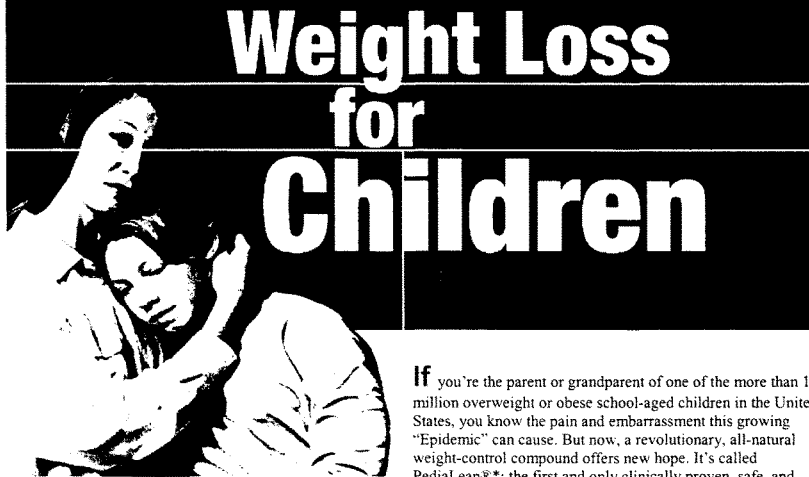
Home | Dermalin | Mamralin | Oxydrene | PediaLean | StriVectin | TestroGel | Thyrovarin



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New Product Update by Klein-Becker usa

Tab 78



Yes! I Would Like To
BUY NOW!

Or Call 1-800-919-9715



"It's just baby fat,' 'She'll grow out of it,' and 'Oh, he's just a growing boy'... these are the traditional excuses parents use to justify their child's overweight condition. The old excuses can no longer stand... especially now that there is a safe,

natural weight-loss compound designed and developed specifically for children. Combined with a proactive program **specifically** created to support **both** parent and child – this natural weight-control compound resulted in significant weight loss in virtually every child studied. For your child's sake, for **your** sake, you must take advantage of this clinically proven solution."

Dr. Nathalie Chevreau, Ph.D., R.D. Director of Women's Health,
Klein-Becker usa

Published Medical Studies

If you're the parent or grandparent of one of the more than 11 million overweight or obese school-aged children in the United States, you know the pain and embarrassment this growing "Epidemic" can cause. But now, a revolutionary, all-natural weight-control compound offers new hope. It's called PediaLean®*: the first and only clinically proven, safe, and effective weight-control compound designed for children and adolescents... and it's finally available in America exclusively from Klein-Becker usa.

What is PediaLean?

The active ingredient in PediaLean® is Peditropin,™ an all-natural, micronized fiber concentrate derived from a plant (tuber called *P. rivieri*). This tuber has been used as a food source for thousands of years, but only recently have scientists discovered effective method for micro-processing the plant into a high-molecular-weight powder which makes it ultimately effective at children's weight-control tool.

Klein-Becker's proprietary micronization process guarantees PediaLean® is not only safe, but is the one and only weight-control compound designed, manufactured, and clinically proven safe and effective for use by overweight children and adolescent

Does PediaLean® work? You bet it does! In a well-controlled clinical trial, each and every child who used PediaLean® as directed lost a significant amount of excess body weight... a success rate of 100%!

Professional Support and a Shoulder to Lean On

But PediaLean® is more than a great weight-loss formula for your child. It's a complete program of online support accessible from home, office, or anywhere you may be. Simply log on to www.WeightLossForChildren.com – the exclusive, easy-to-use, online service developed just for PediaLean® parents – and you

and you'll find a place where all your questions will be answered by our panel of Doctors, Registered Dieticians, and Exercise Specialists... each dedicated to help you and your child succeed.

You'll also get full access to a personalized, easy-to-follow eating and exercise plan for your child based on gender, height, weight, and age. In addition, you will find information on all aspects of children's health as well as practical solutions to difficult problems -- like how to maintain good nutrition using today's "fast foods." But that's not all. The most popular feature of WeightLossForChildren.com is our wonderful "Parents Only" Message Board... a place of compassion and practical advice from a community of parents who have walked in your shoes and are there to help. They understand how you feel because they've been there themselves. There's even a free personalized weight-control plan for you at www.MyFreeDiet.com. You will love both sites!

Order Pedialean® Today!

So order today, then log on to www.WeightLossForChildren.com and begin a new life for you and your child. By the way, as with all Klein-Becker formulations, Pedialean® comes with our no-nonsense, 100% money-back guarantee: simply stated, if you're not completely satisfied with your Pedialean® purchase, return the unused portion within 30 days for a full, prompt, and complete refund... no questions asked! Call now!

Basic Research is very pleased to assist voluntarily the Congressional Committee's understanding of childhood obesity and our effective treatment for this condition. Tragically, obesity has become a growing epidemic among children and adolescents in the United States. Basic Research's commitment to help alleviate this problem has led to its decision to reduce the price of Pedialean... a clinically proven, effective and safe dietary supplement for childhood weight control.

Ingredients!



Go To
WeightLossForChildren.com

New Product Update

Tab 79

Testosterone: Not just for the hardcore

Androgen-Saturated Transepidermal Gel



**BUY ONLINE
NOW!**

Or Call 1-800-919-9715

Testosterone-Boosting Gel Shakes Up U.S. Fitness Market

As we all know, testosterone is responsible for increased muscle mass, increased strength, increased sex drive, aggression, confidence, reduction of body fat and the will to win. If there's ever been a substance at the core of manhood itself — it's testosterone. So how can you raise your testosterone levels without a doctor's prescription? Well, thousands upon thousands of men around the globe have turned to TestroGel®... the androgen-saturated, topically applied gel that boosts testosterone

levels... and we mean really boosts testosterone levels.

Increase Testosterone Without Raising Estradiol Levels

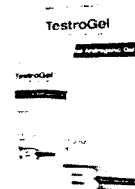
Unlike ordinary pills and powders, TestroGel helps raise testosterone levels without increasing estradiol (the female hormone responsible for decreased sex drive, genital weakness and the embarrassment of gynomastia — female-like breasts on men). That's why TestroGel is known as the preferred prescription alternative around the globe.

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With TestroGel there are no painful applications, no uncomfortable patches to wear, and no annoying pills to take. TestroGel absorbs in seconds, leaving no greasy residue or telltale medicinal odor. No one but you will know why you've suddenly become bigger, more ripped, more powerful, and more aggressive, but everyone will see an incredible difference.

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Put TestroGel to the test! Use TestroGel for just ten days. If you don't have more muscle mass, more strength, and less body fat — if you don't feel more intense, more aggressive, and more powerful — we'll give you your money back... no questions asked. **That's right! TestroGel is guaranteed to work for you or it costs you absolutely nothing!**



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— Dr. Daniel B. Mowrey, Director of Scientific Affairs, Klein-Becker usa

**BUY ONLINE
NOW!**

Or Call 1-800-919-9715

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Home | Dermalin | Mamralin | Oxydrene | PediaLean | StrVectin | TestroGel | Thyrovarin

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KleinBecker.com

Tab 80

TestroGel® (100% Testoxin™)

Transepidermal Androgen-Saturated Gel™



2 oz. Supply
(Approx. 30 applications)

\$95.00

**Add To
Basket Now!**

4 oz. Supply
(Approx. 60 applications)
Save \$10.00

\$180.00

**Add To
Basket Now!**

MamrÄlin-ARa®: The first and only formulation designed to protect a woman's breasts from sag and shrinkage caused by weight loss.



Tab 81

**BUY ONLINE
NOW!**

Or Call 1-800-919-9715

STOP BREAST SAG & SHRINKAGE CAUSED BY DIETING

**If Maintaining The Size And Shape Of
Your Breasts Is Important, Don't Start
Another Weight Loss Plan, Take Another
"Fat-Burner" Or Begin Another Exercise
Program Until You Read This Report!**

None of us like to talk about it. But if you've ever gone on a diet, taken "fat-burners" or begun a vigorous exercise program, then you know the first thing to shrink is your bust size... not your hips, not your thighs, and not your tummy, but your breasts. The more fat you burn, the more weight you lose, the smaller and saggier your breasts become. Exasperating to larger-breasted women... devastating to those less "well-endowed" and one major reason why so many women (consciously or subconsciously) abandon their weight loss plans.

Why Does Dieting Cause Breast Shrinkage?

The predominant tissue causing the bust to become plump and round is fat. That's right, fat... a vast matrix of adipose (fat) tissue surrounding the mammary glands. The more fat you store in your breasts, the bigger, firmer, and rounder your breasts appear.

The reason our breasts shrink during weight loss is relatively simple: fat cells in the female breast effortlessly store excess body fat (that's why they get bigger when we gain weight), and — just as fast as they store excess fat — the fat cells in our breasts are the first to release stored fat when our bodies need it for energy... like when we diet and exercise. So, if you're on a diet and don't do something to impede the release of fat from the breast (especially those of you who are using "fat-burners")... Your breasts will shrink. That's why every woman about to begin a weight loss or exercise program needs MamrÄlin-ARa®... the first (and only) topically applied, transepidermal compound specifically designed to prevent the devastating effects of diet-induced breast sag and shrinkage.



"The Adenosine Receptor Agonists (ARAs) in MamrÄlin-ARa

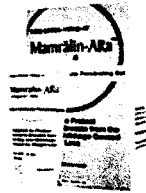
are designed to protect (and in many cases increase) the figure-enhancing fat stores in your bust while dieting."

How Does MamrÄlin-ARa Prevent Breast Shrinkage During Weight Loss?

Just as there are compounds (beta adrenergic stimulants) that encourage fat cells to release stored fat, there are other compounds that encourage fat cells to retain fat. These remarkable compounds, called Adenosine Receptor Agonists (ARAs), are the core of MamrÄlin-ARa's breakthrough topical formulation. Identifying specific ARAs that inhibit fat release was easy. However, producing a safe and effective agent that would deliver ARAs directly into the breast proved much more difficult.

The Breakthrough

Finally, after more than three years of careful investigation, our research scientists developed a proprietary transepidermal gel capable of delivering the highly active, ARA infused preparation deep into the outer layers of fatty breast tissue... inhibiting lipolysis (the process that causes the breast to release stored fat) and stimulating fat uptake and retention. In other words, by transepidermally infusing your breast with ARAs, MamrÄlin-ARa makes it difficult for your body to deplete the fat stores in your breast for energy... maintaining (and in many cases increasing) the figure-enhancing fat stores in your bust — right where you want it. But that's not all... because MamrÄlin-ARa makes it difficult to attack breast fat, it also forces your body to find an alternative source of fat to burn for energy... helping you get rid of the excess, unwanted fat stored in your hips, thighs, abs, and buttocks just a little bit faster.



Avoid Diet Induced Breast Sag and Shrinkage. Order MamrÄlin-ARa Now!

So, if looking great is your goal — applying MamrÄlin-ARa twice-a-day is the best way to avoid diet induced breast sag and shrinkage. MamrÄlin-ARa will ensure that your diet or exercise program will result in the sexy, eye-catching body you want and deserve. Order MamrÄlin-ARa Now! MamrÄlin-ARa: the first and only formulation specifically designed to protect a woman's breasts from the inevitable sag and shrinkage caused by weight loss. Guaranteed to work for you or your money back!

**BUY ONLINE
NOW!**

Or Call 1-800-919-9715

"Share Your Success Story"

**ORDER BY
MAIL**

Home | Dermain | MamrÄlin | Oxidorene | PediaLean | StriVectin | TestroGel | Thyrovarin

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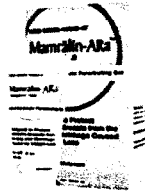


Klein-Becker uses

Tab 82

Mamralin-ARa®

The first and only formulation specifically designed to protect a woman's breasts from the inevitable sag and shrinkage caused by weight loss.



3 oz. Supply
(Approx. 1-Month Supply)

\$109.00

**Add To
Basket Now!**

6 oz Supply
(Approx. 2-Month Supply)
SAVE \$10.00

\$208.00

**Add To
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[Alphagen Biotech Womens Zotrin](#)
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ANOEX™ (Leptoprin™)



Tired Of Diet Failure?

Buy two for free shipping!

Powerful Anorectic Agent Helps Overcome Genetic Link To Obesity

Anorex \$84.99 For the millions of Americans who are significantly overweight (more than 30 lbs. of excess body weight and/or a BMI [body mass index] greater than 30) there is simply no longer any way to deny the genetic link to obesity. That's why ordinary diet pills and so-called "fat magnets" (if they work at all) so often fail to help the significantly overweight. The genetic link to obesity also means that repeated diet failure and chronic overweight is not your fault. Unless a weight-control compound addresses the genetic factor — and helps you overcome your genetic predisposition to obesity — your attempts at weight loss become no more than an exercise in futility (and a waste of time and money).

But now there's Anorex™ — the first weight-control compound designed to mitigate the profound effect that variations in the human genetic code have on the storage, use, and disposition of body fat.

Anorex™ is an extremely powerful anorectic agent and is not intended for use by the casual dieter who is merely attempting to shed five or ten "vanity" pounds. However, if substantial excess body fat is adversely affecting your health and self-esteem, then it's time for you to discover Anorex™ — the first comprehensive weight-loss compound designed specifically to overcome your genetic predisposition.

Anorex™: The Result of an Extraordinary Collaboration

Anorex™ (or more correctly, its patent-protected core compound, Leptoprin™) is the result of an extraordinary collaborative effort between Dr. Daniel B. Mowrey, Director of Scientific Affairs, Klein-Becker usa, Provo, Utah, and Dr. Edward G. Fey, University of Massachusetts Medical Center, Worcester, Massachusetts. Though working independently, both doctors were keenly aware of the growing body of evidence linking obesity to certain genetic "markers." In September of 1998, Drs. Mowrey and Fey discovered each had access to compatible patents for variant methods of regulating obesity. As they familiarized themselves with each

...tting Gel
...trovarin PLS

Urban
Biologics
Ripping Gel
Gut Cutter

Anorex
 \$84.99



others' work, it became clear that combining the patented formulations could overcome genetic anomalies responsible for significant overweight. In fact, a recent report ("The Human Obesity Gene Map: The 1999 Update") published in Obesity Research, the official journal for the North American Association for the Study of Obesity, disclosed, "The number of genes and other markers associated or linked with human obesity phenotypes continues to expand and now reaches well over 200" (Vol. 8 No. 1 Jan. 2000, p.105). For example, gene FABP2, located at 4q28-q31, impacts abdominal fat, body mass index, and fat percentage — while others are more specific, such as gene INS, located at 11p15.5, which influences waist-to-hip ratios in obese women (pp.99-100).

Anorex™ Helps Overcome Genetic Link to Obesity

Anorex™ is the first product designed specifically for the significantly overweight by helping to overcome the genetic link to obesity. **First**, significantly overweight people have a genetically-based tendency to store excess dietary calories as body fat. Anorex™ helps overcome this tendency by effectively increasing the body's ability to destroy calories in specialized "wasting cycles" within fat, muscle, liver and other body cells. **Second**, Anorex™ dramatically interferes with the process of converting calories to fat. **Third**, Anorex™ exerts a profound "lipolytic" action — it "mobilizes" stored fat, moving it out of the fat cell and thereby reducing the size of the fat cell mass. **Fourth**, Anorex™ inhibits the creation of new fat cells (yes, scientists now know that we create new fat cells throughout life). **Fifth**, Anorex™ increases the special process (called apoptosis) in the body that results in the destruction of immature fat cells before they become bloated with fat. **Sixth**, Anorex™ is especially effective in prolonging all of these actions in the body for the longest possible time. In short, Anorex™ is such a breakthrough discovery for the significantly overweight because Anorex™ aids in the defeat of destructive genetic influences on the cellular regulation and coordination of dietary calories: their intake, their conversion to body fat, and their removal from body fat stores. In other words, Anorex takes away "pre-programmed genetic failure" and gives the significantly overweight control over their lives once again.

Anorex™: Now Available in The United States Without Prescription

In a report dated February 19, 2000, Dr. Mowrey stated "Although Anorex™ is much too powerful for the 'casual dieter,' the ability of Anorex™ to help people overcome the genetic implications of obesity leads me to believe Anorex™, and its base formulation Leptoprin™, is the most effective means of providing considerable benefit to that vast population of American men and women who are significantly overweight. That is, until science develops a reliable means of altering the genetic code." If You're Significantly Overweight, You Need Anorex™. If you're significantly overweight (more than 30 lbs. of excess body weight and/or a BMI greater than 30), there is only one weight-control compound specifically designed for you... it's Anorex™. Patent-protected, clinically established, and guaranteed to help you become the thinner, healthier, and more active person you've always wanted to be.

WARNINGS: Do not take this product if you are taking MAO inhibitors or a prescription drug for anticoagulation (thinning of the blood), diabetes, gout or arthritis or any other prescription drug unless directed by a physician. Do not take this product if you have any of the following conditions: high blood pressure, cardiovascular disease, thyroid disease, prostate problems or diabetes. Improper use may be hazardous to your health. Keep out of the reach of children. Consult a physician or licensed health care professional before using this product if you have, or have a family history of, heart disease, thyroid disease, diabetes, high blood pressure, recurrent headaches, depression or other psychiatric condition, glaucoma, difficulty in urinating, prostate enlargement, or seizure disorder, or if you are using any other dietary supplement or over-the-counter drug containing ephedrine, pseudoephedrine, or phenylpropanolamine (ingredients found in certain allergy, asthma, cough/cold and weight control products). If you are sensitive to ephedra or other stimulants, we recommend Anorex-SP™ Stimulant-Free. Exceeding recommended serving may cause serious adverse health effects including heart attacks and stroke. Do not take if sensitive to or if allergic to aspirin. Do not use if pregnant (it is especially important not to use aspirin during the last 3 months of pregnancy unless specifically directed to do so by a physician because it may cause problems in the unborn child or complications during pregnancy), nursing, have asthma, or have stomach problems (such as heartburn, upset stomach or stomach pain) that persist or recur, or if you have ulcers or bleeding problems, unless directed by a physician. If ringing in the ears or temporary loss of hearing occurs, consult a physician before taking again. Discontinue use and call physician or licensed health care professional immediately if you experience rapid heartbeat, dizziness, severe headache, shortness of breath or similar symptoms.

OXYDRENE®
(Crenulin-RCC®)

Deep Tissue Oxygenator for
Viagra® Users and their Partners



Q: What can Oxydrene®
do for you that
Viagra®* can't?

A: "Viagra®* will get you
there, but Oxydrene®
keeps you going."**

Tab 84

BUY ONLINE
NOW!

Or Call 1-800-919-9715

Millions of men taking Viagra®* to solve the problem of erectile dysfunction (ED) have come to the sad conclusion that endurance and stamina are the real keys to mutual satisfaction. The ability to keep going is what separates Oxydrene® from every other compound on the market – and why so many Viagra®* users (and their partners) are taking Oxydrene along with Viagra®* for complete sexual fulfillment.


Let's face it, sexual relations are virtually identical to exercise – the instant your muscles run out of oxygen, your ability to continue becomes a painful exercise in futility. Oxydrene – the clinically proven deep tissue oxygenator – was developed for one specific purpose: to replenish oxygen spent through physical exertion. In other words, Oxydrene provides sufficient oxygen at the cellular level to fully maximize sexual performance, allowing you to recuperate faster, stay longer, and have the ability to perform at your peak all night long.

Lack of oxygen makes you fatigued, fatigue makes you weak. Oxydrene makes you strong. We are so sure of Oxydrene's power that we guarantee you will see and feel a profound difference in ten days or your money back. That's why Oxydrene has been called "Viagra's®* better half." Viagra®* gets you there, but Oxydrene keeps you there. Get your Oxydrene today. You (and your partner) will not be disappointed.

Oxydrene® Will Change Your Life

Increased energy, stamina, and endurance... make no mistake about it, Oxydrene will work for you, just as it has for thousands and thousands around the globe. You will be thrilled with the results — results you can feel and everyone else will notice. Experience the incredible advantage maximized blood and tissue oxygen provides! While increasing blood and tissue oxygen levels sounds like a simple concept... it's taken more than 50 years of clinical and field testing to bring you Oxydrene. Oxydrene's capacity to bind oxygen to blood and tissue maximizes your body's ability to build muscle, reduce fat, and increase energy, stamina, and endurance. That's why thousands of Oxydrene users call it "The Secret Weapon of Winners." Get Oxydrene today and experience the difference! **NEXT>>**





"Young or old, man or woman, sufficient blood and tissue oxygen levels are required to maintain a youthful level of energy, stamina, and endurance."

— Dr. Daniel B. Mowrey, Science Director, Klein-Becker usa

BUY ONLINE NOW!

Or Call 1-800-919-9715

****Clinically proven safe and effective under verified hypoxic conditions.**

*Viagra is a registered trademark of Pfizer, Inc.
Oxydrene is a registered trademark of X.M. International, L.L.C.
Oxydrene is not sponsored or approved by Pfizer, Inc.

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Tab 85

Oxydrene® (Crenulin-RCC®)

Deep Tissue Oxygenator



120 Capsules
(Approx. 1-Month Supply)

\$79.00

**Add To
Basket Now!**

240 Capsules
(Approx. 2-Month Supply)
SAVE \$10.00

\$148.00

**Add To
Basket Now!**

Kelli -

Tab 86

With respect to your inquiry concerning Mitchell Friedlander's background in the dietary supplement industry, following is the information:

In the mid-1980's, Mr. Friedlander was engaged in the marketing of certain products related to weight loss and male pattern baldness. As a result of such marketing activities, Mr. Friedlander faced charges and administrative proceedings in three separate forums. All three of these actions arose from the same set of facts and circumstances.

Mr. Friedlander was charged by the State of Florida in the Circuit Court of the Seventeenth Judicial Circuit, in and for Broward County, with numerous counts of schemes to defraud, Florida RICO violations, cheating, and misleading advertising. All but thirteen counts of scheme to defraud (one count per involved product) were dismissed, and Mr. Friedlander pled nolo contendere to the remaining thirteen counts.

Pursuant to an agreement between Mr. Friedlander and the Broward County prosecutor which was fully accepted and approved by the Court, adjudication of the matter was withheld. Mr. Friedlander had a one-year jail sentence suspended, was placed on probation for five years, paid a fine of \$460 and agreed not to conduct business in the state of Florida during the five year probationary period (he had, at the time of the agreement, relocated to Georgia). The agreement was entered more than sixteen years ago, in March 1988. Mr. Friedlander strictly abided by the terms of the agreement.

Pursuant to well-established Florida law, Mr. Friedlander's nolo contendere plea coupled with a "withhold of adjudication" does not represent a conviction of any crime.

The Federal Trade Commission brought an action against Mr. Friedlander and several corporations with which he was affiliated alleging the use of deceptive advertising arising out of the same facts as the State of Florida matter. Final judgment was entered in the FTC matter in February 1986 by the United States District Court for the Southern District of Florida enjoining the defendant corporations and Mr. Friedlander from making certain narrow, specific representations regarding the ability of a person "to lose weight without exercising or restricting caloric intake." In addition, the defendant corporations and Mr. Friedlander were enjoined from making representations suggesting that any product could "cure baldness or cause new hair to grow." Mr. Friedlander has strictly abided by the terms of this judgment.

Finally, the U.S. Postal Service brought an action arising out of the same set of facts and circumstances. A cease and desist order was entered restricting Mr. Friedlander from using the mails to make the types of claims which were enjoined in the FTC action. Mr. Friedlander has strictly abided by the terms of the order.

24TH STORY of Level 2 printed in FULL format.

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Tab 87

The Associated Press

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March 23, 1988, Wednesday, AM cycle

SECTION: Domestic News

LENGTH: 316 words

HEADLINE: Owner of Mail-Order Company Banned from Living, Working in Florida

DATELINE: FORT LAUDERDALE, Fla.

BODY:

A man accused of making millions by selling worthless mail-order cures for ills from impotency to baldness to obesity has been banished from living and working in Florida.

Mitchell Friedlander, the 38-year-old owner of Robertson-Taylor Co., entered pleas of no contest Tuesday to 13 charges of operating a scheme to defraud.

In return for his pleas, Broward County Circuit Judge Mel Grossman, gave him a suspended one-year jail term, put him on probation for five years and barred him from doing business or living in Florida.

Grossman withheld adjudication in the case, meaning Friedlander will have no criminal record if he complies with probation terms. If he forms a corporation, owns retail outlets or warehouses, or obtains a mail drop in Florida, he can be sent to prison.

Friedlander's mail-order company, which had 400,000 customers and grossed millions in sales, began operating from a Fort Lauderdale office in early 1984, police and his lawyer, William Richey, said.

Through ads in national magazines, it offered pills and lotions to cure baldness, turn fat to muscle, relieve stress, increase breast size, dissolve cellulite, cure impotency, and provide the "ultimate orgasmic experience."

Three months after the business opened, police began investigating customer complaints. In July 1985, police charged Friedlander with 43 counts of racketeering, scheming to defraud, misleading advertising and cheating.

Six weeks later, he was charged with 70 new counts of fraud and grand theft after police searched his office.

Friedlander's no contest plea, which is not an admission of guilt, was prompted after Grossman ruled that none of the evidence gathered during the search would be admissible at trial. The ruling wiped out 70 charges.

The plea came as jury selection was beginning for trial.

Today, Friedlander lives in Atlanta, in debt, according to Richey.



Tab 88

In the Matter of the Complaint Against

INTRA-MEDIC FORMULATIONS, INC.
1110 West Sunrise Boulevard
Ft. Lauderdale, Florida 33311-1337

and

MITCHELL K. FRIEDLANDER
508 Bontona Avenue
Ft. Lauderdale, Florida 33301-2422

and

CUSTOMER SERVICE DISTRIBUTION CENTER, INC.
997 N.E. 11th Avenue Ft.
Lauderdale, Florida 33311-1337

and

CONNOR-FREEMAN LABORATORIES, INC.
1881 N.E. 26th Street, Suite 208
Ft. Lauderdale, Florida 33305-1416

and 1110 West Sunrise Boulevard
Ft. Lauderdale, Florida 33311-1337

and 10100 Linn Station Road, Suite 102
Louisville, Kentucky 40223-3837

RESPONDENTS

P.S. Docket No. 19/182

09/10/85

Bernstein, Edwin S.

APPEARANCES FOR COMPLAINANT:
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Law Department
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Washington, DC 20005-5002

Mitchell K. Friedlander

c/o The Robertson
Taylor Company
1110 West Sunrise Blvd.
Ft. Lauderdale, Florida 33311-1337

POSTAL SERVICE DECISION

On September 21, 1984, the Consumer Protection Division, United States Postal Service (Complainant) filed a Complaint alleging that Respondents Intra-Medic Formulations, Inc. and Mitchell K. Friedlander violated 39 U.S. Code § 3005 by selling Anorex-CCK, a purported weight loss product, through the use of the mail by false representations. The Complaint was amended by Orders of January 8, January 28 and May 23, 1985 to add Respondent Connor-Freeman Laboratories, Inc. and its three mailing addresses. The January 28 Order also permitted revised allegations of false representations, and confirmed an earlier Order that added Respondent Customer Service Distribution Center, Inc. (Tr. 396).

Paragraph 7 of the Amended Complaint alleged that Respondents falsely represent:

- (a) Ingestion of Anorex-CCK in accordance with the label instructions will result in rapid, permanent weight loss.
- (b) The weight loss results claimed for Anorex-CCK may be achieved without effort, calorie-restricted diets or exercise.
- (c) Cholecystokinin (CCK), the primary active ingredient of Anorex-CCK, is responsible for causing rapid, permanent weight loss in users, without effort, calorie-restricted diets or exercise.
- (d) Reliable and competent scientific evidence demonstrates that the cholecystokinin in Anorex-CCK, orally ingested, is effective as described in 7(c) above.
- (e) The bovine tissue in Anorex-CCK is the only naturally occurring source of cholecystokinin.

Respondents denied that they violated 39 U.S. Code § 3005. At Respondents' request, this case together with PS Docket Nos. 19/104 and 19/162 was scheduled for expedited hearing pursuant to 39 C.F.R. 952.17(a) (Judge Cohen's Order of February 1, 1985). I was designated Acting Judicial Officer for that purpose.

Commencing February 12, 1985 Complainant presented the testimonies of Richard C. Eastman, M.D., William R. Ayers, M.D., and Albert I. Mendeloff, M.D. Respondents presented the testimonies of Stephen C. Woods, Ph.D., Thomas M. S. Wolever, B.M., Dan Sarel, Ph.D., Lynda M. Maddox, Ph.D., and Ruth B. Smith, Ph.D. By stipulation, Respondents' advertisements and various other exhibits as identified on Complainant's exhibit list were received in evidence (Tr. 2006-15).

During the hearing, Respondents offered as exhibits two collections of scientific articles which they designated as "Anorex-CCK (Cholecystokinin) Source Book" and "Guar Source Book." Upon no objection these source books were received into evidence, although they were not given exhibit numbers since the books were to be furnished later and some of the articles duplicated other exhibits (Tr. 4690J-O). The Anorex-CCK Source Book is hereby designated as RX3-54 and the Guar Source Book is hereby designated as RX3-55. The articles contained in the Anorex-CCK Source Book are listed in Appendix A to this decision.

Respondents offered as an exhibit the videotaped deposition of Joseph E. Morrow, Ph.D. Dr. Morrow conducted a survey and based upon that survey concluded that the money-back guarantee that Respondents offered was a crucial factor in persuading the majority of users surveyed to buy products. Although Complainant objected to the admission of this exhibit, I received it into evidence subject to a showing in post-hearing proposed findings and conclusions that the deposition is relevant (Tr. 4794-96). Respondents' post-hearing submissions have failed to show that the deposition is relevant. In view of the holdings in *Farley v. Heininger*, 105 F.2d 79, 84 (D.C. Cir. 1939); *Borg-Johnson Electronics, Inc. v. Christenberry*, 169 F. Supp. 746, 751 (S.D.N.Y. 1959) and other cases that a promise of a refund if a customer is dissatisfied will not dispel the effect of false advertisements, I find the deposition to be irrelevant and therefore inadmissible. The transcript and the videotape of the deposition are hereby designated as RX3-56 and RX3-56A respectively and will be retained as rejected exhibits.

At the hearing, Respondents also offered an affidavit and report of Kenneth W. Clarkson, Ph.D. Upon objection by Complainant, the affidavit and report were rejected as irrelevant (Tr. 5906-07,

Conference on the Record of April 15, 1985, pp. 5-6). The affidavit and report are hereby designated as RX3-57 and will be retained as a rejected exhibit.

By Order of May 20, 1985 the parties were directed to submit proposed findings of fact, proposed conclusions of law, and memo randa. Proposed findings and conclusions were to be specific and supported by citations. The parties were directed to file reply submissions specifically stating agreement or disagreement with the opposing party's proposed findings and conclusions and providing supporting citations and alternate findings or conclusions where there was disagreement. Complainant filed 86 pages of proposed findings and conclusions on June 7, 1985. After requesting and being given a 10 day extension of time in which to file their submission, Respondents on June 18, 1985 filed a three page submission which contained no specific citations to evidence or legal authority. Complainant filed reply submissions on June 20 and July 12, 1985. Respondents filed a reply submission on July 8, 1985 (Respondents July 8 submission). All proposed findings, proposed conclusions and arguments have been considered. To the extent indicated, they have been adopted. Otherwise they have been rejected as irrelevant or not supported by the evidence.

FINDINGS OF FACT

I. The Use of the Mail

Mitchell K. Friedlander owns Intra-Medic Formulations, Inc. Intra-Medic wholly owns Customer Service Distribution Center, Inc. and Connor-Freeman Laboratories, Inc. A similar finding was made in the January 28, 1985 Decision and Order on Motion to Dismiss and this was not denied by Respondents in their July 8 submission.

Mitchell K. Friedlander is the president and principal decision maker in Respondent corporations which he wholly owns and controls (January 28, 1985 Decision and Order on Motion to Dismiss). It was determined that there was a complete identity of interests between Mr. Friedlander and his corporations, despite Respondents' protests to the contrary. Therefore, Lee H. Harter, Esq. was considered to also represent Mr. Friedlander. Mr. Friedlander was permitted to personally participate in the hearing as a matter of courtesy and convenience to Respondents (Tr. 2176-77, my Memorandum For Record dated May 6, 1985).

The Complaint set forth Mitchell K. Friedlander's address as 2175 State Road 84, Dock 12, Ft. Lauderdale, Florida 33312-4839. How ever, in a May 1, 1985 Motion, Complainant requested that Mr.

Friedlander's address be amended as 508 Bontona Avenue, Ft. Lauderdale, Florida 33301-2422. That part of the motion was denied due to Complainant's failure to cite evidence to support this change. Complainant's proposed finding no. 3 correctly asserted that this address was admitted in the response to Request for Admissions No. 8 filed by the corporate Respondents on January 29, 1985. Therefore, I grant the motion to amend Mr. Friedlander's address to 508 Bontona Avenue, Ft. Lauderdale, Florida 33301-2422. However, in accordance with Mr. Friedlander's request, service of papers will also be made to him c/o The Robertson-Taylor Company, 1110 West Sunrise Blvd., Ft. Lauderdale, Florida 33311-1337.

Respondent corporations solicit orders by mail in connection with the sale of Anorex-CCK. These orders are solicited for Intra-Medic at

1110 W. Sunrise Blvd., Ft. Lauderdale, Florida 33311 (CX3-33, 35, 36b); for Customer Service at 997 N.E. 11th Avenue, Ft. Lauderdale, Florida 33311-1337 (CX3-48, 50, 54); and for Connor-Freeman at 1881 N.E. 26th Street, Suite 208, Ft. Lauderdale, Florida 33305 (CX3-41, 42, 48, 56(e) and (f)); at 1110 W. Sunrise Boulevard, Ft. Lauderdale, Florida 33311 (attachments to May 1, 1985 Motion to Amend, granted by Order dated May 23, 1985); and at 10100 Linn Station Road, Suite 102, Louisville, Kentucky 40223 (CX3-51).

Respondents' advertisements appear in publications of general circulation (CX3-33, 42, 51, admitted in Respondents' July 8 submission). Respondents are all part of a single enterprise directed by Mitchell K. Friedlander through various corporations using various advertisements for Anorex-CCK.

II. The Advertising Representations Respondents' advertising materials, including product inserts accompanying reorder solicitations, make the representations alleged in subparagraphs 7(a), (b), (c) and (d) of the Complaint. However, the advertising materials do not make the representation alleged in 7(e). Specific reasons for these findings are as follows:

(a) Ingestion of Anorex-CCK in accordance with the label instructions will result in rapid, permanent weight loss.

Respondents' July 8 submission did not dispute this proposed finding. The May 20, 1985 Order required each party to reply to the opposing party's proposed findings. The parties were advised that unless an opposing party's proposed finding was specifically denied with supporting citations and an alternate finding, that proposed finding would be deemed admitted. Respondents' statement, "no objection," is consequently deemed an admission. Therefore, I find that the representation was made. This finding is also based upon quotations from advertisements set forth in pages 7-14 of Complainant's proposed findings.

(b) The weight loss results claimed for Anorex-CCK may be achieved without effort, calorie-restricted diets or exercise.

Respondents' July 8 submission also does not dispute this proposed finding. Respondents' only statement was "no objection." Accordingly, this finding is deemed admitted, and I find that the representation was made. This finding is also based upon quotations from advertisements set forth in pages 14-17 of Complainant's proposed findings.

(c) Cholecystokinin (CCK), the primary active ingredient of Anorex-CCK, is responsible for causing rapid, permanent weight loss in users, without effort, calorie-restricted diets or exercise.

(d) Reliable and competent scientific evidence demonstrates that the cholecystokinin in Anorex-CCK, orally ingested, is effective as described in 7(c) above.

With respect to 7(c), the language of Respondents' advertisements conveys the unmistakable message that it is CCK in Anorex-CCK that causes the claimed weight-loss effects. This idea is reinforced by use of the letters CCK in the product's name. The advertisements state:

Medical science has just dropped a long-awaited bombshell on the diet industry -- a powerful weight loss formulation with the tongue-twisting name of cholecystokinin.

* * * * *

What makes the discovery of cholecystokinin a real diet bombshell? Not only does the compound cause rapid weight loss, but its discovery literally exploded all previous theories about losing weight and the cause of obesity.

* * * * * What intrigues researchers is that CCK overcomes the biggest obstacles to weight loss: diet and exercise. CCK puts the body in an anorectic state - a state in which the body rejects excess calories ...

* * * * * [O]nly Anorex-CCK contains the powerful weight loss compound extracted through a patented production process (CX3-33, p. 2). EXPLOSIVE WEIGHT LOSS DISCOVERY A significant weight loss breakthrough of unprecedented magnitude has just been revealed. A compound with the tongue-twisting name of cholecystokinin (CCK) that will soon become a household word for every American man and woman who wants or needs to lose weight and we mean lots of weight (10, 20, 30, 50 pounds or more) including YOU] This potent, powerful, isolated peptide actually eliminates the cause of fat formation...So QUICKLY and so EFFECTIVELY you will know from the very start why it has taken more than 15 years of research and over 200 medically documented studies to finally bring you ANOREX-CCK - THE ULTIMATE CURE FOR FAT. WHY HAS IT TAKEN ANOREX-CCK SO LONG TO REACH THE MARKETPLACE? The answer is really quite simple: while ANOREX-CCK was proven to cause weight loss, a natural source for the compound was not available. Now, after years of research and extensive experimentation, an independent laboratory with expertise in biotechnology finally uncovered a naturally-occurring source of CCK -- a source that could be taken orally in tablet form. This discovery was the key to making ANOREX-CCK available to the millions of overweight men and women who diet each year. But there's only one catch: ANOREX-CCK is expensive to produce (CX3-41, 3-56b, p. 2). FACT: LABORATORY ANIMALS INJECTED WITH CCK LITERALLY STARVED THEMSELVES TO DEATH (CX3-41).

CCK puts the body in an anorectic state - a state in which the body rejects excess calories (CX3-51, p. 2, 3-56b, p. 2).

The product labels and package insert instruction book reinforce the message that CCK is the active principle. The labels state:

CONTENTS: Each tablet provides:

Bovine tissue (a natural source of Cholecystokinin-CCK) 350 mg . . . (CX3-38, 3-45, 3-52)

Other advertisements of Respondents state:

All you need to lose weight is to take ANOREX-CCK as directed. That's it] Only ANOREX-CCK contains the single natural source of cholecystokinin (CCK, for short), the potent weight loss compound that not only exploded all outdated theories about obesity, but has made losing weight as easy as taking this miraculous agent. (CX3-47 p. 2, 3-53 p. 2).

... It's all because of ANOREX-CCK. That's right] Research published ... concluded the awesome weight loss powers of CCK are dose dependent. Your weight loss is regulated by the amount of CCK to put into your system therefore the more Anorex-CCK you take the more weight you will lose.

While CCK was proven to cause weight loss, a natural source for the compound was not available. Now... an independent laboratory ... finally uncovered a naturally-occurring source of CCK -- a source that could be taken orally in tablet form. This discovery was the key to making ANOREX-CCK available ...

The basic raw materials are expensive to produce and must be properly prepared and designed to insure the required absorption of CCK within the body -- absorption vital to produce the visible and measurable weight loss you demand and deserve.

The above language appeared in a copy of an advertisement attached as an exhibit to Complainant's May 1, 1985 Further Motion to Amend Complaint. Complainant alleged, and the advertisement and an attached affidavit of Postal Inspector Cantley indicated that the advertisement appeared in the New York Post on February 8, 1985. Respondents did not dispute the authenticity of this advertisement either in their May 22 written opposition to the motion or at any other time. Therefore, this advertisement will be considered as evidence.

With respect to 7(d), the advertisements represent:

. . . researchers have presented over 200 studies published in medical journals around the world demonstrating CCK's miraculous weight loss powers . . .

CCK has proven time and time again that it has the unique ability to cause rapid weight loss with little or no effort on the part of the dieter . . .

After years of research and a lot of detective work, a Wisconsin-based firm with expertise in biotechnology finally uncovered a naturally-occurring source of CCK -- a source that could be taken orally in tablet form (CX3-33 p. 2).

EXPLOSIVE WEIGHT LOSS DISCOVERY.

. . . it has taken more than 15 years of research and over 200 medically documented studies to finally bring you ANOREX-CCK - an ultimate cure for fat.

What intrigued researchers most is that CCK overcomes the two biggest obstacles to weight loss . . . this medically documented published report underlined the supreme and uncompromising powers of CCK (CX3-51, p. 1).

. . . it's all because of ANOREX-CCK. That's right] Research published in the American Journal of Clinical Nutrition (May 30, 1977, pp. 758-761) concluded the awesome weight loss powers of CCK are dose dependent (CX3-51, p. 2).

This is truly a major breakthrough . . .

N.J. Lester, Chief CCK Researcher,

A.R.C. Medical Services (CX3-41, 3-51).

Respondents contend that representations about CCK alleged in subparagraphs 7(c) and (d) are not material. Respondents argue that consumers would purchase the product without relying upon representations about CCK. Respondents presented testimonies of three marketing experts. Dan Sarel, Ph.D., Professor of Marketing at the University of Miami, Florida, has been working in the area of consumer decision-making and advertising effectiveness for the past 10 years (RX3-45). He defined a material representation as one that has a significant impact on a person's decision (Tr. 5689). He concluded that representations 7(c) and (d) are not material (Tr. 5690, 5694). He gave no reason for the conclusion except that it was based upon his education and experience.

Ruth B. Smith, Ph.D., Assistant Professor of Marketing at the University of Maryland, has published several papers in the marketing field (RX3-46). She defined a material representation as that portion of an advertisement on which the consumer focuses and considers important (Tr. 5790). She also testified that representations 7(c) and (d) are not material. She based her opinion on her knowledge of the literature and "ad comprehension information processing" (Tr. 5791).

Lynda M. Maddox, Ph.D., is Associate Professor of Business Administration at George Washington University, Washington, D.C., where she teaches advertising and marketing. She is involved in research and publishing in her field (RX3-47). She defined a material representation as the principal criterion upon which a consumer makes a purchase decision (Tr. 5848). Her view is that representations 7(c) and (d) are not material because consumers would purchase the product for its overall effect, rather than because it contained the ingredient CCK (Tr. 5849). She based this opinion upon her training and experience (Tr. 5850).

Generally, I agree with these witnesses' definitions of materiality. *Chaachou v. American Central Insurance Company*, 241 F.2d 889, 893 (5th Cir. 1957), defined a material representation as one that would "cause the other party to do other than that which would have been done had the truth been told." Applying this definition, representations are material if they have the effect of helping to induce individuals to purchase the product.

Respondents' representations are directed at the ordinary consumer. It has been consistently held that a trier of fact is qualified to determine the effects of various representations on the minds of ordinary people and whether representations are material, regardless of the opinions of experts. *Steinberg v. Indemnity Insurance Co. of North America*, 364 F.2d 266, 274 (5th Cir. 1966); *Vibra Brush Corp. v. Schaffer*, 152 F. Supp. 461, 468 (S.D.N.Y. 1957); *rev'd on other grounds*, 256 F.2d 681 (2nd Cir. 1958); *Delta Enterprises, P.S. 14/72* (P.S.D. July 3, 1984).

I have carefully considered the views of these experts. I do not agree with their conclusions that the representations in 7(c) and (d) are not material. Although the word "cholecystokinin" is not one that the ordinary consumer would know, Respondents' advertisements elevate this ingredient to great importance. For example, the first paragraph of CX3-33, p. 2, after the heading "MEDICAL UPDATE: SCIENCE CONQUERS FAT," states:

Medical science has just dropped a long-awaited bombshell on the diet industry - a powerful weight loss formulation with the tongue-twisting name of cholecystokinin.

In CX3-41 and 51, after headings of "FAT CURE REVEALED" and "Rare and Powerful Anorectic Agent UNCOVERED," another conspicuous heading states:

FACT: LABORATORY ANIMALS INJECTED WITH CCK LITERALLY STARVED THEMSELVES TO DEATH]

After another heading, "EXPLOSIVE WEIGHT LOSS DISCOVERY," the advertisement continues:

A significant weight loss breakthrough of unprecedented magnitude has just been revealed. A compound with the tongue-twisting name of cholecystokinin (CCK) that will soon become a household word for every American man and woman who needs to lose weight and we mean lots of weight . . .

That same advertisement also states: "We stumbled across the substance that everyone's looking for . . ."

The fact that Respondents' product is named Anorex-CCK, after these advertisements have described cholecystokinin as "rare and powerful," an "incredible diet breakthrough," a "fat cure," an "explosive weight loss discovery," and have identified CCK as being the initials for cholecystokinin, stresses the important role which the ingredient plays in accomplishing the product's represented results. Respondents' advertisements repeatedly refer to "cholecystokinin" or "CCK." The name "cholecystokinin" or its abbreviation "CCK" is mentioned approximately 24 times in CX 3-33, 15 times in CX3-41 and 15 times in CX3-51. Further, the product name which includes the initials is used approximately 14 times in CX 3-33, 24 times in CX3-41 and 46 times in CX3-51.

Respondents' experts did not indicate why the advertising language about CCK would not impress the average consumer. They simply stated that generally, based upon their training and experience, the language about CCK was not material. For the reasons set forth herein, I find that the representations in 7(c) and (d) are material.

(e) The bovine tissue in Anorex-CCK is the only naturally occurring source of cholecystokinin.

This representation is not made in Respondents' advertising materials. Respondents correctly state that there is no reference to bovine tissue anywhere in their advertisements (July 8 submission). The term "bovine tissue" only appears on the label of the product itself. Therefore, Respondents did not make the representation alleged in 7(e).

III. Qualifications of the Scientific Witnesses

Medical doctors Richard C. Eastman, William R. Ayers and Albert I. Mendeloff testified for Complainant. Medical doctor Thomas M. S. Wolever and Stephen C. Woods, Ph.D., testified for Respondents.

Dr. Richard C. Eastman

Dr. Richard C. Eastman is Associate Professor of Medicine at the Georgetown University Medical School, Washington, D.C., and chief of the Division of Endocrinology and Metabolism, an area which includes the treatment of obesity. Dr. Eastman is consultant to Georgetown's Diet Management and Eating Disorders Program. He also consults directly with patients, some of whom have obesity problems. He is director for clinical research for the diabetes unit. He is a board certified internist (Tr. 2043-45, CX3-67). Dr. Eastman has impressive credentials, having published approximately 25 articles. I found Dr. Eastman to be highly knowledgeable about weight loss principles and about peptide

chemistry. He testified in a sincere, forthright manner and carefully considered the questions in an effort to be helpful and truthful. I found him to be an extremely reliable witness.

Dr. William R. Ayers

Dr. William R. Ayers is Associate Professor of Internal Medicine and Associate Dean for undergraduate medical education at the Georgetown University Medical School (Tr. 2194). He is certified in internal medicine (Tr. 2195), a fellow in the American College of Physicians (Tr. 2198), and co-founder and former director of the Diet Management Clinic at the Georgetown University Hospital (Tr. 2199-2200). He has published articles on the management of obesity and on the use of computers in medicine (Tr. 2224, CX3-65). I found Dr. Ayers to be a credible witness. He demonstrated great expertise concerning principles of weight loss and diet management. He provided a logical analysis of scientific studies. However, as Dr. Ayers admitted, he is not a peptide chemist (Tr. 4447). His testimony about forms of peptides contained errors (Tr. 4447-48, 5159-61) and, therefore, was not reliable.

Dr. Albert I. Mendeloff

Dr. Albert I. Mendeloff is Professor of Medicine at Johns Hopkins University School of Medicine, Baltimore, Maryland (Tr. 2858). He is a gastroenterologist, a physician who specializes in digestive diseases and disorders of the digestive system. He is a fellow in gastroenterology, past president of the American Gastroenterological Association (Tr. 2859), Governor of the American College of Physicians for the State of Maryland (Tr. 2852) and editor of the *American Journal of Clinical Nutrition* (Tr. 2864, CX3-66). His research and practice interests encompass nutritional disorders, absorption and digestion, dietary fiber, diabetes and obesity (Tr. 2865-66). Respondents stated that Dr. Mendeloff "is eminently well qualified to testify and evaluate the studies" (Tr. 2867), and Respondents described him as "an expert's expert" (Tr. 2844). Dr. Mendeloff testified credibly and showed much expertise and care in his testimony. While more knowledgeable about guar, a substance involved in the companion cases, he demonstrated expertise concerning weight loss concepts, cholecystokinin and scientific studies. I found him to be an impressive and highly reliable witness.

Respondents accused Dr. Mendeloff of being untruthful and biased. They first argued that he misrepresented a guar study that he had conducted. Later they contended that he was biased because: (1) he was involved in a competing mail order business, (2) he may have incorrectly believed that Respondents delayed payment of his witness fee, and (3) he made negative comments about Respondents to Dr. Wolever. None of these accusations led me to conclude that Dr. Mendeloff testified untruthfully.

Dr. Mendeloff testified that he conducted a study using a grant from the United States Department of Agriculture for the purpose of determining guar's safety. Guar was experimentally administered in bars made by the National Biscuit Company. Placebo bars, which tasted exactly the same were also developed and administered. Dr. Mendeloff stated that these were "fairly high calorie bars." At the end of the six month study, no differences in subjects' body weights were noted (Tr. 3090-94). He stated that this experiment demonstrated how tough it is to make people lose weight and that the subjects kept eating "even though they had all these extra calories we provided them" (Tr. 3093). Respondents contended that Dr. Mendeloff's co-researcher, Dr. Michael McIvor, contradicted several of Dr. Mendeloff's statements about the study in a recently taped telephone interview. Respondents were not permitted to introduce the recording of the conversation or the testimony of their interviewer, Mr. Lester, to prove the truth of Dr. McIvor's alleged statements, but they were permitted to call Dr. McIvor as a witness (Tr. 3199-3201, 3261-62). Dr. McIvor agreed to testify (Tr. 3351), but Respondents subsequently decided not to call him (Lee H. Harter's February 25 telegram). Therefore, Respondents never substantiated their accusation that Dr. Mendeloff did not testify credibly about the study.

Respondents also argued that Dr. Mendeloff was biased because, according to Mr. Friedlander, "We have been informed that Dr. Mendeloff is selling medication through the mail in direct competition with me" (Tr. 4937). Mr. Friedlander appeared to refer to a "mail order diet" allegedly distributed by the American Digestive Disease Society, a non-profit organization with which Dr. Mendeloff is associated (Tr. 4937-39, 4944, 4956-57, 5066-67). I found this accusation to be too far-fetched to constitute proof of bias (Tr. 4938, 4940). Dr. Mendeloff's association with the sale and distribution of diets by the American Digestive Disease Society does not place him in direct competition with Respondents, nor does it provide him a motive to testify falsely about Respondents' products and medical and scientific matters.

In a motion to strike testimonies of Drs. Ayers and Mendeloff filed June 12, 1985, Respondents argued that because of a postscript in a September 13, 1984 letter from Ms. McFeeley to Dr. Mendeloff referring to a "payment problem" which Respondents contended referred to a delay in their payment of Dr. Mendeloff's witness fee through no fault of theirs, Dr. Mendeloff became biased against Respondents. This accusation also seems absurd. I do not believe that a man of Dr. Mendeloff's stature would testify falsely because of a delay in payment of his bill.

The final accusation of bias relates to Dr. Wolever's testimony. Dr. Wolever testified that he telephoned Dr. Mendeloff on April 9, 1985, the evening after Dr. Wolever's first day of testimony in this hearing. Dr. Wolever stated that Dr. Mendeloff said that Respondents were crooks who, after one mail box was closed down, moved to another city and opened another one (Tr. 5606). Although this testimony indicates Dr. Mendeloff's negative view of Respondents as of April 9, Dr. Wolever's statements do not destroy Dr. Mendeloff's credibility. Dr. Mendeloff completed his testimony almost three weeks before this conversation with Dr. Wolever. Assuming the accuracy of Dr. Wolever's testimony, it is not clear whether Dr. Mendeloff's negative opinion formed by April 9 preceded any of his testimony or that these views effected his testimony. It would not be surprising, after the many incidents in which Respondents verbally attacked Dr. Mendeloff during his testimony, that Dr. Mendeloff subsequently formed a negative impression of Respondents.

Dr. Stephen C. Woods

Dr. Stephen C. Woods is Professor of Psychology, chairman of the Department of Psychology, and Adjunct Professor of Medicine at the University of Washington. Dr. Woods holds the Ph.D. in physiology, biophysics and psychology. He has worked in the field of endocrinology since the late 1960s and has authored more than 100 scientific articles, the majority of which deal with metabolism, food intake, and peptide hormones. Dr. Woods is the National Science Foundation's expert on food intake. He serves on the editorial boards of two peer review journals, American Journal of Physiology and Behavioral Neurobiology. He is organizer of the 1986 International Congress of Physiology of Food and Food Intake (Tr. 5113-15, RX3-36).

Although Dr. Woods' credentials were outstanding with respect to his work concerning CCK, I found him to be all too often assuming an advocate-like stance. Perhaps his personal involvement with CCK prevented him from being more objective. Dr. Woods' strong reaction to Dr. Ayers' statement that a satiating role for CCK has recently been fully disproved, (RX3-8, p. 7), which Dr. Woods apparently regarded as an affront to his entire life's work (Tr. 2126, 5160), may have caused him to become too much of an advocate for Respondents.

Dr. Thomas M. S. Wolever

Dr. Thomas Wolever is a licensed physician in England and in Ontario, Canada (Tr. 5405-06). He is

currently working toward a Ph.D. in the Department of Nutritional Sciences at the University of Toronto (RX3-39). His doctoral research involves nutrition in the treatment of diabetes and lipid problems (Tr. 5404). Dr. Wolever did not testify about Anorex-CCK. He mainly testified about guar, a product involved in another case, but some of his testimony also related to relevant issues concerning scientific method.

IV.

Definition of Terms and Background Findings

Dr. Ayers stated, and Respondents accepted the definition, that obesity is the state of being 15 percent or more over the ideal weight for one's height, age and sex as defined by tables published periodically by, among others, the Metropolitan Life Insurance Company (Tr. 2201-02, Respondents' July 8 submission, p. 11, para. 20). As Drs. Ayers and Mendeloff testified, obesity is a complex problem that is not simple to treat. Nutrition, energy balance, exercise and behavior are important aspects of the problem (Tr. 2202-03, 2268-69, 2873-76). Dr. Wolever also characterized obesity as a complex problem (Tr. 5463). To lose weight, a person must create an energy or calorie deficit so that the body will use stored energy or fat to meet its current energy needs (Tr. 2203, 3134, 3684).

Satiety in humans is the sense of fullness that normally leads to cessation of eating. Dr. Ayers gave this definition (Tr. 4762-63), and Dr. Woods agreed that the definition was reasonable (Tr. 5215). Dr. Eastman's similar definition was "the sense of having had enough to eat, being full" (Tr. 2092). Satiety signals that cause a lean person to stop eating are not equally effective for obese persons. Dr. Ayers testified that satiety does not necessarily cause obese people to eat less, that there is no necessary relationship between increased satiety and weight loss, and that the normal satiety signals do not apply in obese people (Tr. 3381, 4128). When Dr. Woods was asked whether he believed "that producing the feeling of satiety in an obese person leads inevitably to weight loss for that person," he replied, "Certainly not." (Tr. 5289-90). Dr. Wolever agreed that just because a substance produces satiety does not necessarily mean that the substance also produces weight loss (Tr. 5462-63, 5415). Dr. Mendeloff emphasized that many patients who say they feel full in hunger-satiety ratings continue to eat, ignoring the feeling of fullness (Tr. 3841).

Permanent weight loss in obese people is extremely difficult to accomplish. Dr. Eastman stated that if a patient loses weight, remains thin and does not regain the weight for five years, the patient is considered cured of obesity. But the recidivism rate for obesity is extremely high, and 95-98 percent of people in weight loss programs regain their lost weight regardless of the program used (Tr. 2084). Dr. Woods agreed that it is difficult to prevent regaining weight lost (Tr. 5291). He doesn't know if permanent weight loss exists, and prefers to redefine "permanent" to mean "continuous" (Tr. 5153). Dr. Mendeloff agreed that weight loss and weight gain are chronic problems (Tr. 3069). Dr. Wolever stated that even if weight is lost, the effect will not necessarily be long lasting (Tr. 5525, 5557).

As scientific experts for both sides testified, to establish a claim that a substance will be effective to achieve a particular result, the claim must be supported by sound scientific evidence (Tr. 2079-82, 2273, 3068, 5283, 5434, 5550-51). Dr. Ayers said that efficacy claims for Anorex-CCK must be treated as false in the absence of information to support them (Tr. 2972-74). Dr. Woods said that until a substance is tested using the mode of administration for which claims are made, there is no way to know how that substance will work (Tr. 5283). He stated that in the absence of data, a claim or hypothesis is an open question; there is simply no information (Tr. 5197-98). Dr. Wolever also indicated that data are required in order to support a medical opinion (Tr. 5434-35, 5550-51).

Formation of a scientific or medical consensus requires that results of studies be disseminated among members of the scientific community and be reviewed by others working in the field. Presentations of data at meetings and conferences lend themselves to that function, as do having papers reviewed by experts in the field prior to their publication in peer reviewed journals (Tr. 2270, 2956-57, 3072). Persons who perform work and follow work in a field are in positions to be aware of a consensus in that field. As Dr. Eastman indicated, the leading figures in CCK research are Drs. Stephen Woods, Gerard Smith and James Gibbs (Tr. 2109). Drs. Ayers, Eastman and Mendeloff also are qualified to testify about a consensus in the field of weight loss and about the ingredients in Anorex-CCK because of their training and experience in weight loss and their literature searches of these subjects. V. The Truth or Falsity of the Representations

The parties disagree on the composition of Anorex-CCK. Complainant contends that it is proper to conclude that Anorex-CCK consists of two ingredients: (1) cholecystokinin, and (2) carboxymethylcellulose (CBC). Only these two ingredients are listed on labels found on Anorex-CCK containers which Complainant obtained in three separate test purchases (CX3-38, 3-45, 3-52). Respondents contend that there was a mistake in these labels and that Anorex-CCK also includes guar gum, vegetable bran and caffeine and is, in fact, identical to a product called Appecurb manufactured by GenTrac, Inc. (Tr. 2439).

In order to prove the identical nature of Anorex-CCK and Appecurb, Respondents offered six documents as exhibits. Upon objection, these documents were not admitted into evidence. The six documents were found to be inadmissible hearsay evidence lacking sufficient guarantees of trustworthiness (Decision and Order dated June 10, 1985). Since the beginning of the hearing in February 1985, I have told Respondents that if they wished to prove that the product labels were in error, they should offer the testimonies of knowledgeable witnesses subject to cross-examination. I can find no justification for Respondents' failure to present such testimonies. Testimonies could have been scheduled in accordance with witnesses' other commitments, just as other witnesses were accommodated over the course of this lengthy hearing. Respondents went to great effort and showed unusual ingenuity in presenting other witnesses, including those from Canada and Florida. Complainant even suggested a confidentially agreement or a protective order to safeguard any proprietary information or trade secrets of Respondents' witnesses (Tr. 5739, 5897). Respondents' failure to present this testimony leads me to conclude that such testimony might not have been as favorable to Respondents as statements contained in the rejected exhibits, which are not subject to cross-examination.

The first pages of Complainant's exhibits CX3-63 and 3-71 contain statements that Appecurb is the "primary ingredient" or "primary component" of Anorex-CCK. I find these statements no more reliable than those in the rejected exhibits, and in and of themselves insufficient to overcome the evidence of the Anorex-CCK labels. Therefore, in accordance with the three product labels, I find that Anorex-CCK consists of:

CONTENTS: Each tablet provides Bovine tissue (a natural source of cholecystokinin-(CCK) 350 mg., carboxymethylcellulose 650 mg.

A statement of contents on a product label is presumptive evidence of the product's ingredients. Sister Fannie Howard, P.S. 1/101 (I.D. July 10, 1972). In fact, even in cases of conflicting evidence, ingredients listed on product labels have been relied upon as correct. Carter-Ross Labs, P.S. 5/163 (I.D. July 25, 1977); Emil-John Research; P.S. 5/162 (I.D. July 21, 1977).

During the hearing Mr. Friedlander invited Dr. Mendeloff to call Respondents "if you have any doubts about the authenticity of the CCK formulation" (Tr. 3183). Dr. Mendeloff responded by telephoning Respondents' office requesting information. He received a bottle of Anorex-CCK along with a collection

of articles about CCK. The product was labeled identically to the three labels received in evidence (Tr. 4013-15).

Carboxymethylcellulose (CBC) has not been established as a weight loss agent. Dr. Ayers described CBC as a fiber product which has been used as a filler or additive for a variety of products (Tr. 2305). Although it has sometimes been claimed that CBC causes satiety (Tr. 2306), Dr. Ayers stated that the quantities of CBC in Respondents' product would not cause weight loss (Tr. 2310). Dr. Mendeloff agreed that CBC is a filler which would have no effect on satiety or weight loss (Tr. 3107-08, 4990, 5008). In fact, Respondents denied claiming that CBC causes satiety (Tr. 2306).

Anorex-CCK's other ingredient is more controversial. During the hearing and in their post-hearing submission, Respondents contended that CCK "is not an isolated ingredient of Anorex-CCK, but rather one

of many polypeptides contained in the freeze dried cranial tissue extract contained in Anorex-CCK" (July 8 submission, p. 5). However, as I have previously found in this decision, Respondents' advertisements fail to mention bovine tissue and repeatedly emphasize the sensational value of CCK in their product. They dramatically describe CCK as "rare and powerful," an "incredible diet breakthrough," a "fat cure," a "diet bombshell" dropped by medical science, an "explosive weight loss discovery" a "significant weight loss breakthrough of unprecedented magnitude," and having "awesome weight loss powers." These superlative descriptions of CCK itself with no mention of bovine tissue in the advertisements support the conclusion that it is CCK and not bovine tissue that is the product's claimed mechanism of action.

I also note that Dr. Woods' position changed from his pre-hearing affidavits emphasizing the role of CCK to his testimony during the hearing that it was perhaps the bovine tissue which produced weight loss results. The following is typical of his pre-hearing declarations:

The important and relevant aspect of the extracted bovine tissue is that the extraction is done in such a way as to insure a high yield of the naturally occurring peptide, cholecystokinin (CCK) as well as other biochemically related compounds (CX3-68, pp. 2-3) Emphasis added .

Bovine tissue comes from the cow or ox family (Tr. 3106). Although Respondents' July 8 submission contends that Anorex-CCK contains freeze dried cranial tissue, there is no evidence in the record to support this assertion. Moreover, there is no evidence of any scientific theory that bovine tissue causes weight loss.

Respondents' Anorex-CCK Source Book was introduced into evidence by Respondents as a compilation of 24 scientific articles in support of their case (Tr. 4690 J-O). All of these articles relate to CCK. I have been unable to find any emphasis upon bovine tissue in any of these articles or, except for the GenTrac study, in any other scientific article in evidence in this case. If bovine tissue caused weight loss, beefsteak, also bovine tissue (Tr. 5050), might become a diet product. Assays of Anorex-CCK do show that it contains CCK. In order to determine whether Anorex-CCK fulfills Respondents' claims, it is CCK which must be evaluated for weight loss properties.

CCK is a small peptide hormone that was discovered in 1943. It is composed of amino acids of varying chain links. For instance, CCK-4 has four amino acids; CCK-8 has eight (Tr. 2095, 3108). CCK is found in human tissue and in the tissue of all mammals that have been tested for CCK (Tr. 2097). It is released in the body when food enters the small intestine (Tr. 2108, RX3-12, 3-54(14), 3-54(15)). CCK was first identified as having two major functions: (1) emptying the gall bladder, and (2) stimulating the pancreas

to secrete enzymes necessary for digestion (Tr. 2096, 3108). Dr. Eastman explained that in 1973 CCK was further identified as a substance which produces a feeling of satiety. To produce satiety, large amounts of CCK have been injected either intravenously or into the abdominal cavity (Tr. 2096-98). Dr. Mendeloff agreed that CCK so injected influences satiety and food intake (Tr. 3111).

However, orally administered CCK has not been shown to be effective to produce satiety. Although CCK is actively being studied by research scientists (Tr. 4768), none of the published literature reviewed or received in evidence involves administration other than by injection or infusion. No studies were reported in published literature in which CCK was given orally (Tr. 3110-11). All of Complainant's witnesses concluded that CCK given orally would be ineffective to produce satiety (Tr. 2958-59, 2109-10, 3130). Dr. Eastman testified:

In general, hormones that are peptides are not absorbed orally - nor are they effective orally, because they are digested by the peptide acids or digested enzymes which break down meat which is protein.

....

... So that the consensus would be 99.9 percent of the people would predict that it's not effective orally.

....

Some of the leading figures in the field feel it is not effective orally, have so written in print, and have even tried it. And, my opinion would side with the consensus in that regard. If one were going to give this hormone for this effect, one would not give it orally (Tr. 2109-10).

Dr. Eastman identified the leading figures in CCK research as Drs. Stephen C. Woods, Gerard P. Smith and James Gibbs (Tr. 2109). Dr. Mendeloff confirmed that there is not a single published article "in the vast literature on cholecystokinin which indicates that CCK has an effect when given orally" (Tr. 3010-11). Dr. Mendeloff testified that he had telephoned Dr. Smith "and asked him whether there was some new information which I wasn't privy to which stated that this material was effective by mouth and he said absolutely not" (Tr. 3113).

In a chapter written for a 1984 publication entitled "Gut Hormone Hypothesis of Postprandial Satiety," Dr. Gerard P. Smith confirmed that an extract of CCK, CCK-8, injected in the abdominal cavity will inhibit food intake in animals and people. Dr. Smith stated, "the fact that CCK-8 is not active when given orally is an additional therapeutic constraint" (CX 3-58, p. 72). Although Respondents argued that this statement applied only to CCK-8, there is no published scientific evidence that any form of CCK whatsoever is effective orally.

Dr. James Gibbs indicated similar reservations. In a draft of an article to be published in Dietary Treatment and Prevention of Obesity, Dr. Gibbs wrote, "The crucial questions for treatment - whether CCK or BBS bombesin, another peptide can reduce the excess body weight of obese patients when the peptides are repeatedly administered over extended periods, and whether they can do it safely - have not been tested yet" (CX 3-57, p. 102). Dr. Woods agreed with Dr. Gibbs' statement (Tr. 5295). Dr. Woods testified that there is an "absence of any data in animals or humans on giving CCK orally." However, Dr. Woods added, "... it may well be that that's the most efficient way to take the compound ... I don't know" (Tr. 5333, RX 3-38, p. 2).

Dr. Ayers testified about his telephone conversation with Dr. Gibbs. Dr. Ayers stated that he and Dr. Gibbs agreed that orally administered CCK is not effective to cause weight loss in humans (Tr. 2976).

Further, the amounts of CCK in Anorex-CCK are far less than most studies of injected CCK have found to be efficacious to produce satiety and reduced food intake. Dr. Ayers asked Dr. Rosalyn Yalow to assay Anorex-CCK for cholecystokinin (Tr. 2111, 2991). Dr. Yalow won a Nobel prize for developing the radioimmunoassay method (Tr. 2110, 5136). Drs. Eastman and Mendeloff relied upon the assay in testifying (Tr. 2110-11, 3110), and Dr. Woods accepted it as reasonably accurate (Tr. 5278). Mr. Friedlander also stated that he had no problems at all with the Yalow assay (Tr. 2997).

At Dr. Eastman's request, Dr. Jerry Gardner of the National Institutes of Health performed a bioassay of Anorex-CCK (Tr. 2116).

Dr. Eastman explained that a bioassay measures the ability of CCK in the product to stimulate cells in the pancreas, or the product's actual biological activity, whereas the radioimmunological assay measures the concentration of a hormone. As a result, it is quite possible to have wide discrepancies in CCK measurements between these two types of assays. Such discrepancies do not necessarily indicate that one of the assays is inaccurate. There may be large amounts of CCK in the radioimmunological assay which are not biologically active (Tr. 2116-17). As a result, the quantities of CCK found in the Yalow assay were 500 times greater than those found in the Gardner assay (Tr. 2117, 3110).

As Dr. Eastman testified without contradiction, based upon the quantities found in the Yalow assay, one would have to take anywhere from two to 65 tablets per minute during the course of a meal to obtain doses comparable to those which have produced satiety in humans by injection. Based upon the quantities found to be biologically active in the Gardner assay, one would have to take about 500 tablets per minute during the course of a meal. This assumes 100 percent effectiveness of CCK taken orally, an assumption lacking a scientific basis (Tr. 2117-18). Dr. Mendeloff agreed that the amounts of CCK found in Anorex-CCK by either assay are extremely small. He added that there is no evidence that even a large amount of CCK taken orally can be "absorbed from the gut" (Tr. 3110). Dr. Woods agreed that the dosage prescribed in the Anorex-CCK label, two tablets before each meal, is at most one-tenth of the required dose of CCK shown to reduce food intake when CCK was injected (Tr. 5280).

Additionally, Dr. Ayers testified that the most potent natural stimulus to the production of CCK is food in the gut. Overweight people, who eat more than they should, produce CCK through the food that they eat. The fact that despite this they remain overweight is evidence that the CCK in their stomachs is not working for them to help them to lose weight (Tr. 2960-61, 3673).

Respondents argue that the GenTrac study (CX3-63) is sufficient evidence to overcome the consensus of medical opinion that CCK taken orally is not effective to cause satiety or weight loss.

I find the GenTrac study to be irrelevant. That study tested a product known as Appecurb which contained guar gum, vegetable bran and caffeine in addition to bovine tissue extract and CBC. Respondents have failed to show by competent, persuasive evidence that Appecurb is substantially similar to the product described on the labels of Anorex-CCK obtained in the three test purchases. The GenTrac study, therefore, is not pertinent to Respondents' Anorex-CCK product. Further, even if Respondents had shown that Appecurb and Anorex-CCK are identical products, this one in-house study does not overcome the consensus of informed scientific opinion that CCK taken orally will not result in weight loss.

GenTrac, Inc. studied 39 subjects who were recruited by newspaper advertisement and subsequently divided in two groups, a test group and a control group. After an initial random assignment, subjects were moved between groups to balance the average weight per subject. Over a four-week period the test group was given two tablets of Appecurb at a time, while the control group was given only one placebo

tablet at a time. During the four-week period the subjects who took Appecurb lost an average of 12.05 pounds per subject, while the placebo group lost 2.15 pounds per subject (CX3-63, 3-71, 3-69 para 3c). The study has not been replicated (Tr. 2140), nor has it been published in a peer reviewed journal. Other than Dr. Woods, none of the witnesses have seen the underlying data on which the report at CX3-63 is based.

As previously stated, the experts agreed, and Respondents conceded (July 8 submission, p. 12), that to establish a claim that a substance will be effective to achieve a particular result, the claim must be established by sound scientific evidence (Tr. 2079-82, 2125, 2273, 3068, 5283, 5197-98, 5435, 5550-51). Whenever possible, controlled, double-blind studies should be conducted (Ayers Tr. 2273-74; Eastman 2081-82, 2754; Mendeloff 3067-71; Woods 5312; Wolever 5565). In a controlled, double-blind study the subjects are divided into two groups, one group receiving the test product, the other group receiving an inert placebo closely resembling the test product. In a double-blind study neither the subjects nor those administering the substances know which group is receiving the experimental substance or which group is receiving the placebo. If the subjects do not know who is getting which substance, but the administrators are aware of the difference, the study is only single-blind. A single-blind study is given less scientific weight because of its potential for bias (Tr. 2358, 3124). It is not clear from the evidence presented whether or not the GenTrac subjects were prevented from learning the difference between the experimental and control groups. Although Dr. Woods described the difference between receiving one pill and two as unimportant and trivial (Tr. 5147), Complainant's three experts' views that this difference challenges the study's credibility are more

plausible (Tr. 2138, 2358, 3124). I find that the credibility of the study is weakened because of the difference in the number of tablets given the two groups and the strong possibility that the subjects were aware of the difference.

Another weakness was GenTrac's failure to monitor the subjects' dietary intake and exercise. A study should control for other variables which could effect its results. For a weight loss study such variables include diet and exercise (Eastman Tr. 2079-80, 2089, 2141, 2149; Mendeloff 3067, 3125-26; Woods 5297). Dr. Woods learned that GenTrac "wanted subjects who were on a low-calorie and/or weight maintaining diet" (CX3-69, para 3B). In the absence of pre-study and continuing food intake records, there is no way to know what effect the subjects' dietary regimens had on results. Similarly, the subjects' exercise was not monitored. This too may have effected results.

The fact that the GenTrac study was an in-house manufacturer's study which was not submitted for peer-review scrutiny and not replicated also reduces the weight of its findings. As Dr. Ayers testified, in-house studies by pharmaceutical companies are not unusual. They produce preliminary data such as appropriate dosage schedules and information about side effects. These preliminary studies are used as a basis for further controlled, blind studies (Tr. 2964-65).

It is also important that results of studies be reviewed by scientists working in the field. Presentations of data at meetings and conferences are important, as are publications in peer reviewed journals (Tr. 2270, 3072). Journals that are peer reviewed require

review of each submitted paper by two or more experts in the particular field (Tr. 2049-50, 2864-65, 2224-25). The author may be asked to provide additional data or rewrite portions of the paper before it is accepted for publication (Tr. 2864-65, 5339). One important function of peer reviewed journals is to enable members of the scientific community to learn of new work in the field. Another function of publication, especially with respect to new or unexpected results, is to invite further investigations. Although Dr. Woods urged GenTrac to publish the study, GenTrac rejected his recommendation (Tr. 5339). When a study such as the one conducted by GenTrac produces results which conflict with the

consensus of informed medical opinion and are thus new and unexpected, replication is especially required for those results to be accepted in the medical community.

Dr. Mendeloff testified that the medical community is not going to accept just one study of this type. The study would require replication by an independent source, at "least one other study, to reproduce this, before, I think, anyone would take it very seriously" (Tr. 3070-71). Dr. Ayers testified that "findings ... must be replicated in the hands of someone else so that any possible bias can be excluded ..." (Tr. 2270, 2301). Dr. Eastman explained that a single group's findings might be subjected to unknown biases and the findings would have to be confirmed before they would be widely accepted by the scientific community (Tr. 2140). Dr. Wolever also agreed that one single report is not enough to convince the scientific community that anything works, and replication is generally required for the results to be established (Tr. 5561-62). Dr. Woods also

advocates replication for unexpected findings. He stated, "when they give me - bring me back findings that I think are unexpected, I have them do the study again." When asked to explain why he would require replication, Dr. Woods replied "because I'm a skeptic. And I would like to see if it comes out the same way. You have tremendous statistical power if you get the same results in two independent replications" (Tr. 5310).

According to Complainant's scientific experts, the GenTrac study produced new and unexpected findings and should have been replicated in order to gain acceptance in the medical and scientific communities. Dr. Wolever did not discuss the GenTrac study. Dr. Woods agreed that the results of the study are unique (Tr. 5305). However he disagreed that the study's weight loss results are unexpected because GenTrac expected Appecurb to produce weight loss rather than weight gain (Tr. 5311). I think that a more appropriate definition of "unexpected" would be results unexpected because they differ from an informed consensus in the medical and scientific community.

In summary, the informed consensus of medical and scientific opinion is that Anorex-CCK, consisting of the amounts of CCK and CBC listed in Respondents' product labels will not cause weight loss. The GenTrac study applies to a product which contains different ingredients. It is therefore, not relevant to Anorex-CCK. Even if the GenTrac study was relevant, it is insufficient evidence to over come the informed consensus of medical and scientific opinion that CCK given orally will not cause satiety or weight loss. Cholecystokinin has potential value as an aid to a weight loss program.

Unfortunately, science has not yet determined how to harness CCK's appetite-reducing properties in oral form. If that time comes, as demonstrated by valid scientific evidence, carefully-worded weight loss representations for such products will be valid. But based upon present scientific knowledge, Respondents' grandiose claims about Anorex-CCK are untrue. Therefore, I find that the following representations set forth in paragraph 7 subparagraphs (a) through (d) are materially false.

- (a) Ingestion of Anorex-CCK in accordance with the label instructions will result in rapid, permanent weight loss.
- (b) The weight loss results claimed for Anorex-CCK may be achieved without effort, calorie-restricted diets or exercise.
- (c) Cholecystokinin (CCK), the primary active ingredient of Anorex-CCK, is responsible for causing rapid, permanent weight loss in users, without effort, calorie-restricted diets or exercise.
- (d) Reliable and competent scientific evidence demonstrates that the cholecystokinin in Anorex-CCK,

orally ingested, is effective as described in 7(c) above.

CONCLUSIONS OF LAW

1. Postal Service False Representation Orders do not violate the First Amendment of the Constitution. Donaldson v. Read Magazine, 333 U.S. 178 (1948); Lynch v. Blount, 330 F. Supp. 689 (S.D.N.Y. 1971); Hollywood House International, Inc. v. Klassen, 508 F.2d 1276 (9th Cir. 1974); and United States Postal Service v. Beamish, 466 F.2d 804 (3d Cir. 1972). In the latter case, the Court held "Advertisers possess no constitutional right to disseminate false or misleading materials. Therefore, Congress has the power to prohibit such deceptions through appropriate legislation." p. 807. See also: Bolger v. Young's Drug Products Corp., 463 U.S. 60 (1983).
2. The Corporate Respondents solicit money through the mail in connection with their sale of Anorex-CCK at the addresses listed in the caption of this proceeding.
3. An advertisement must be considered as a whole and its meaning will be determined in the light of its probable effect on persons of ordinary minds. Donaldson v. Read Magazine, Inc., supra; Vibra Brush Corp. v. Schaffer, 152 F. Supp. 461 (S.D.N.Y. 1957). Rev'd on other grounds, 256 F.2d 681 (2d Cir. 1958).
4. The impression of promotional representations on the ordinary mind generally is a question for the judge to determine. Expert testimony on interpretation is not required, but it is within the discretion of the judge to permit such testimony. Vibra Brush Corp. v. Schaffer, supra. The impression of advertising on the ordinary mind may be determined by the trier of fact solely on the basis of the advertising itself. Vibra Brush Corp. v. Schaffer; Delta Enterprises, P.S. 14/72 et al, (P.S.D. July 3, 1984).
5. Express misrepresentations are not required. It is the net impression that the advertisement as a whole is likely to make upon individuals to whom it is directed that is important. Even if a solicitation is so worded as to not make an express representation, but is artfully designed to mislead those responding to it, the false representation statute is applicable. G. J. Howard Co. v. Cassidy, 162 F. Supp. 568 (E.D.N.Y. 1958); See also, Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, 425 U.S. 748 (1976), quoting United States v. 95 Barrels of Vinegar, 265 U.S. 438, 443 (1924): "It is not difficult to choose statements, designs and devices which will not deceive." In Vibra Brush Corp. v. Schaffer, supra, the Court stated:

It is not each separate word or a clause here and there of an advertisement which determines its force, but the totality of its contents and the impression of the entire advertisement upon the general populace. p. 465.

Similarly, in American Image Corp. v. United States Postal Service, 370 F. Supp. 964 (S.D.N.Y. 1974) the Court held: "The cases are clear that such advertisements are to be viewed not with a lawyer's eye to 'fine spun distinctions' but with an eye to their over-all effect on the average reader."
6. False representations may also be made in order verification letters and package insert materials since these may be relied upon in connection with reorders. Iso-Tensor Plan, P.S. Docket No. 3/30 (P.S.D. May 23, 1975).
7. Where an advertisement is ambiguous or capable of more than one meaning, if one of those meanings is false, the advertisement will be held to be misleading. Rhodes Pharmacal Co. v. Federal Trade

Commission, 208 F.2d 382, 387 (7th Cir. 1953); Ralph J. Galliano, P.S. 19/15, (P.S.D. p. 9 May 2, 1985); Bruce Roberts Co., P.O.D. 3/78, (I.D., August 16, 1971); Moneymakers et al., P.S. 16/1, (I.D. June 20, 1983).

8. Applying the foregoing standards, the average person who reads Respondents' advertisements would interpret them substantially as characterized in subparagraphs 7 (a), (b), (c) and (d), but not (e) of the Complaint.

9. As expressed in Chaachou v. American Central Insurance Co., 241 F.2d 889, 893 (5th Cir. 1957), a representation is material if it would ". . . cause the [other] party to do other than that which would

have been done had the truth been told." Applying the Chaachou test, the representations in subparagraphs 7(a), (b), (c), and (d) are material because they have the effect of inducing individuals to remit money through the mail to purchase Anorex-CCK.

10. A statement of contents on a product label is presumptive evidence of the product's ingredients. Sister Fannie Howard, P.S. 1/101 (I.D. July 21, 1972). In fact, even in cases of conflicting evidence, ingredients listed on product labels may be relied upon as correct. Carter-Ross Labs, P.S. 5/163 (I.D. July 25, 1977); Emil-John Research, P.S. 5/162 (I.D. July 21, 1977).

11. Complainant has established through qualified expert testimony that the informed consensus of scientific and medical opinion is that Respondents' representations are false. Where Complainant shows that representations in issue are not accepted as true by such a consensus, this showing establishes a *prima facie* case that the representations are in fact false. Cosvetic Laboratories, P.S. 8/160 (P.S.D. July 22, 1982). Once Complainant presents a *prima facie* case of falsity, the burden of going forward with evidence to rebut this showing (though not the burden of proof which always remains with Complainant) moves to Respondent who must adduce evidence either that the consensus does not exist or that the claim of effectiveness is true despite the lack of acceptance by the medical community. Peak Laboratories, Inc. v. United States Postal Service, 556 F. 2nd 1387 (5th Cir. 1977); Frank E. Bush, Inc. v. United States Postal Service, 84 Civ. 8756 (LBS) (S.D.N.Y. 1985); Cosvetic Laboratories, *supra*. Respondents have failed to rebut Complainant's *prima facie* case in either of these ways. Accordingly, the representations alleged in subparagraphs 7(a), (b), (c) and (d) are materially false as a matter of law.

12. Complainant has established its case by the preponderance of competent and probative evidence. Complainant's expert witnesses testified with substantial unanimity that representations made in Respondents' advertisements are false. These expert witnesses stated that their opinions reflected mainstream scientific thought, and each gave detailed bases, not only for his own opinion, but for the process by which a scientific consensus is formed. By contrast, Respondents' witness, Dr. Woods, relied solely upon the GenTrac study to support Respondents' claims.

13. Respondents relied upon Reilly v. Pinkus, 388 U.S. 269 (1949), frequently throughout the hearing (e.g. Tr. 2815-20). Respondents appear to believe that Reilly stands for the proposition that if, in a case brought pursuant to 39 U.S.C. § 3005, Respondents put forward evidence tending to show that their product performs as claimed, the Postal Service's case must necessarily fail. Reilly does not go so far as to change the standard of evidence from a preponderance to some higher one as Respondents suggest. Reilly's dictum cautioned the Postal Service to avoid crushing new or developing ideas. Reilly did not tell the agency to avoid proper enforcement actions where unproved ideas are promoted as established fact. Reilly stated:

In the science of medicine, as in other sciences, experimentation is the spur of progress. It would amount to condemnation of new ideas without a trial to give the Postmaster General power to condemn new ideas as fraudulent solely because some cling to traditional opinions with unquestioning tenacity. P. 274 The Court in Reilly was concerned with placing a "limitation upon findings of fraud under the mail statutes when the charges concern medical practices in fields where knowledge has not yet been crystalized in the crucible of experience." Knowledge in the areas of weight loss and peptide hormones have been sufficiently well scrutinized that one may state the long-established consensus with respect to several scientific facts: One cannot lose weight without adjustment of caloric balance. Evidence is necessary to support claims of efficacy. Neither CCK nor CBC, the specified ingredients of Anorex-CCK, are established by evidence to cause weight loss given orally in the amounts contained. Had Respondents produced evidence of properly conducted, replicated tests showing that Anorex-CCK performed as claimed, both as to results and to mechanism of action since advertisements make both kinds of claims, this case would have been subject to the cautions of the Reilly Court. However, no such "minority school of thought" was established by Respondents' evidence.

14. A promise to refund if a customer is dissatisfied will not dispel the effect of false advertisements. Farley v. Heininger, 105 F.2d 79, 84 (D.C. Cir. 1939); Borg-Johnson Electronics, Inc., v. Christenberry, 169 F. Supp. 746, 751 (S.D.N.Y. 1959).

15. The Corporate Respondents in this proceeding are conducting a scheme for obtaining money or property through the mail by means of materially false representations within the meaning of 39 U.S. Code § 3005 through the sale of Anorex-CCK.

16. Mitchell K. Friedlander formulates, directs and controls the policies of the corporate Respondents. Therefore, it is necessary that the Cease and Desist Order includes Mitchell K. Friedlander, See: Federal Trade Commission v. Standard Education Society, 302 U.S. 112 (1937); Benrus Watch Company v. E.T.C., 352 F.2d 313, (8th Cir. 1965).

Accordingly, a False Representation Order and a Cease and Desist Order are issued herewith.



Tab 89

In the Matter of the Complaints Against

W. G. CHARLES COMPANY
7770 West Oakland Park Blvd.
Landmark Bank Building
Sunrise, FL 33321-6729, et al

P.S. Docket No. 19/105; P.S. Docket No. 19/161; P.S. Docket No.20/32

09/30/85

Mason, Randolph D.

APPEARANCES FOR COMPLAINANT:

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POSTAL SERVICE DECISION

The proceeding in Docket No. 19/105 was initiated on July 3, 1984, when the General Counsel filed a Complaint against the following Respondents: W.G. Charles Company at 7770 West Oakland Park Boulevard, Landmark Bank Building, Suite 210, Sunrise, Florida 33321-6729, and at 3952 N. Southport, Chicago, Illinois 60613-2606; and Mitchell K. Friedlander at 2175 State Road 84, Ft. Lauderdale, Florida 33312-4839; and Harris Friedlander at 2175 State Road 84, Dock 12 #1, Ft. Lauderdale, Florida 33312-4839; and Michael Meade at 3952 N. Southport, Chicago, Illinois 60613-2606. On August 31, 1984, the General Counsel filed a Complaint in Docket No. 19/161 against the following Respondents: The Robertson-Taylor Company at 1110 West Sunrise Boulevard, Ft. Lauderdale, Florida 33311-1337; Intra-Medic Formulations, Inc. at 7770 West Oakland Park Boulevard, Suite 210, Sunrise, Florida 33321-6729; and Mitchell K. Friedlander and Harris Friedlander at the addresses set forth for them above.

P.S. Docket No. 19/105; P.S. Docket No. 19/161; P.S. Docket No. 20/32 -- W. G. CHAR... Page 2 of 22

A Complaint was also filed on November 16, 1984 in Docket No. 20/32 againsts the following Respondents: J.F. Pharmaceuticals, Inc. at 7770 W. Oakland Park Blvd., Suite 210, Sunrise, Florida 33321-6729; and at 10 Bay Street, Suite 119, Westport, Connecticut 06880-4315, and at 3317 Montrose, Suite 1210, Houston, Texas 77006-3946; Intra-Medic Formulations, Inc. at the address set forth for it above; Mitchell K. Friedlander at 508 Bontona Avenue, Ft. Lauderdale, Florida 33301-2422; W.G. Charles Company at 7770 West Oakland Park Blvd., Suite 210, Sunrise, Florida 33321-6729; and Customer Service Distribution Center, Inc., at 997 NW 11th Avenue, Ft. Lauderdale, Florida 33311-1337

The Complaints in Docket Nos. 19/105 and 19/161 were also amended on September 14, 1984, to allege that Harris Friedlander was active in the conduct of Respondents' business. On December 11, 1984, all Complaints were amended to include Customer Service Distribution Center as a Respondent (Tr. 394-396, December 11, 1984). Also, by Order dated May 24, 1985, Harris Friedlander was added as a Respondent in Docket No. 20/32 and Michael Meade was added as a Respondent in Docket Nos. 19/161 and 20/32. Finally, on June 6, 1985, all Complaints in the instant cases were amended to correct typographical errors and propose different language for the Cease and Desist Orders. In addition, the Complaint in Docket No. 19/105 was amended to delete P8(b) which had alleged that the product would cause a "measurable increase" in size and weight of the female user's breast.

The Complaints alleged that Respondents are engaged in conducting a scheme or device for obtaining money or property through the mails by means of false representations concerning the following products in violation of 39 USC § 3005: Macrocell-D58 Liquid Concentrate (Docket No. 19/105); Mamralin-BX2 (Docket No. 19/161); and Breast Formula XP-39 (Docket No. 20/32). Respondents deny that any violation of the statute has occurred. The Complaints alleged in each case that Respondents falsely represent, directly or indirectly, in substance and effect, whether by affirmative statements, implication or omission that:

"Topical application of [the product] will cause a noticeable enlargement of the female user's breasts."

The instant cases are part of a group of 11 related cases. n1 In December of 1984, Administrative Law Judge Edwin S. Bernstein conducted a six-day evidentiary hearing in the eleven cases to determine, in part, whether Michael Meade and Harris Friedlander had been properly named in various complaints. Thereafter, Respondents requested that Docket Nos. 19/104, 19/162, and 19/182 be severed from the group and heard on an expedited basis by Judge Bernstein as Acting Judicial Officer. This had the effect of postponing the trial of the instant cases (Judicial Officer's Order dated February 1, 1985).

n1 P.S. Docket Nos. 19/103, 19/104, 19/105, 19/161, 19/162, 19/179, 19/182, 19/183, 19/184, 20/16, and 20/32.

In April of 1985 Respondents requested that the instant cases also be heard on an expedited basis and that the final agency decisions be issued by any of the Administrative Law Judges. The undersigned Administrative Law Judge was later designated to serve as Acting Judicial Officer to process, hear and issue the final agency decision in the captioned cases (Judicial Officer's Order dated April 19, 1985).

A survey of the record in the expedited cases before Judge Bernstein revealed an unduly burdensome and protracted record caused, in part, by repetitive and argumentative questions and a multitude of dilatory motions and surprises. In order to streamline the trial of the instant cases, a comprehensive pre-trial order was issued on May 8, 1985 by the Acting Judicial Officer. This order provided, in part, that: (a) all motions that may reasonably be expected to arise during trial shall be filed no later than 10 days

before trial; (b) direct and rebuttal testimony shall be filed in writing no later than 20 days and 13 days, respectively, before the trial; (c) the parties shall exchange detailed proposed findings of fact and conclusions of law no later than 20 days prior to the trial; and, (d) upon receipt of these proposed findings, each party shall underline the findings and conclusions that are disputed, put brackets around the findings that are admitted, and leave unmarked the findings which are admitted but deemed irrelevant. In addition to the above "underlining" procedure, the parties were required to critique the other parties' proposed findings. The parties were instructed that in order to eliminate surprise or prejudice, parties who had not identified their facts, witnesses, and physical or documentary exhibits in their proposed findings shall, except upon a showing of good cause, be precluded from offering such proof at trial. Finally, in order to prevent unduly long, repetitive, and argumentative cross-examination, the parties were required to file in writing all reasonably anticipated cross-examination questions with the Acting Judicial Officer (without service on opposing parties) no less than 7 days before the hearing. It was stated that additional questions may be allowed in the interest of justice if they could not reasonably have been anticipated. Finally, all exhibits had to be exchanged no later than 20 days prior to the hearing. In order to accommodate the parties, the May 8 pre-trial order was amended on May 24 and May 29, 1985.

On May 24, 1985, the Acting Judicial Officer designated Lee Harter, Esq., to conduct all examinations of witnesses, make all motions, arguments, and objections at trial, and file all documents required by pre-trial orders on behalf of Respondent Mitchell Friedlander and the corporate Respondents. In the proceedings before Judge Bernstein, Mitchell Friedlander was unable to present his case in a manner consistent with a fair and orderly proceeding. The record is replete with instances in which Mr. Harter represented Mr. Friedlander. Mitchell wanted to represent himself on scientific matters and to be represented by Mr. Harter on legal, procedural, and evidentiary matters. The designation of Mr. Harter is in accordance with *Brasier v. Jeary* 256 F.2d 474 (8th Cir. 1958), cert. denied, 358 U.S. 867 (1958), which held that a party has no right to conduct his own case and have the aid of counsel to speak and argue for him at the same time. Thereafter, Mr. Harter continued to insist that he was only representing the "corporate Respondents," which are wholly owned by Mitchell Friedlander. All such filings have been treated as being, in substance, also filed on behalf of Mitchell.

In accordance with the critique and underlining procedure set forth in the May 8th pre-trial order, on June 12, Respondents filed a marked copy of Complainant's Proposed Findings of Fact and Conclusions of Law (See attachment to Respondents' Critique). Complainant had filed separate proposed findings in each of the captioned docket numbers; however, Respondents indicated that the only disputed sentences in the proposed findings for all three cases were those sentences which it had underlined in Complainant's proposed findings for Docket No. 20/32. All Respondents stipulated that all of Complainant's proposed findings in Docket Nos. 19/105 and 19/161 are admitted (or admitted but considered irrelevant) except for those sentences which are identical to the underlined (disputed) portions of Complainant's proposed findings in Docket No. 20/32. (Memorandum of Telephone Conversations dated June 18, 1985; Tr. 52, June 20, 1985).

After taking into consideration the alleged financial difficulties of the Respondents and all other factors presented, medical emergencies dictated that a portion of the trial be held in Washington, DC on June 17 and 18, 1985. Respondents refused to attend, and for a variety of reasons stated by the Acting Judicial Officer on the record, were deemed to have waived their right to cross-examine the Complainant's expert witnesses. Accordingly, the direct testimony of Peter H. Wendschch, M.D.; Estelle R. Ramey, M.D.; and Yvonne T. Maddox, M.D., were taken ex parte. This testimony had previously been submitted by Complainants as written direct testimony under the pre-trial procedure. The remainder of the hearing took place on June 20, 1985 in Ft. Lauderdale, Florida. Appearances were made by Lee Harter, Esq., and Mitchell K. Friedlander; however, no appearances were made by or on behalf of Harris Friedlander n2 or Michael Meade. Dr. Wendschuh appeared again at this hearing and was cross-

examined by Mr. Harter. Although nominally appearing only for the corporate Respondents, Mr. Harter continually represented Mitchell Friedlander throughout these proceedings (June 20 Tr. 94, 106, 109, 110, 212-214, 222).

n2 Harris attended a portion of the June 20 hearing but declined to participate.

Michael Meade and Harris Friedlander failed to participate in these cases in a meaningful way. With the exception of proposed findings filed on May 29, 1985, consisting of four sentences, Michael Meade and Harris Friedlander failed to file pre-trial submissions required by the May 8 pre-trial order; they made no appearance at either hearing location. They appeared to be relying upon the presentation made by Mr. Harter to defend their cases (See, e.g., "Response of Michael Meade of May 8 Order to Show Cause," at p. 5, filed May 20, 1985; same adopted by Harris on May 21, 1985). It is noted that they also failed to appear in the lengthy main hearing on the false representation issues before Judge Bernstein in the related cases.

Complainant's unopposed motion to correct the transcript filed on July 9, 1985, is hereby granted.

The pre-trial procedure and the conduct of the trial itself afforded the parties a full opportunity to be heard, adduce relevant evidence and examine and cross-examine witnesses. Respondents chose not to present their purported "courtroom demonstration" of three women using the product and elected not to cross-examine two of Complainant's three expert witnesses. After the hearing, Complainant filed post-trial proposed findings of fact and conclusions of law on July 19, 1985 which have been duly considered. Due to withdrawal of counsel, Respondents were given until September 6, 1985, to file their post-trial brief. No such brief was filed.

During the trial Respondents made a motion to stay the proceedings based on an alleged criminal investigation being conducted by the Postal Service. Respondents argued that they should not be required to proceed with their case because it would violate their 5th Amendment right to remain silent and that Complainant might abuse the civil process to gain evidence for the alleged criminal investigation. I denied this motion at the trial; I hereby reaffirm this ruling for the reasons which I previously stated on the record (Tr. 79-82, June 20, 1985), and for the additional reasons set forth below.

In summary, Respondents failed to submit any evidence which tended to prove the existence of a Postal Service criminal investigation. The notations, abbreviations, and boilerplate language on USPS documents offered by Respondents (RX-1) do not even make one suspicious. In contrast, Complainant's counsel represented that there was no USPS criminal investigation (Tr. 42-43). In addition, even if such an investigation had existed, Respondents failed to show how they would be prejudiced by going forward with their case. In this regard, the pre-trial order asked Respondents to submit their entire case in writing prior to the oral hearing. The only evidence that they planned to submit was the product demonstration and the testimony of the three women subjects, which was described in detail and presented verbatim in the pre-trial submissions. Thus there was little that Complainant would discover by requiring Respondents to go forward. All exhibits had been received before trial. With regard to the demonstrative evidence, itself, Respondents' alleged preference to present this to a jury does not constitute a valid reason to stay these proceedings. Moreover, there is no secret to the demonstration; it could be independently performed by the government without the benefit of any evidence herein.

Finally, the stay was properly denied because the public interest protecting consumers from the false representations in these cases outweighs any damage to Respondents that might arguably have occurred by going forward with the civil proceedings. In this regard, Respondents have shown no special circumstances in which the nature of these proceedings demonstrably prejudices any substantial rights.

SEC v. Dresser Industries, Inc., 628 F.2d 1368 (D.C. Cir. 1980), cert. denied 449 U.S. 993 (1980);
United States v. Kordel, 397 U.S. 1, at 11-13 (1970).

To the extent indicated below, proposed findings and conclusions have been adopted; otherwise they have been rejected as irrelevant or contrary to the evidence. Based on the entire record herein, including my observation of the witnesses and their demeanor, the exhibits, stipulations, and other relevant evidence adduced at the hearing, I make the following Findings of Fact and Conclusions of Law:

FINDINGS AND CONCLUSIONS

REGARDING MICHAEL MEADE AND HARRIS FRIEDLANDER AS RESPONDENTS

In December of 1984, Administrative Law Judge Edwin S. Bernstein held a 6-day evidentiary hearing to determine whether Harris Friedlander and Michael Meade were properly named as Respondents in one or more of the instant cases plus the eight related cases. After hearing all of the evidence and considering the parties' briefs, Judge Bernstein issued a Decision on January 28, 1985. He found that these two Respondents held important, responsible positions and are deeply involved in the Respondent corporations' business activities. Accordingly, he held that they had been properly named as Respondents and that any orders issued should be applied to them.

Subsequent to the decision of the Administrative Law Judge, Complainant moved, *inter alia*, to amend two of the instant complaints, requesting that Meade and Harris be added as Respondents in Docket No. 20/32 and that Meade be added in Docket No. 19/161. Both Meade and Harris objected to these amendments on the ground that the January 28 Decision of the Administrative Law Judge was incorrect. By Order of May 24, 1985, the Acting Judicial Officer included Meade and Harris as Respondents but gave them the opportunity to incorporate their exceptions to the January 28 Decision in their pre-trial documents and in any post-trial briefs.

In paragraphs 9 and 10 of Complainant's pre-trial proposed findings of fact, it was alleged that Harris, vice president of W. G. Charles and Intra-Medic (the parent company) and Meade, the corporations' general manager, both hold important, responsible positions in the corporate Respondents and are deeply involved in their business activities. Complainant cited the January 28 Decision at pages 4-7, and 15. Although Harris and Meade did not file responses as required by the pre-trial orders of May 8 and 24, 1985, the "corporate respondents" disputed paragraphs 9 and 10 in their marked copy filed June 12, 1985. Respondents' critique of the same date simply disputes these findings "for the reasons set forth in Harris Friedlander and Michael Meade's Attorney's Memorandum of Law [filed before the January 28 Decision]" and their Motion to Reconsider the January 28 Decision filed on June 12 in Docket Nos. 19/104, 19/162, and 19/182.

After carefully reviewing the January 28 Decision of the Administrative Law Judge, and the underlying record, it is concluded that the findings of fact are fully supported by a preponderance of the evidence of record and that the conclusions of law are correct. In reaching this conclusion, the credibility determinations with respect to both Meade and Harris Friedlander are sustained since the Administrative Law Judge was in the best position to judge their demeanor. NLRB v. Florida Medical Center, Inc., 576 F.2d 666, 671 (5th Cir. 1978).

The record fully supports the finding that Harris Friedlander and Meade hold important, responsible positions and are deeply involved in the corporations' business activities. Harris is the vice president of several of the corporations. He and his brother Mitchell have a relationship of close mutual trust. Harris supervises workers and is the only person who opens the mail and removes the cash that is received in

P.S. Docket No. 19/105; P.S. Docket No. 19/161; P.S. Docket No. 20/32 -- W. G. CHAR... Page 6 of 22

the mail. Further, he made complaints to the Postal Service on behalf of the corporations regarding cash losses (See citations in January 28, 1985 Decision).

Michael Meade is the corporations' General Manager, and had a salary of \$52,000 per year (Tr. 1853, Dec. 19, 1984). In view of the small size of the companies, he is significantly involved in the management of the corporation Respondents.

Orders should be issued against both Harris Friedlander and Michael Meade in order to reduce the threat of evasion of any cease and desist orders issued against Mitchell Friedlander. Federal Trade Commission v. Standard Education Society, 302 U.S. 112 (1937). Moreover, where individuals are engaged in an egregious practice which is designed to mislead the public, the nature of the violation further justifies the imposition of orders on company officials. Bartlett Carpet Mills, Inc. v. Consumer Product Safety Comm., 635 F.2d 299 (4th Cir. 1980). The evidence of record supports a finding that the sale of a product purporting to enlarge breasts is, in fact, an egregious practice.

Finally, in their Motion for Reconsideration of the January 28 Decision, Respondents contended that the decision should be reversed based upon their assertions that Postal Inspector Cantley lied in testifying, and that Complainant did not comply with the Jencks rule in connection with Cantley's testimony. This argument is rejected because Cantley's testimony was either irrelevant or unnecessary for the purpose of deciding the instant issues. The Postal Service forms which he identified were under seal and therefore independently admissible under Federal Rule of Evidence 902(1). These forms revealed the positions held by Harris and Meade (CX2-7a and 7c; CX2-1a; CX2-1b; CX2-6a). Since Cantley's testimony was unnecessary to the January 28, 1985 Decision, Cantley's credibility is irrelevant. This conclusion is in accord with the related case of W. G. Charles Company, P.S. Docket No. 19/104, 19/162 (P.S.D. September 10, 1985 at pp. 7-9).

Accordingly, Harris Friedlander and Michael Meade are proper Respondents and orders will be issued against them individually.

REMAINING FINDINGS OF FACT

Most of the remaining findings were stipulated by Lee Harter, Esq., for the so-called "corporate Respondents" (and, in substance, Mitchell Friedlander) in the underlined copy of Complainant's pre-trial Proposed Findings of Fact filed as an attachment to Respondents' Critique on June 12, 1985. The other Respondents failed to respond to Complainant's pre-trial proposed findings, and are accordingly deemed to admit those findings. See Order of May 24, 1985, emphasizing the importance of a response by every Respondent. However, all findings are fully supported by the transcript and exhibits and citations to the record have been made below.

ADDITIONAL FINDINGS FOR DOCKET NO. 19/105

1. Respondent W.G. Charles Company ("W.G. Charles") is a corporation organized and doing business under and by virtue of the laws of the State of Florida (CX2-26).
2. Respondent Customer Service Distribution Center, Inc. ("Customer Service") is a corporation organized and doing business under and by virtue of the laws of the State of Florida (CX2-27).
3. The corporate Respondents have their principal place of business at 1110 West Sunrise Blvd., Ft. Lauderdale, Florida (CX2-28).

4. Respondent Mitchell K. Friedlander, an individual, wholly owns the corporation Intra-Medic Formulations, Inc. ("Intra-Medic") which, in turn, is the sole owner of Respondents W.G. Charles and Customer Service (CX2-28).
5. Respondent Mitchell K. Friedlander is the sole director and president of W.G. Charles and Customer Service (January 28 Decision; Ans., Dec. 31, 1984; CX2-1(b)).
6. As the sole director and president of the corporate Respondents, Mitchell Friedlander is in a position to formulate, direct and control both the policies and the daily operations of the corporate Respondents, and, in fact, does so (CX2-4, p. 3; Jan. 28 Decision; See additional citations in Complainant's proposed findings).
7. Respondent Mitchell K. Friedlander is responsible for decisions concerning the advertising to be used for the products that W.G. Charles sells (December Tr. 1735; CX2-4 at p. 3).
8. Respondent Harris Friedlander, vice-president of W.G. Charles and Intra-Medic, holds an important, responsible position in the corporate Respondents and is deeply involved in their business activities (See pp. 10-13, supra).
9. Respondent Michael Meade, the corporations' general manager, holds an important, responsible position in the corporate Respondents and is deeply involved in their business activities (See pp. 10-13, supra).
10. Respondent W.G. Charles advertises the product Macrocell-D58 for sale (CX-27, 33, 36, 38, 41, 45, 46).
11. Consumers may purchase the product Macrocell-D58 by sending payment through the United States mails (Id.).
12. Payment and orders for Macrocell-D58 are directed to: The W.G. Charles Company, 3952 North Southport, Chicago, Illinois 60613 (Id.).
13. Respondent Customer Service Distribution Center, Inc. ships the product Macrocell-D58 to customers, handles inquiries and correspondence concerning the product, and processes payment and orders for the product (CX-30, 34, 43, 46).
14. Payment and orders for Macrocell-D58 are also directed to: Customer Service Distribution Center, Inc., 997 N.W. 11th Avenue, Fort Lauderdale, FL 33311. In particular, when the product is shipped to customers who have not remitted full payment for it, such customers are directed to remit the balance due to Customer Service at this address (CX-46).
15. Macrocell-D58 is labeled to contain the following ingredients: Water, Aloe Extract, Cucumber Extract, Niacin, Glycerin, Comfrey Extract, Sodium PCA, Polysorbate 20, Octoxynol-9, Chamomile Extract, Propylene Glycol, Collagen Amino Acids, Ginseng Extract, Isopropyl Alcohol, Carbomer 940, Allantoin, Panthenol, Imidazolidinyl Urea, Methyl Paraben, Menthol, TEA, Fragrance (CX-31, 44).
16. Instructions for use of Macrocell-D58 are substantially similar to those for use of Breast Formula XP-39 and are nearly identical to those for use of Mamralin-BX2. These instructions are:

"STEP 1. After thoroughly cleansing your breasts with mild soap or cleansing cream, shake bottle well

and then dispense a half dropper full of MACROCELL-D58 into the palm of your hand.

STEP 2. Apply MACROCELL-D58 with your fingertips to the entire breast area. Massage vigorously for 3 to 5 minutes.

STEP 3. Soak a clean towel in hot (not scalding) water and hold it firmly to your breasts until it cools. Remove wet towel and pat dry.

...

Use Elan Vital's MACROCELL-D58 4 to 7 times weekly until results are maximized. Then use 2 to 4 times a week to retain your breasts new, radiant, magnetic glow (CX-33, 45).

17. Macrocell-D58 is advertised in national magazines (CX-26, 27, 35-37).

18. At least two different formats are used in magazine advertisements for Macrocell-D58 (CX-26, 35).

19. Macrocell-D58 is also offered for sale to consumers in the instructions brochure accompanying the product (CX-33, 45).

20. Macrocell-D58 may also be ordered by consumers from the order coupon appearing in a letter notifying consumers that an order of Macrocell-D58 has been received by W.G. Charles (CX-41).

21. Respondents' promotional materials make the representation alleged in P8(a) of the Complaint, that "topical application of Macrocell-D58 Liquid Concentrate will cause a noticeable enlargement of the female user's breasts." The following excerpts from Respondents' promotional materials for the product demonstrate that they make the above representation:

(a) Exhibits CX-26, 27, 35, and 36

1. "A breakthrough for Women Who Want More] LARGER BREASTS GUARANTEED.

2. LARGER BREASTS WITHOUT SURGERY.

At last, a REVOLUTIONARY approach to breast enlargement. A highly sophisticated formulation verified by research chemists and unsurpassed in its ability to expand the cellular substructure of the female breast.

That's right] Now you can INCREASE the size of the BREAST itself, not just the bustline, but your ACTUAL CUP SIZE, where it really counts]

MACROCELL-D58 CREATES CELLULAR EXPANSION.

MACROCELL-D58 is a powerfully effective, scientific formulation that has the ability to penetrate deep into the outer layers of breast tissue preparing the breast's cellular sub-structure for ACCELERATED GROWTH. In simple terms, the cells of your breast will now have the capacity to ABSORB ADDITIONAL VOLUME similar to the way a sponge absorbs water. As this absorption [sic] begins, your breasts INCREASE in both SIZE and weight. Your breasts will develop a new satisfying feel of FULLNESS as the entire breast EXPANDS to magnificent new proportions right before your eyes AND THAT'S GUARANTEED.

3. INCREASE YOUR ACTUAL CUPSIZE]

4. NOTICE: Because MACROCELL-D58 causes the breasts to become both larger and heavier, MACROCELL-D58 is fortified with tissue strengtheners to help prevent the possibility of sagging due to accelerated growth. MACROCELL-D58 is not to be used by pregnant or lactating women.

5. You know how much ATTENTION women with large breasts demand from men. And you also know how it feels to see OTHER WOMEN get all that attention just because their breasts are larger than yours. Now you can fight back with MACROCELL-D58, the ultimate breast enhancer.

6. MACROCELL-D58 creates "MACRO-CELLULAR" absorption [sic] over the entire breast area. Visible expansion begins with the very first application.

I understand that if I am not totally satisfied with the visible increase in my breast size, I will get a complete refund including the \$2.00 for postage and handling.

(b) Letter to purchaser with order coupon (CX-41):

"With MACROCELL-D58 you will begin a REVOLUTIONARY APPROACH to breast enlargement - Not just an increase in your bustline, but a NOTICEABLE increase in your actual cup size. From the very first application, your breasts will develop a new SATISFYING FEELING OF FULLNESS and your NEW APPEARANCE AND CONFIDENCE will be the eye-catching envy of other, less well-endowed, women.

The MACROCELL-D58 formulation is the culmination of research in the growing field of macro-cellular expansion - the SCIENTIFIC METHOD of breast development that makes creams, weight gain powders and exercise contraptions totally obsolete. Now you will experience the breasts of your dreams and know the PERSONAL SATISFACTION and confidence of women with large breasts.

MACROCELL D-58 will PRODUCE VISIBLE RESULTS with your very FIRST APPLICATION. In fact, we are so positive that this PENETRATING breast enlarging compound will be all that you've dreamed about, that we are proud to offer you a FULL 20% DISCOUNT ON YOUR NEXT PURCHASE OF MACROCELL-D58."

(c) The Macrocell-D58 instruction booklet and order form (CX-33 and CX-45):

"AN EXCITING NEW EXPERIENCE FOR YOUR BREASTS

You will feel your breasts come alive as MACROCELL-D58 tightens, smooths, enlarges and firms the breasts, producing visible results so dramatic that . . . well, you'll see. A proven formulation from the cosmetic chemists at Elan Vital.

MACROCELL-D58 is a unique blend of natural skin salts, collagen, amino acids, herbal plants, flower extracts that regenerate the outer layers of the breast tissue to work the formulations magic."

ADDITIONAL FINDINGS FOR DOCKET NO. 19/161

1. Respondents, The Robertson-Taylor Company ("Robertson-Taylor"), Intra-Medic Formulations, Inc. ("Intra-Medic"), Customer Service Distribution Center, Inc. ("Customer Service") are corporations organized and doing business under and by virtue of the laws of the State of Florida (CX2-25; CX2-24;

CX2-27).

2. Respondents Robertson-Taylor and Customer Service are subsidiaries of Respondent Intra-Medic (CX 2-28 at pp. 1-2; CX-6, 7, 12, 17, 18, 19, 21, 22).

3. The corporate Respondents all have their principal place of business at 1110 West Sunrise Blvd., Ft. Lauderdale, Florida (CX2-28 at p. 2).

4. Respondent Mitchell K. Friedlander, an individual, wholly owns Respondent Intra-Medic which, in turn, is the sole owner of Respondents Robertson-Taylor and Customer Service (CX2-28 at p. 2; See, Decision of Jan. 28, 1985).

5. Respondent Mitchell K. Friedlander is the sole director and president of Robertson-Taylor, Customer Service, and Intra-Medic (Decision of 1/28/85 at p. 3; CX2-24, 25, 27; CX2-4 at p. 2; Answer of corporate Respondents of December 31, 1984 at p. 4; CX2-11).

6. As the sole director and president of the corporate Respondents, Mitchell Friedlander is in a position to formulate, direct and control both the policies and the daily operations of the corporate Respondents, and, in fact, does so (Decision of 1/28/85 at pp. 3 and 15; CX 2-4 at p. 3).

7. Respondent Mitchell Friedlander is responsible for decisions concerning the advertising to be used and the products that Intra-Medic and Robertson-Taylor sells (December Tr. 1735; CX2-4 at p. 3).

8. Respondent Harris Friedlander, vice-president of Robertson-Taylor and Intra-Medic, holds an important, responsible position in the corporate Respondents and is deeply involved in their business activities (See pp. 10-13, supra).

9. Respondent Michael Meade, the corporations' general manager, holds an important, responsible position in the corporate Respondents and is deeply involved in their business activities (See pp. 10-13, supra).

10. Respondent Robertson-Taylor advertises the product Mamralin-BX2 for sale (CX-1, 2, 4, 7, 12, 14, 16, 18, 22, 24).

11. Consumers may purchase the product Mamralin-BX2 by sending payment through the United States mails (Id.).

12. Payment and orders for Mamralin-BX2 are directed to: The Robertson-Taylor Company, 1110 W. Sunrise Blvd., Ft. Lauderdale, Florida 33311 (Id.).

13. Respondent Customer Service ships the product Mamralin-BX2 to customers, handles correspondence concerning the product and processes payments and orders for the product (CX-9, 13, 20, 23) (envelopes in which products were sent and packing slips accompanying product).

14. Payment and orders for Mamralin-BX2 are also directed to: Customer Service Distribution Center, Inc., 997 N.W. 11th Avenue, Fort Lauderdale, Florida 33311. In particular, when the product is shipped to customers who have not remitted full payment for it, such customers are directed to remit the balance due to Customer Service at this address (CX-13, 23) (packing slips accompanying product).

15. Mamralin-BX2 is labeled to contain the same ingredients as Breast Formula XP-39 and Macrocell-

D58 with the following exception: Mamralin-BX2 is labeled to contain two additional ingredients, F.D.&C. Red #33 and F.D.&C. Red #4 (CX-10, 21).

16. Instructions for use of Mamralin-BX2 are nearly identical to those for Macrocell-D58 and substantially the same as those for Breast-Formula XP-39 (CX-12, 22).

17. Mamralin-BX2 is advertised in national magazines (CX-1-3, 14-16, 24).

18. At least three different formats are used in magazine advertisements for Mamralin-BX2 (CX-1, CX-14 and CX-24).

19. Mamralin-BX2 is also offered for sale to consumers in the instructions brochure accompanying the product (CX-12, 22).

20. Mamralin-BX2 may also be ordered by consumers from the order coupon appearing on a letter notifying consumers that their order of Mamralin-BX2 has been received by Robertson-Taylor (CX-7, 18).

21. Respondents' promotional materials make the representation alleged in paragraph 8 of the Complaint that "topical application of Mamralin-BX2 will cause a noticeable enlargement of the female user's breasts." The following excerpts from Respondents' advertisements and instructions booklet for the product demonstrate that they make the above representation:

(a) Advertisement which appeared in the June 1984 issue of *Cosmopolitan* magazine (CX-1 and 2):

"FACT: Every woman has the ability to increase the size of her breasts. Including you] Increase in the actual cup size, not just the size of your back. (Face it, if you are a size 32AA or a 38AA you still have the problem of small breasts.) But now there is MAMRALIN-BX2 .

MEDICAL EXPERTS HAVE PRODUCED LARGER BREASTS FOR THOUSANDS OF LUCKY WOMEN]

According to most medical experts, the only way for you to permanently increase the size of your breasts is to undergo expensive and sometimes dangerous breast augmentation surgery. But you don't have to give up]

NOW YOU HAVE A CHOICE]

What if you could find a treatment which will produce attention-grabbing, larger, firmer breasts without expensive surgery? What if this exclusive, scientifically developed treatment was not only enjoyable to apply but worked with incredible speed? What if you were able to obtain this treatment now without prescription or embarrassment? Furthermore, what if this formula was guaranteed to work for you or it costs you nothing? Would you be interested? Of course you would] And you're not alone]

FIRST TIME AVAILABLE FOR NON-CLINICAL USE]

MAMRALIN-BX2 was formulated during ongoing research at The Robertson-Taylor Co., a division of Intra-Medic Formulations, Inc. Our research team engaged in the development of biotherapeutic treatments, had a goal: create a formula which could channel specific body mass to designated areas of the body capable of naturally induced expansion. The breasts, (because of the extraordinary properties of

breast tissue) are capable of this type of expansion and the MAMRALIN-BX2 FORMULA can trigger the precise mechanisms which will produce larger, more sensual breasts. And do this fast, safely, and without the permanence or scarring you gamble with if you undergo breast augmentation surgery."

(b) "A WINNING FIGURE WILL MAKE YOU A WINNER] NEW] MAMRALIN-BX2 .

MAMRALIN-BX2 is a new effective scientific compound that is capable of channeling added amounts of body mass to specific areas of the body that are capable of naturally induced expansion. The breasts (because of the extraordinary properties of breast tissue) are capable of this type of expansion, and the MAMRLIN-BX2 FORMULA can trigger the precise mechanisms which will produce larger, more sensitive, sensual breasts, and do it fast, safely and without the permanence or scarring you gamble with if you undergo breast augmentation surgery.

THE SECRET IS THE EXCLUSIVE MAMRALIN-BX2 FORMULA

The MAMRALIN-BX2 FORMULA is a precise blend of compounds that, when massaged into the breasts, will create a series of biological actions that will, simply stated, expand the capacity of the breast to accept additional body mass.

The application of the MAMRALIN-BX2 FORMULA is both soothing and pleasant. Your breasts will "tingle" with a new sensuous warmth that will tell you the MAMRALIN-BX2 FORMULA is going to work. In a few short moments you will actually see and feel the difference. And that's guaranteed]

YOU NO LONGER HAVE TO FEEL SHORT-CHANGED]

Face it, women with beautiful breasts seem to always be surrounded by men. Instead of making flimsy excuses (like -- "I wouldn't want breasts that size") take the positive step. Order MAMRALIN-BX2 today and see how it feels to be the center of attention instead of the one left standing alone making flimsy excuses.

BE A WINNER]

Forget what you have heard about 'powdered drinks' that make you gain weight all over or ineffective exercise contraptions that do nothing but build up your back muscles. MAMRALIN-BX2 is the one for you. MAMRALIN-BX2 is applied directly to the breast where it goes to work directly on the breast" (CX-14).

(c) Instruction Brochure and Order Form (CX-12 and 22):

"MAMRALIN-BX2 WILL ACTUALLY INCREASE YOUR CUP SIZE . . . FROM THE VERY FIRST APPLICATION]

Get ready] You are about to experience a wonderful transformation . . . the result of a medical breakthrough that literally expands the capacity of your breasts to accept additional mass. The result? You can now have larger, firmer, more sensual breasts, and you will see and feel the difference right from the start.

The research teams of the Robertson-Taylor Co. have developed the breast expanding MAMRALIN-BX2 formulation -- a potent blend of tissue expanding compounds that will enlarge your breasts and give you the eye-catching figure of your dreams. With the first application, you will feel the

MAMRALIN-BX2 tingle -- the sensual warmth that lets you know that the powerful tissue-expanding compounds are working their breast-enhancing magic. Yes, MAMRALIN-BX2 is the intelligent alternative to dangerous, permanent breast augmentation therapy.

Now look in the mirror. How does it feel to have larger, more sensual breasts. They said it couldn't be done, but now the proof is right before your eyes."

ADDITIONAL FINDINGS FOR DOCKET NO. 20/32

1. Respondents Intra-Medic Formulations, Inc. ("Intra-Medic"); W.G. Charles Company ("W.G. Charles"); J.F. Pharmaceuticals, Inc. ("J.F. Pharmaceuticals"); and Customer Service Distribution Center, Inc. ("Customer Service") are corporations organized and doing business under and by virtue of the laws of the State of Florida (CX2-22; CX2-26; CX2-27; CX2-24; CX2-28).
2. Respondents W.G. Charles, J.F. Pharmaceuticals and Customer Service are subsidiaries of Respondent Intra-Medic (CX2-28 at pp. 1-2).
3. The corporate Respondents all have their principal place of business at 1110 West Sunrise Blvd., Ft. Lauderdale, Florida (CX2-28 at p. 2).
4. Respondent Intra-Medic wholly owns Respondents W.G. Charles, J.F. Pharmaceuticals and Customer Service (CX2-28 at p. 3; See Decision of 1/28/85 at p. 3).
5. Respondent Mitchell K. Friedlander, an individual, wholly owns Intra-Medic (CX2-28 at p. 2; Decision of 1/28/85 at p. 3).
6. Mitchell K. Friedlander is the sole director and president of Intra-Medic, W. G. Charles, J.F. Pharmaceuticals and Customer Service (CX2-22, 24, 26, 27; See Decision of 1/28/85 at p. 3; CX2-4 at p. 2; Ans. of 12/31/84 at p. 4; CX2-1(b); CX2-6(b); CX2-11).
7. As the sole director and president of the corporate Respondents, Mitchell Friedlander is in a position to formulate, direct and control both the policies and the daily operations of the corporate Respondents, and, in fact, does so (See Decision of 1/18/85 at pp. 3 and 15; CX2-4 at p. 3; See additional citations in Complainant's brief).
8. Respondent Mitchell K. Friedlander is responsible for decisions concerning the advertising used for the products that Intra-Medic and W.G. Charles sell (Tr. 1735; CX2-4 at p. 3).
9. Respondent Harris Friedlander, vice-president of W.G. Charles and Intra-Medic, holds an important, responsible position in the corporate Respondents and is deeply involved in their business activities (See pp. 10-13, *supra*).
10. Respondent Michael Meade, the corporations' general manager, holds an important, responsible position in the corporate Respondents and is deeply involved in their business activities (See pp. 10-13, *supra*).
11. Respondents J.F. Pharmaceuticals and W.G. Charles (CX-66) advertise the product Breast Formula XP-39 for sale (CX-47, 48, 50, 55, 57, 58, 60, 64, 66).
12. Consumers may purchase the product Breast Formula XP-39 by sending payment through the United

States mails (Id.).

13. Payment and orders for Breast Formula XP-39 are directed to: J.F. Pharmaceuticals, Inc., at 3317 Montrose, Suite 1210, Houston, Texas 77006 and at 10 Bay Street, Suite 119, Westport, CT 06880 (CX-48, 55, 58, 64, 66).

14. Respondent Customer Service distributes the product Breast Formula XP-39 and processes payments and orders for the product (CX-53, 63; CX-56, 65).

15. Payment and orders for Breast Formula XP-39 are also directed to: Customer Service Distribution Center, Inc., 997 N.W. 11th Avenue, Fort Lauderdale, FL 33311. In particular, when the product is shipped to customers who have not remitted full payment for it, such customers are directed to remit the balance due to Customer Service at this address (CX-56, 65).

16. Breast Formula XP-39 is labeled to contain: Water, Aloe Extract, Cucumber Extract, Niacin, Glycerin, Comfrey Extract, Sodium PCA, Polysorbate 20, Octoxynol-9, Chamomile Extract, Propylene Glycol, Collagen Amino Acids, Ginseng Extract, Isopropyl Alcohol, Carbomer 940, Allantoin, Panthenol, Imidazolidinyl Urea, Methyl Paraben, Menthol, Tea, Fragrance (CX-53, 54, 63).

17. Instructions accompanying the product are substantially the same as instructions for Macrocell-D58 and Mamrolin-BX2, *supra* (Additional FOF #16 for Docket No. 19/105) (CX-55; CX-64).

18. Breast Formula XP-39 is advertised in national magazines (CX47-49, 57-59, 66-67).

19. At least three different formats are used in magazine advertisements for Breast Formula XP-39 (CX-47, 57, 66).

20. Breast Formula XP-39 is also offered for sale to consumers in the Instructions Brochure which accompanies the product (CX-55, 64).

21. Respondents' promotional materials make the representation alleged in P6 of the Complaint that, "topical application of Breast Formula XP-39 will cause a noticeable enlargement of the female user's breasts." The following excerpts from Respondents' advertisements and re-order booklet for the product demonstrate that they make the above representation.

(a) "Thermal Infusion Technique Developed for Women Who Have Dreamed About LARGER BREASTS:

Can you imagine actually watching and feeling your bust increase in size right before your eyes. At last you will be able to experience the POWER and CONFIDENCE you know larger breasted women always seem to use to their advantage.

EXPERIENCE ALL THAT YOU'VE BEEN MISSING For those times when beautiful breasts make a difference, you'll be glad you have Breast Formula XP-39 on hand. WHAT ARE YOU WAITING FOR? You have nothing to lose and everything to gain. Breast Formula XP-39 is guaranteed to work for you just as it has for thousands of women who once thought that having a larger bust was only a dream. Order Right Now]" (CX-47, 48; CX-57, 58).

(b) "Thermal Infusion Technique Developed Especially for Women Who Have Always Dreamed About Terrific Breasts.

Are you concerned about your breasts and would you like to quickly, easily and safely create a fullness that will change your entire outward image? NOW you can, with the exclusive Breast Formula XP-39.

EXPERIENCE ALL THAT YOU'VE BEEN MISSING For those times when beautiful breasts make a difference, you'll be glad you have Breast Formula XP-39 on hand. WHAT ARE YOU WAITING FOR? You have nothing to lose and everything to gain. Breast Formula XP-39 is guaranteed to work for you just as it has for thousands of women who once thought that having a larger bust was only a dream. Order Right Now]" (CX-66).

(c) Breast Formula XP-39 Instructions Brochure and Order Form (CX-55 and 64):

"With BREAST FORMULA XP-39 you will notice the difference immediately -- and so will everyone else. BREAST FORMULA XP-39, with its proven Thermal Infusion Technique, is the confidence builder that has literally worked wonders for thousands of women who once thought that larger breasts were only for the fortunate few. Now, you too will know the power, confidence and sensual beauty of fuller, larger breasts with your very first application.

You will love the immediate feeling of fullness and sensual warmth as your breasts undergo the XP-39 transformation. This easy to use formulation delivers tissue-expanding compounds deep into the breast itself. In just a few minutes you will see your breasts become fuller and feel your breasts become more sensitive to the touch. You will finally know what has been missing in your life for so many years."

FURTHER FINDINGS OF FACT FOR ALL CASES

A. The Witnesses

1. Peter H. Wendschuh, M.D.

Dr. Wendschuh received his M.D. degree from the University of Miami in 1978. Prior to that time, as a National Science Foundation fellow, Dr. Wendschuh had earned a Ph.D. in organic chemistry from the University of California at Berkeley in 1971. Dr. Wendschuh completed an internship in internal medicine in 1979 at the Jackson Memorial Medical Center in Miami; he completed a residency in dermatology in 1982, also at the Jackson Memorial Medical Center in Miami. He also earned board certification in the specialty of dermatology in 1982 (CX-68; CX-72, p. 1 (Written direct testimony filed May 31, 1985)).

Since earning his board certification in dermatology, Dr. Wendschuh has engaged in private practice in dermatology. He is currently on the staffs of eight hospitals in the greater Miami area. He is also an Assistant Clinical Professor at the University of Miami Department of Dermatology (CX-68; CX-72, p. 1). Dr. Wendschuh keeps current in the field of dermatology by attending medical conferences at which current developments in dermatology are discussed, and by personal contacts with other physicians specializing in dermatology. In addition, he regularly reads several medical journals, including *Archives of Dermatology*, *Journal of the American Medical Association*, *Journal of the American Academy of Dermatology*, *Capsules and Comments on Dermatology* and *Skin Allergy News*. (CX-72 pp. 1-2).

As a dermatologist, Dr. Wendschuh is well qualified to testify as an expert on the effects Respondents' products have when topically applied to a user's skin. (CX-68; CX-72; June 17 Tr. 35-36). Dr. Wendschuh's opinion regarding the effects of Respondents' product when topically applied to a female user's breasts is in conformity with the informed consensus of medical and scientific opinion (CX-72, pp. 2-4; June 17 Tr. 35-37). Dr. Wendschuh's testimony was forthright and credible.

2. Estelle R. Ramey, Ph.D.

Dr. Ramey received her Ph.D. in physiology, with special training in endocrinology, in 1950 from the University of Chicago. At that time, she was awarded a U.S. Public Health Service Postdoctoral Fellowship in Endocrinology to work at the Michael Reese Hospital Research Institute in Chicago. The selection process for this fellowship was highly competitive: applicants were sponsored by their universities, and only one in fifty applicants was awarded funding. Dr. Ramey became an Assistant Professor in the Department of Physiology at the University of Chicago School of Medicine in 1950. For the next six years, she taught endocrinology to medical students and trained several Ph.D. candidates in endocrinology. During those years, she also did research in the relationship of glands and the nervous system to stress responses, as well as in the field of diabetes mellitus (CX-70; CX-71, p. 1 (Written direct testimony filed May 31, 1985).

In 1956, Dr. Ramey joined the staff of the Georgetown University Medical School where, since 1965, she has been a full professor in the Department of Physiology and Biophysics. At Georgetown, she has continued her endocrine research and teaching of medical, dental and graduate students (CX-70; CX-71, pp. 1-2).

Dr. Ramey has received numerous academic and civic awards during the course of her career, including election to the Phi Beta Kappa Society. She was honored as the Mergler Scholar in Physiology at the University of Chicago, which is a scholarship awarded periodically to the University's outstanding student in physiology. In 1973, she was named Outstanding Alumna from the University of Chicago. Every year, Phi Beta Kappa chooses approximately eight outstanding scholars on a nationwide basis to be its "Visiting Scholars," an honor which entails lecturing at universities throughout the country on the scholars' various areas of expertise. Dr. Ramey was chosen as a Visiting Scholar by Phi Beta Kappa for the academic year 1981-82. She holds honorary degrees from nine universities, including Georgetown University and Emory University (CX-70; CX-71, p. 2).

Dr. Ramey has authored or co-authored approximately one hundred scientific papers or abstracts for publication in peer-review professional publications or for presentation to professional meetings in the areas of physiology and endocrinology (CX-70; CX-71, p. 2). Throughout her career, Dr. Ramey has participated in research projects in the fields of endocrinology and physiology. Over the last several years, her research and lectures have concerned the sex hormones, (e.g., estrogen, progesterone, testosterone), and the effects of hormonal and sex differences in various physiological responses (CX-70; CX-71, pp. 2-3).

Dr. Ramey regularly attends, and has lectured at, meetings of the American Physiological Society, the Endocrine Society, and the American Diabetes Association. She has also chaired sessions at these organizations' meetings. She has also presented papers at meetings of the international Endocrine Society, and the International Physiological Society. Last year, the National Science Foundation sponsored her attendance at an International Conference on Science Education (CX-71, p. 3).

Dr. Ramey regularly reads, and has published in, the American Journal of Physiology and the Journal of Endocrinology. She also regularly reads the Journal of Clinical Endocrinology and the New England Journal of Medicine. From 1978 through 1982, Dr. Ramey was a member of the Advisory Committee to the Director of the National Institute of Health (CX-71, p. 3).

Dr. Ramey is well qualified to testify as an expert in physiology and endocrinology, and thus on the effects of Respondents' product when applied to a female user's breasts (CX-70; CX-71; June 17 Tr. 17-18). Dr. Ramey's opinion regarding the effects of Respondents' product when topically applied to a

female user's breasts is in conformity with the informed consensus of medical and scientific opinion (CX-71, p. 4; June 17 Tr. 17-18).

3. Yvonne T. Maddox, Ph.D.

Dr. Maddox received her Ph.D. in physiology from Georgetown University in 1981. At that time, she was awarded a Post Doctoral Fellowship by the National Institute of Health to pursue research in cardiovascular physiology in the Department of Physiology at Georgetown University. Since 1983, she has been a Research Assistant Professor in the Department of Physiology at the Georgetown University Medical Center, where she currently teaches. She also currently holds a position as research project peer reviewer for the United States Department of Agriculture. Her membership in professional societies includes membership in the Society for Experimental Biology and Medicine, the American Federation for Clinical Research, and the New York Academy of Sciences. She is Vice President of the Sigma Xi Scientific Research Society, and will be President of the Society next year, a highly prestigious honor determined by appointment. She was a recipient of the American Pharmacological Society Fellowship in 1977, and the Mamie Doud Eisenhower Award from the American Heart Association in 1983-84; the selection process for both of these awards is highly competitive. She was also chosen to be a Visiting Scientist to the French Atomic Energy Commission in 1984, where she lectured to scientists of the Commission (CX-69; CX-73, pp. 1-2 (Written direct testimony filed May 31, 1985)).

Dr. Maddox has authored or co-authored over thirty-five papers or abstracts for publication in peer-review professional publications. She has also participated in numerous research projects in the fields of endocrinology and physiology, many of which have concerned the sex hormones and sexual differences between men and women. Her particular specialization concerns the sex hormones as they affect the vascular system (CX-73, p. 2).

Dr. Maddox helps organize the Winter Prostaglandin Conference, membership in which is considered highly desirable by the scientific community and is by invitation only. Every third year, the conference is international. She also regularly attends meetings of the Reticuloendothelial Society, a national organization of researchers who study the cells involved in the immune system, and the Society for Gerontology (CX-73, p. 2).

She regularly reads, and has published in, the Journal of Pharmacology and Experimental Therapeutics, and Nature. She also regularly reads the American Journal of Physiology and the Journal of Endocrinology (CX-69; CX-73, p. 3).

Dr. Maddox is well qualified to testify as an expert in physiology and endocrinology, and thus on the effects of Respondents' product when applied to a female user's breasts (CX-69; CX-73, pp. 1-3; June 18 Tr. 6). Dr. Maddox's opinion regarding the effects of Respondents' product when topically applied to a female user's breasts is in conformity with the informed consensus of medical and scientific opinion (CX-73, pp. 3-4; June 18, Tr. 6).

The Truth or Falsity of the Representations

The following findings of fact are based upon the testimony of Drs. Wendschuh, Maddox and Ramey, whose testimony represents the informed consensus of medical and scientific opinion with respect to the issues to which their testimony relates.

1. Dermatology is the medical specialty concerned with the skin (CX-72, p. 2). Physiology is the study of body systems and how they work. Endocrinology is the study of hormones and their function within

the body (CX-71, p. 4; CX-73, p. 4).

2. The female breasts are major secondary sex characteristics that appear at puberty. The human female's chromosomes direct the hypothalamus to release factors that signal the pituitary gland to release the hormone estrogen in the pubescent girl. Before menarche, both males and females have mammary glands that consist of only a few ducts surrounded by connective tissue. A male's mammary glands remain this way. In females, however, at the onset of puberty, the duct tissue is stimulated by the hormone estrogen to elongate and branch out. The connective tissue proliferates and becomes infiltrated with fat, and the breast begins to assume the shape of the mature female gland. When the female's ovulation cycle begins, the hormone progesterone is secreted by the pituitary and the characteristic structure of the breast during childbearing years is developed (CX-71, pp. 4-5).

3. Breast development is caused by hormonal activity within the individual's body. To trigger the hormonal activity, the brain must be stimulated by chromosomal information to activate the pituitary gland, which in turn, will release the hormones. All women have approximately the same amount of mammary gland tissue -- about a teaspoonful. Difference in breast size and shape are completely determined by the amounts of fatty and connective tissue each woman has. How much fatty and connective tissue a woman has is determined by her genetic composition, and by how much excess body fat she may acquire through life. In other words, every female is genetically unique as to how much her body will respond -- i.e., what the size and shape of breasts will be -- to the estrogen secreted by the pituitary gland at puberty (CX-71, pp. 5-6; June 17 Tr. 18-19). Moreover, a woman's breasts are not identical in size. Normally, most women have one breast that is slightly larger than the other (June 17 Tr. 19, 3-31; June 18 Tr. 11).

4. In addition to fat and connective tissue, the breast is composed of the nipple, where the ducts converge, and alveoli (the dark pigmented areas surrounding the nipples). The alveoli-nipple area is the only part of the breast that contains muscle fiber. This area is extremely sensitive, and, because of the muscle tissue in it, can become erect if touched or exposed to heat or cold. The breast is attached by connective tissue to the underlying chest muscles, the pectorals (CX-71, p. 6).

5. Once the female's ovulatory cycles have begun, and her breasts have developed into their mature shape, two aspects of her life cycle will sufficiently stimulate the brain to cause hormonal activity to alter the size and shape of her breasts (CX-71, p. 6).

6. Tissue changes occur in the female breast with each menstrual cycle (roughly a 28-day period). During the first half of the cycle, high levels of ovarian estrogens in the blood stimulate the reproduction of cells in the glandular ducts and the alveoli (the dark pigmented area surrounding the nipple). Increasing amounts of progesterone cause the ducts to dilate and alveolar cells to differentiate from secretory cells. Once ovulation occurs, there is also increased bloodflow to the breasts. In the week before menstruation, some women experience fluid retention in the breasts. The increased cellular growth caused by the ovarian estrogens in the blood, the enlarged duct diameters and newly formed alveoli cells caused by the increased progesterone levels, all contribute to this engorgement. Once menstruation ceases, the proliferate tissue begins to regress and is reabsorbed (CX-71, pp. 6-7; June 17 Tr. 19; June 18 Tr. 7)

7. Breast enlargement also occurs during pregnancy and lactation. The changes to the breast that occur during pregnancy are much greater than those that occur premenstrually. Each breast gains nearly a pound in weight by the end of the pregnancy. The increased size and weight are due to the glandular cells being partially filled with secretion, an increased number of blood vessels, and increased amounts of connective tissue and fat. The hormones that stimulate and prepare the breasts during pregnancy are the sex steroids from the ovaries and placenta. Other placental, pituitary and metabolic hormones also

contribute to the duct and alveoli growth and differentiation into secreting cells (CX-71, p. 7; June 17 Tr. 19-20).

8. Once the baby is born, prolactin, a hormone from the anterior pituitary, causes the glandular cells to secrete large quantities of milk. As long as nursing continues, the mother will produce milk, and her breasts will accordingly remain enlarged (CX-71, p. 7).

9. Puberty, menstruation, pregnancy and lactation, and times of overall body weight gain, are the only times healthy breasts become noticeably enlarged. With the exception of overall body weight gain, all of these are due to complex hormonal activities within the female body. The extent to which the hormonal activity produces physiological changes in the woman is determined by her inherited genetic make-up (CX-71, pp. 7-8; CX-73, p. 6; June 17 Tr. 20-22).

10. Accordingly, not topically applied cream or lotion will cause a woman's breasts to become noticeably larger (CX-71, p. 8; CX-73, p. 6; June 17 Tr. 23; June 18 Tr. 7).

11. Consequently, at this point in time, the only medically and scientifically acceptable method to enlarge the female breast is by surgical implantation (CX-71, p. 8; June 17 Tr. 23-24; June 18 Tr. 7-8).

12. The ingredients in Respondents' product are not capable of producing a noticeable enlargement of the female user's breasts. This is because, as stated before, only complex hormonal activity and subsequent physiological reactions by the body, can cause breast enlargement (CX-71, p. 8; CX-73, p. 7).

13. Respondents' product, if topically applied, may cause a slight blush to spread over the area to which the product is applied. This is due to the presence of niacin in the products (CX-73, p. 5). Niacin, when topically applied, does penetrate the skin, causing its surface capillaries to increase their blood flow (CX-72, p. 4; CX-73, p. 5; June 17 Tr. 37-38; June 18 Tr. 9). This activity, however, would not cause a noticeable enlargement of the breast, if applied thereto (CX-72, p. 4; CX-73, p. 5; June 17 Tr. 37-38; June 18 Tr. 9). Just as a person's face does not get larger if she blushes, a woman's breasts would not get larger because of the blush that would occur there as a result of topically applying niacin to her breasts (CX-73, p. 5; June 17 Tr. 37).

14. Most of the remaining ingredients in the products are either aromatic or softening agents. Allantoin helps heal wounds and stimulates the growth of healthy tissue at the wound site. However, its ability to penetrate intact skin has not been demonstrated, and there is no evidence that it will stimulate the growth of normal breast tissue or in any other way enlarge the breast. Panthenol is taken orally to increase intestinal peristalsis and tone. Again, there is no evidence that it will penetrate the skin. Collagen is the major structural protein of the dermis; there is no evidence that the major amino acids in collagen can penetrate the skin if topically applied (CX-72, p. 4; CX-73, pp. 5-6).

Little is known about the medical effects of the remaining active ingredients. Aloe extract has been used as a purgative. Comfrey extract has been used to heal ulcers -- it is a potential carcinogen. Chamomile extract has been used as an emetic, and may be anti-inflammatory. Cucumber extract is an astringent and has a cooling effect on the skin (CX-72, pp. 4-5; CX-73, p. 6). There are anecdotal reports that ginseng, if taken orally, may cause hypertension and mastalgia, a condition of painful breasts (CX-72, p. 5; CX-73, p. 6).

The remaining ingredients essentially comprise the vehicle by which the applied ingredients discussed above are applied to the skin. One of them, methyl paraben, can cause contact dermatitis (CX-72, p. 5;

CX-73, p. 6).

15. Placing a hot towel on one's breasts, as per Respondents' directions for use of the products, may cause a slight edema to occur. The subject might flex her pectoral muscles in reaction of the heat. This would occur whether or not the person placing a hot towel on her breasts also applied Respondents' product to her breasts. Moreover, repeatedly placing a hot towel on her breasts could cause considerable irritation, and possibly, pain (CX-71, p. 8; CX-72, p. 5; CX-73, p. 8; June 17 Tr. 26, 31).

16. After having conducted searches of the medical literature in the area of breast growth and development, as well as on the ingredients in Respondents' products, neither Doctor Wendschuh nor Doctor Maddox discovered any medical or scientific study linking any of these ingredients to healthy breast development or enlargement (CX-72, pp. 3-4; CX-73, pp. 4-5; June 17 Tr. 22-23; 36; June 18 Tr. 6, 13).

17. Dr. Wendschuh conducted extensive computer searches of the referenced medical and scientific literature in Medline as far back as 1966. He also searched the Toxicology Data Base, Chemline and a pharmacological data base. He also reviewed the Merck Index and various biochemistry and pharmacological textbooks. Dr. Wendschuh found no reports or studies which linked the ingredients in Respondents' product in any way to breast enlargement (CX-72, pp. 3-4; June 17 Tr. 36, 37).

18. Dr. Maddox conducted extensive computer searches of the referenced medical literature in both the Index Medicus and Med Line, going back to the early 1960s in her searches. In addition, she reviewed standard medical textbooks, the Merck Index, and a dictionary of Cosmetic Ingredients. Dr. Maddox found no reports or studies which linked the ingredients in Respondents' product in any way to breast enlargement (CX-73, pp. 4-5; June 18 Tr. 6).

19. Each of the doctors who testified on behalf of Complainant is well qualified to testify on the quality and type of evidence required to establish a product's or formula's efficacy (CX-71, pp. 1-3, 8-9; CX-72, pp. 1-2, 5; CX-73, pp. 1-3, 7; June 17 Tr. 17-18; June 18 Tr. 6).

For a product's efficacy to be accepted by the scientific and medical communities, clinical trials should be administered. These trials should be "double blind," that is, neither the administrators of the tests nor the subjects should know the purpose behind the test or the product involved. In addition, there should be at least one "control" group, that is, a group to which a placebo is administered. Again, neither the subjects of this group nor the administrators should know what the product is or whether it is a placebo. In addition, the group receiving the placebo should, at some appropriate point in the experiment, receive the actual drug and vice versa. Again, no one involved with the test should be aware of the change. The tests should be designed so that all body systems are involved; for example, there should be dermatological studies, vascular studies, and endocrinological studies (CX-71, p. 9; CX-72, p. 6; CX-73, pp. 7-8; June 17 Tr. 24-26; June 18 Tr. 9-10).

20. If any such study had been conducted on Respondents' product, or any ingredient therein, that demonstrated that the product caused breast enlargement, that study would have been discovered by Dr. Wendschuh and Dr. Maddox in their research of the medical and scientific literature. Moreover, it would be well known by Drs. Maddox, Ramey and Wendschuh because it would be a revolutionary development in their areas of expertise, endocrinology, physiology and dermatology. The lack of such a study indicates that Respondents' product does not cause a noticeable enlargement of the female user's breast (CX-71, pp. 9-10; CX-72, pp. 6-7; CX-73, p. 8; June 17 Tr. 22-23, 35-37; June 18 Tr. 13).

21. Anecdotal reports are unreliable indicia of a formula's efficacy. In the instant case, in an unscientific

demonstration where lay users would have applied Respondents' product as directed, any apparent change in the size of their breasts would not be due to the product. Rather, it would be due to the effects of the hot towel, simple changes in posture, or flexing of the pectoral muscles, and the possible erection of the alveoli-nipple area due to exposure to heat and rubbing. Moreover, the demonstration would fail to overcome the fact that no scientific or medical studies have been conducted which establish that the product can achieve such a result (CX-71, p. 10; CX-72, p. 7; CX-73, pp. 8-9; June 17 Tr. 26-28, 30-31; June 18 Tr. 8-9, 11-12).

22. The foregoing findings of fact establish that Respondents' representation is materially false as a matter of fact.

CONCLUSIONS OF LAW

1. Where an individual, in this case Mitchell K. Friedlander, is the sole owner, director, and president of the corporate Respondents and this individual is in a position to control, formulate and direct the policies and daily activities of the corporations, and in fact, does so, he may be named in his individual capacity in the cease and desist order. Cf., *FTC v. Standard Education Soc.*, 302 U.S. 112 (1937); *United States v. Johnson*, 541 F.2d 710, 713, (8th Cir. 1976) cert. denied, 429 U.S. 1093 (1977); *Sunshine Art Studios, Inc. v. FTC*, 481 F.2d 1171, 1175 (1st Cir. 1973); *Bruhn's Freezer Meats, Inc. v. United States Dept. of Agriculture*, 438 F.2d 1332, 1343 (8th Cir. 1971).

2. Where there is evidence that the individual, here Mitchell K. Friedlander, was responsible for the advertising used by the corporate Respondents -- and misrepresentations in such advertising form the crux of the statutory violation -- it is imperative that the individual be bound in his personal capacity in order to make the cease and desist order fully effective. Cf., *Tractor Training Service v. Federal Trade Com.*, 227 F.2d 420 (9th Cir. 1955), cert. denied, 350 U.S. 1005 (1956); *FTC v. Standard Education Soc.*, *supra*.

3. Respondents Michael Meade and Harris Friedlander should be named in their individual capacities in the cease and desist orders issued (Findings and Conclusions, *supra*, pp. 10-13).

4. The meaning of a solicitation's representations is to be judged from a consideration of the advertisement in its totality and the impression it would most probably create in ordinary minds. *Donaldson v. Read Magazine, Inc.*, 333 U.S. 178 (1948); *Borg-Johnson Electronics, Inc. v. Christenberry*, 169 F. Supp. 746 (S.D.N.Y. 1959); *Vibra-Brush Corp. v. Schaffer*, 152 F. Supp. 461 (S.D.N.Y. 1957), *Rev'd on other grounds*, 256 F.2d 681 (2nd Cir. 1958).

5. Applying the above criteria to Respondents' promotional materials, it is evident that Respondents' promotional materials submitted into evidence in this proceeding make the representation alleged in each of the Complaints. Moreover, Respondents admitted making the representations in their pre-trial submissions.

6. The person of ordinary mind would interpret Respondents' promotional materials as making the representations alleged in paragraphs 8(a), 8, and 6 of the Complaints in Docket Nos. 19/105, 19/161, and 20/32, respectively.

7. Respondents' brochures which accompany the products when purchased, are part of the promotional materials employed by Respondents in the sale of their products. The brochures make the above representations alleged in the Complaints. These brochures reinforce the original ads and result in reorders; moreover, there is no basis to assume that the original deception would be cleared up before

the reorder form was put to use. Iso Tensor Plan, P.S. Docket No. 3/30, (P.S.D. May 23, 1975, pp. 27-28).

8. A money back guarantee does not dispel the effect of an advertisement's representations. Farley v. Heinger, 105 F.2d 79 (D.C. Cir. 1939), cert. den. 308 U.S. 587 (1939); Borg-Johnson Electronics, Inc. v. Christenberry, 169 F. Supp. 746 (S.D.N.Y. 1959). Accordingly, Respondents' motion to admit the "Morrow deposition" is denied. Moreover, Respondents failed to mention this evidence and argument in their submissions pursuant to the May 8 pre-trial order, and are deemed to have abandoned this motion. The same motion was also denied in W.G. Charles Co., P.S. Docket Nos. 19/104, 19/162 (P.S.D. Sep. 10, 1985 at 6) and Intra-Medic Formulations, Inc., P.S. Docket No. 19/182 (P.S.D. Sep. 10, 1985 at 4).

9. The representations found to have been made by Respondents are material representations since they would induce a consumer to purchase the product.

10. The jurisdiction of the Postal Service under 39 U.S.C. § 3005 is established when it is shown that a Respondent has solicited money through the mails. Respondents' advertisements seek money through the mail, and proof of actual receipt of remittances through the mail by a Respondent is not required. IAAIC, P.S. Docket No. 13/173 (P.S.D. December 29, 1982). Moreover, the June 12 submission by the "corporate respondents" stipulates to such use of the mails.

11. The fact that a medical expert witness has not personally used or tested a product does not in any way discredit his testimony. Original Cosmetics Products, Inc. v. Strachan, 459 F. Supp. 496 (S.D.N.Y. 1978), aff'd mem. no. 78-6165 (2nd Cir. April 30, 1979); Feil v. Federal Trade Com. 285 F.2d 879, 893 (9th Cir. 1960).

12. Complainant has established its case by a preponderance of the competent, reliable and probative evidence of record. S.E.C. v. Savoy Industries, 587 F.2d 1149, 1168 (D.C. Cir. 1978).

13. The representations alleged to be false in the Complaints, as amended, are materially false as a matter of fact.

14. Respondents are engaged in conducting a scheme for obtaining money or property through the mails by means of materially false representations. Accordingly, a False Representation Order and Cease and Desist orders under 39 U.S.C. § 3005 are issued herewith.



Tab 90

In the Matter of the Complaint Against

W. G. Charles COMPANY
7770 West Oakland Park Boulevard
Landmark Bank Building Suite 210
Sunrise, Florida 33321-6729

and

3952 N. Southport
Chicago, Illinois 60613-2606

and

CUSTOMER SERVICE DISTRIBUTION CENTER, INC.
997 N.W. 11th Avenue
Ft. Lauderdale, Florida 33311-1337

and

MITCHELL K. FRIEDLANDER
508 Bontona Avenue
Ft. Lauderdale, Florida 33301-2422

and

HARRIS FRIEDLANDER
2175 State Road 84, Dock 12 #1
Ft. Lauderdale, Florida 33312-4839

and

MICHAEL MEADE
2615 N. E. 49th Street
Ft. Lauderdale, Florida 33308-4846,

RESPONDENTS

P.S. Docket No. 19/104;
P.S. Docket No. 19/162

09/10/85

Bernstein, Edwin S.

In the Matter of the Complaint Against

THE ROBERTSON-TAYLOR COMPANY
1110 West Sunrise Boulevard
Ft. Lauderdale, Florida 33311-1337

and

INTRA-MEDIC FORMULATIONS, INC.
7770 West Oakland Park Boulevard Suite 210
Sunrise, Florida 33321-6729

and

CUSTOMER SERVICE DISTRIBUTION CENTER, INC.
997 N.W. 11th Avenue
Ft. Lauderdale, Florida 33311-1337

and

MITCHELL K. FRIEDLANDER
508 Bontona Avenue
Ft. Lauderdale, Florida 33301-2422

and

HARRIS FRIEDLANDER
2175 State Road 84, Dock 12 #1
Ft. Lauderdale, Florida 33312-4839

and

MICHAEL MEADE

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POSTAL SERVICE DECISION

P.S. Docket No. 19/104; P.S. Docket No. 19/162 -- W. G. Charles COMPANY, and CUS... Page 3 of 33

On July 3, 1984, the Consumer Protection Division, United States Postal Service (Complainant) filed a Complaint in Docket No. 19/104 alleging that W. G. Charles Company, Mitchell K. Friedlander, Harris Friedlander and Michael Meade violated 39 U.S. Code § 3005 by selling Intercal-SX, a purported weight loss product, through the use of the mail by false representations.

On August 31, 1984, Complainant filed a similar Complaint in Docket No. 19/162 alleging that The Robertson-Taylor Company, Intra-Medic Formulations, Inc., Mitchell K. Friedlander, and Harris Friedlander violated 39 U.S. Code § 3005 by selling Metabolite-2050, also a purported weight loss product, through the use of the mail by false representations. The product in each case consisted of guar gum tablets to be taken in divided doses totaling 15 grams daily.

On November 15, 1984, Complainant filed a motion to amend the captions of these cases and other cases, by adding Respondent,

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Customer Service Distribution Center, Inc. at 997 N.W. 11th Avenue, Ft. Lauderdale, Florida 33311. Upon no opposition, the motion was granted (Tr. 394).

The Complaint in Docket No. 19/104 alleged that Respondents falsely represent:

- (a) Ingestion of Intercal-SX will cause significant weight loss in virtually all users.
- (b) Ingestion of Intercal-SX will cause significant weight loss without calorie restricted diets or exercise.
- (c) Ingestion of Intercal-SX prevents foods from being converted into stored fat.
- (d) The weight loss claims for Intercal-SX are supported by the results of scientifically sound clinical studies.
- (e) Respondents have accurately reproduced an excerpt from Acta Medica Scandinavia, Vol. 208, pp. 45-48 in certain of its printed advertisements, including Exhibit 1.

The Complaint in Docket No. 19/162 alleged that Respondents falsely represent:

- (a) Ingestion of Metabolite-2050 will cause significant weight loss in virtually all users.
- (b) Ingestion of Metabolite-2050 will cause significant weight loss without willpower, calorie restricted diets or exercise.
- (c) Ingestion of Metabolite-2050 prevents foods from being converted into stored fat.
- (d) The weight loss claims for Metabolite-2050 are supported by the results of scientifically sound clinical studies.
- (e) Respondents have accurately reproduced an excerpt from Acta Medica Scandinavia, Vol. 208, pp. 45-48 in certain of its printed advertisements, including Exhibit 1.
- (f) An obese person who takes Metabolite-2050 may reasonably expect to lose weight while continuing to eat all he or she wants.

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Respondents denied that they violated 39 U.S. Code 3005. At Respondents' request the cases, together with P.S. Docket No.19/182, were scheduled for expedited hearing pursuant to 39 C.F.R. 952.17(a) (Judge Cohen's Order of February 1, 1985). I was designated Acting Judicial Officer for that purpose. Harris Friedlander and Michael Meade did not attend the expedited hearing or appear by counsel. However, by notarized letter to me dated February 11 and filed February 13, 1985, Harris Friedlander consented to the expedited hearing and wrote, "The questions I would ask of Complainant's witnesses re: Intercal and Metabolite have been furnished to Co-Respondents, and the evidence they plan to offer is acceptable to me on the products." By notarized letter to me also dated February 11 and filed February 13, 1985, Michael Meade made the same statements, but limited to Intercal-SX in Docket No. 19/104.

Commencing February 12, 1985 Complainant presented the testimonies of Richard C. Eastman, M.D., William R. Ayers, M.D., and Albert I. Mendeloff, M.D. Respondents presented the testimonies of Thomas M. S. Wolever, B.M., Stephen C. Woods, Ph.D., Dan Sarel, Ph.D., Lynda M. Maddox, Ph.D., and Ruth B. Smith, Ph.D. By stipulation, Respondents' advertisements and various other exhibits as identified in Complainant's exhibit list were received in evidence (Tr. 2006-15).

During the hearing, Respondents offered as exhibits two collections of scientific articles which they designated as "Anorex-CCK (Cholecystokinin) Source Book" and "Guar Source Book." Upon no objection these source books were received into evidence, although they were not given exhibit numbers since the books were to be furnished later and some of the articles duplicated other exhibits (Tr. 4690J-O). The Anorex-CCK Source Book is hereby

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designated as RX3-54 and the Guar Source Book is hereby designated as RX3-55. The articles contained in the Guar Source Book are listed in Appendix A to this decision.

Respondents offered as an exhibit the videotaped deposition of Joseph E. Morrow, Ph.D. Dr. Morrow conducted a survey and based upon that survey concluded that the money-back guarantee that Robertson Taylor offered in the sale of Metabolite-2050 and other products was a crucial factor in persuading the majority of users surveyed to buy the products. Although Complainant objected to the admission of this exhibit, I received it into evidence subject to a showing in post-hearing proposed findings and conclusions that the deposition is relevant (Tr. 4794-96). Respondents post-hearing submissions have failed to show that the deposition is relevant. In view of the holdings in *Farley v. Heining*, 105 F.2d 79, 84 (D.C. Cir. 1939); *Borg-Johnson Electronics, Inc. v. Christenberry*, 169 F. Supp. 746, 751 (S.D.N.Y. 1959) and other cases that a promise of a refund if a customer is dissatisfied will not dispel the effect of false advertisements, I find the deposition to be irrelevant and therefore inadmissible. The transcript and the videotape of the deposition are hereby designated as RX3-56 and RX3-56A respectively and will be retained as rejected exhibits.

At the hearing, Respondents also offered an affidavit and report of Kenneth W. Clarkson, Ph.D. Upon objection by Complainant, the affidavit and report were rejected as irrelevant (Tr. 5906-07, Conference on the Record of April 15, 1985, pp. 5-6). The affidavit and report are hereby designated as RX3-57 and will be retained as a rejected exhibit.

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By Order dated May 20, 1985 the parties were directed to submit proposed findings of fact, proposed

conclusions of law, and memoranda. Proposed findings and conclusions were to be specific and supported by citations. The parties were directed to file reply submissions specifically stating agreement or disagreement with the opposing party's proposed findings and conclusions, and providing supporting citations and alternate findings and conclusions where there was disagreement. Complainant filed 76 pages of proposed findings and conclusions on June 10, 1985. After requesting a 10 day extension of time, Respondents on June 18, 1985 filed a two-page submission which contained no specific citations to evidence or legal authority. Complainants filed reply submissions on June 19 and July 12, 1985. Respondents filed a reply submission on July 8, 1985 (Respondents' July 8 submission). All proposed findings, proposed conclusions and arguments have been considered. To the extent indicated, they have been adopted. Otherwise they have been rejected as irrelevant or not supported by the evidence.

DECISION ON MOTION FOR RECONSIDERATION AND

REVERSAL OF JANUARY 28, 1985 DECISION AND

ORDER ON MOTION TO DISMISS COMPLAINTS AGAINST

HARRIS FRIEDLANDER AND MICHAEL MEADE

After receiving and considering testimony and other evidence at a hearing in December 1984 and considering the parties' proposed findings of fact and conclusions of law, by Decision and Order dated January 28, 1985 I determined that Harris Friedlander was properly named a Respondent in Docket Nos. 19/104, 19/162 and other cases, and that Michael Meade was properly named a Respondent in Docket No. 19/104 and other cases. By Order dated May 17, 1985, Michael Meade was added as a Respondent in Docket No. 19/162, since Docket Nos. 19/104 and 19/162 involve identical products and the same evidence.

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By Order dated May 20, Respondents Harris Friedlander and Michael Meade were advised that at the time set for filing proposed findings and conclusions, they could also file memoranda supporting reconsideration and reversal of the January 28 Decision. These memoranda were filed on June 12. Complainant filed a response on June 18. Upon reconsideration of the entire record and all of the briefs and memoranda, I find the January 28 Decision to be correct.

The memorandum urging reversal indicated no basis for reversal. In the separate memorandum urging reconsideration, Respondents contended the decision should be reversed based upon their assertions that Postal Inspector Cantley lied in testifying, and that Complainant did not comply with the Jencks Rule in connection with Inspector Cantley's testimony.

It is not necessary to determine whether Respondents' allegations are correct because the January 28 Decision and Order would have been factually and legally supported by the evidence even if Inspector Cantley had not testified. Inspector Cantley's November 1984 testimony, which relates to different issues, was not considered in connection with the January 28 Decision. His testimony at the December hearing was limited to: (1) describing locations of Respondents' business, and (2) describing several Postal Service forms and a letter by Lee H. Harter, Esq. The locations of Respondents' business were not relevant to the issues addressed in the January 28 Decision. The Postal Service forms were under seal and, therefore, self-authenticating and independently admissible pursuant to Federal Rule of Evidence 902(1). Inspector Cantley's testimony about the various blocks on the forms was also not necessary to the

Decision. The importance of the forms was that two of them were signed by Harris Friedlander as vice president (CX3-7a and 7c); one was signed by Michael Meade as general manager (CX2-1a); two were signed by Mitchell K. Friedlander who referred to Harris Friedlander as vice president of W. G. Charles (CX2-1b) and Bio Technic Labs (CX2-6a); and the letter of Mr. Harter as attorney for Robertson-Taylor referred to Harris Friedlander as a responsible corporate representative (CX2-8). Not only were all of these exhibits under seal with the exception of Mr. Harter's letter, but Harris Friedlander and Michael Meade did not deny that they had signed the forms as vice president and general manager, respectively, and did not deny the authenticity of the signatures of Mitchell Friedlander and Lee H. Harter, also present at the hearing. Since this evidence was reliable and admissible without Inspector Cantley's testimony, issues as to Inspector Cantley's credibility are irrelevant.

Therefore, the January 28, 1985 Decision and Order is affirmed.

FINDINGS OF FACT

I. The Use of the Mail

Mitchell K. Friedlander owns Intra-Medic Formulations, Inc. Intra-Medic wholly owns W. G. Charles Company, The Robertson-Taylor Company and Customer Service Distribution Center, Inc. A similar finding was made in the January 28, 1985 Decision and Order on Motion to Dismiss and this was not denied by Respondents in their July 8 submission.

Mitchell K. Friedlander is the president and principal decision maker in Respondent corporations which he wholly owns and controls. (January 28, 1985 Decision and Order on Motion to Dismiss). It was determined that there was a complete identity of interests between Mr. Friedlander and his corporations, despite Respondents' protests to the contrary. Therefore, Lee H. Harter, Esq. was considered to also represent Mr. Friedlander. Mr. Friedlander was permitted to personally participate in the hearing as a matter of courtesy and convenience to Respondents (Tr. 2176-77; my Memorandum For Record dated May 6, 1985).

Mitchell K. Friedlander's residence address is 508 Bontona Avenue, Ft. Lauderdale, Florida 33310. (Response to Request for Admissions No. 8 in Docket No. 19/182 filed by the Corporate Respondents on January 29, 1985). However, in accordance with Mr. Friedlander's request, service of papers will also be made to him c/o The Robertson-Taylor Company, 1110 West Sunrise Blvd., Ft. Lauderdale, FL 33311-1337. Michael Meade and Harris Friedlander are properly named as individual Respondents in these cases (Orders of January 28 and May 17, 1985; Decision on Motion for Reconsideration and Reversal herein).

Harris Friedlander's residence address is 2175 State Road 84, Ft. Lauderdale, Florida 33312 (Tr. 1726). However, in accordance with Harris Friedlander's request, service of papers will also be made to him at 1110 W. Sunrise Boulevard, Ft. Lauderdale, Florida 33311 (Letter of Harris Friedlander to Judge Bernstein filed February 13, 1985).

Michael Meade's residence address is 2615 N.E. 49th Street, Ft. Lauderdale, Florida (Complainant's

P.S. Docket No. 19/104; P.S. Docket No. 19/162 -- W. G. Charles COMPANY, and CUS... Page 7 of 33

proposed finding no. 6, Tr. 1790). Therefore, the address in the captions for Michael Meade is amended to this address. However, in accordance with Mr. Meade's request, service of papers will also be made to him at 1110 W. Sunrise Boulevard, Ft. Lauderdale, Florida 33311 (Letter of Michael Meade to Judge Bernstein filed February 13, 1985).

Respondents solicit orders through the mail for Intercal-SX to W. G. Charles Company, 3952 N. Southport, Chicago, Illinois 60613. (C3-1, 2, 3b, c and g, 7, p. 3, 8d, f, g, 9, and 10; admitted in Respondents' July 8 submission).

Respondents solicit orders through the mail for Metabolite-2050 to The Robertson-Taylor Company at 1110 W. Sunrise Boulevard, Ft. Lauderdale, Florida 33311 (CX3-24, 25, 27b and e, 31c, and 32, admitted in Respondents' July 8 submission) and at 135 E. Oakland Park Boulevard, Ft. Lauderdale, Florida 33334 (CX 3-11, 12, 14b, 14c, 19, and 23c; admitted in Respondents' July 8 submission).

Any mail stop order for Docket Nos. 19/104 and 19/162 should also apply to Customer Service Distribution Center, Inc. at 997 N.W. 11th Avenue, Ft. Lauderdale, Florida 33311 since Respondents' products are received in packages using that return address. These packages contain packing slips which also use that name and address (CX3-6, 28 and 30). Therefore, customers may reasonably be expected to use the Customer Service address for inquiries, problems and reorders.

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However, Complainant has not supported the inclusion of 7770 West Oakland Park Boulevard, Landmark Bank Building, Suite 210, Sunrise, Florida 33321-6729 as an address for which mail to W. G. Charles Company should be stopped in Docket No. 19/104, or as an address for which mail to Intra-Medic Formulations, Inc. should be stopped on Docket No. 19/162. Respondents' advertisements appear in publications of general circulation (CX3-9, 10, 11, 17, 24, and 32; admitted in Respondents' July 8 submission).

Respondents are all part of a single enterprise directed by Mitchell K. Friedlander through various corporations using various advertisements for Intercal-SX and Metabolite-2050.

II. The Advertising Representations (P.S. Docket No. 19/104)

Respondents' advertising materials, including product inserts accompanying reorder solicitations, make the representations alleged in subparagraphs 8 (a), (b), (c), (d), and (e) of the Complaint. Specific reasons for these findings are as follows:

(a) Ingestion of Intercal-SX will cause significant weight loss in virtually all users.

CX3-1, 8f and 10

LOSE WEIGHT WITHOUT DIETING]

Works from within your body to form a protective coating around the foods you eat, reducing the total number of calories BEFORE THEY CAN BE TURNED INTO POCKETS OF STORED FAT]

INTERCAL-SX is a powerful, bio-active formula that "NEUTRALIZES" EXCESS CALORIES from within your body. INTERCAL-SX actually absorbs excess fats and carbohydrates AFTER YOU HAVE EATEN THEM, preventing their further conversion into pockets of unsightly, figuredestroying stored

fat.

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No matter how overweight you are, no matter how many "diets" you've tried before, no matter how many weeks, months, or years you have been trying to lose excess pounds and inches of stubborn fat, flab and cellulite just to be frustrated by "diet programs" that are impossible to live with. No matter how many times you have failed before, (believe us, you are not alone) this time will be different. THIS TIME YOU ARE GUARANTEED SUCCESS WITH INTERCAL-SX.

YES] Everyone who used INTERCAL-SX lost weight]

EVERYONE]

The results are medically documented.

Use of words such as "highly significant decrease in body weight," "powerful," and "neutralizes excess calories" conveys the impression that this product causes significant weight loss. Language such as "everyone," and "GUARANTEED SUCCESS," represents that the weight loss this product causes can be expected by virtually all users.

CX-3c, 8d, and 9

Guaranteed weight loss without dieting

LOSE UP TO 68 POUNDS WITHOUT DIETING

At last, the scientific community has developed what can only be called the "miracle" weight loss compound a potent and powerful compound that is specifically designed for tough, adult weight loss problems. That's right] No matter how long you've been overweight, no matter how hard you've tried to lose those embarrassing excess pounds and inches only to fall short of your goal, now there is a scientifically-developed, medically-verified answer to your adult weight loss problem -- INTERCAL-SX

NEVER BE FAT AGAIN]

The language, "Lose up to 68 pounds without dieting" conveys the impression to the average reader that the results can reasonably be expected. See: Weider Distributors, Inc., P.S. Docket No. 3/27

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(P.S.D. Nov. 4, 1974); Iso-Tensor Plan, P.S. Docket No. 3/30 (P.S.D. May 23, 1975); The New Body Boutique, Inc., P.S. Docket No. 10/169 (P.S.D. July 7, 1982).

Quantification of expected weight loss results, combined with representations that the product has been medically verified, conveys the impression that significant weight loss results may be expected by the user. Those assertions, together with the claim that any user, regardless of past experience with diet products, can expect to lose weight, convey the impression that the significant weight loss results can be expected by virtually all users.

Also the warning emphasizes the product's great effectiveness. It states, "NOTICE: Intercal-SX is an extremely powerful potent and effective weight loss compound."

CX3-3b, a product insert, reads:

With INTERCAL-SX you will be beginning a most REVOLUTIONARY WEIGHT LOSS program. This caloric "neutralizing" formulation has the industry buzzing because INTERCAL-SX lets you LOSE WEIGHT EFFORTLESSLY -- WITHOUT DIETING, CALORIE COUNTING AND EXERCISE. You can forget about failure, no matter how many times you have tried to lose weight only to abandon your intentions out of frustration. INTERCAL-SX will help you reach YOUR GOAL so quickly, you won't have time to become discouraged. And that's GUARANTEED. But don't take our word for it -- or the medically documented double-blind study that conclusively proved that EVERYONE who took the INTERCAL-SX formulation LOST SIGNIFICANT AMOUNTS OF WEIGHT -- see for yourself. We're confident that you will be amazed at the results.

The claims that this is a "revolutionary" weight loss product, that there are no "failures," that the product "neutralizes," that the effects are "medically documented," and that "everyone" lost significant amounts of weight, convey the impression that virtually all users will lose significant amounts of weight.

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CX3-7, an instruction booklet that accompanies Intercal-SX, states: WITH THE EXCLUSIVE INTERCAL-SX YOU WILL LOSE ALL OF THE WEIGHT YOU WANT TO LOSE -- AUTOMATICALLY. for the serious dieter who needs to lose more than 20 pounds, INTERCAL-SX eliminates any chance for you to fail.

There is no chance of failure because INTERCAL-SX does it all-scientifically.

Medical studies have documented the amazing success of this wonderful weight loss formulation. In a medically documented, double-blind study performed at a major university, it was conclusively shown that everyone who used the INTERCAL-SX formulation -- Yes 100 percent of those who undertook the study -- lost weight this same guaranteed weight loss is yours.

Because INTERCAL-SX is so powerful, and its weight loss effects are automatic, you can quit worrying about ever again being fat.

The claims that users can lose "all" the weight they wish, that this program is for users who wish to lose "more than 20 pounds," that there are no "failures," that the effects are medically documented, and that the effects are "guaranteed" and "automatic" with this "powerful" product together convey the impression that the product causes significant amounts of weight loss in virtually all users.

(b) Ingestion of Intercal-SX will cause significant weight loss without calorie restricted diets or exercise.

CX3-1, 8f and 10

LOSE WEIGHT WITHOUT DIETING]

Works from within your body to form a protective coating around the foods you eat, reducing the total number of calories BEFORE THEY CAN BE TURNED INTO POCKETS OF STORED FAT]

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INTERCAL-SX is a powerful, bio-active formula that "NEUTRALIZES" EXCESS CALORIES from within your body. INTERCAL SX actually absorbs excess fats and carbohydrates AFTER YOU HAVE EATEN THEM, preventing their further conversion into pockets of unsightly, figure-destroying stored fat.

This revolutionary new concept not only eliminates dieting, eliminates calorie counting, eliminates strenuous exercise, but most importantly eliminates fat, flab and ugly cellulite so easily, so effectively and so efficiently that you will soon know exactly why the entire diet industry is talking about this exciting breakthrough discovery.

By claiming that users will lose weight without the need for "calorie counting," and that Intercal-SX "eliminates dieting," the advertisements represent that users can lose weight "without dieting."

CX3-3c, 8d and 9

Guaranteed Weight Loss Without Dieting ...

Without Strenuous Exercise ... Without Giving Up

The Foods You Love To Eat.

LOSE UP TO 68 POUNDS WITHOUT DIETING

NEVER BE FAT AGAIN]

This revolutionary new concept not only eliminates dieting, eliminates calorie counting ...

By claiming that users will "never" be fat again, regardless of attention to diets, without giving up foods they love to eat, Respondents convey the impression that the product causes significant weight loss in users without the need for calorie-restricted diets.

CX3-3b

LOSE WEIGHT EFFORTLESSLY -- WITHOUT DIETING,

CALORIE COUNTING AND EXERCISE.

The representation of significant weight loss in users without calorie-restricted diets or exercise is expressed in the above language.

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CX3-7

INTERCAL-SX eliminates any chance for you to fail. This special formulation works by itself, WITHOUT dieting, WITHOUT calorie counting . . . This advertisement represents that the user need only ingest the product to lose weight, since it "works by itself." Further, users do not need to adjust their caloric balances by dieting.

(c) Ingestion of Intercal-SX prevents foods from being converted into stored fat.

CX3-1, 8f and 10

Works from within your body to form a protective coating around the foods you eat, reducing the total number of calories BEFORE THEY CAN BE TURNED INTO POCKETS OF STORED FAT]

INTERCAL-SX is a powerful, bio-active formula that "NEUTRALIZES" EXCESS CALORIES from within your body. INTERCAL-SX actually absorbs excess fats and carbohydrates after you have eaten them, preventing their further conversion into pockets of unsightly, figure-destroying stored fat.

These quotations describe the mechanism of action; the product blocks the absorption of calories by forming a "protective coating" around calories or by "absorbing " them, thereby "preventing" their conversion into stored fat.

CX3-3c, 8d and 9

Now you can eat all you want and still lose weight] INTERCAL-SX actually bonds with ingested foods, thereby altering the time contact is made with the intestinal membrane.

INTERCAL-SX was developed and tested for adults only (anyone over 18 years of age) because the adult metabolism requires a very special weight loss formulation -- a powerful action-specific compound that helps to "short circuit" the fat building cycle BEFORE your body turns excess calories into figure-destroying fat.

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These advertisements claim that Intercal-SX "bonds" with food, alters the food's contact with the intestinal wall, and "short circuits" the fat building cycle before the body turns excess calories into fat. In this way, the advertisements convey the impression that ingestion of Intercal-SX prevents foods from being converted into stored fat.

CX3-7

This proven, powerful formulation works from WITHIN to limit your system's ability to absorb excess fat-creating calories.

INTERCAL-SX is the proven automatic caloric "neutralizing" compound.

This advertisement also represents that the product "limits" the body's ability to "absorb ... calories" and describes Intercal-SX as a caloric-neutralizing compound.

(d) The weight loss claims for Intercal-SX are supported by the results of scientifically sound clinical studies.

This proposed finding was not disputed in Respondents' July 8 submission. The May 20, 1985 Order required each party to reply to the opposing party's proposed findings. The parties were advised that unless an opposing party's proposed finding was specifically denied with supporting citations and an alternate finding, it would be deemed admitted. Respondents' comment, "no objection," is consequently deemed an admission. Therefore, I find that this representation was made. This finding is also based

upon quotations from advertisements set forth in pages 15-18 of Complainant's proposed findings.

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(e) Respondents have accurately reproduced an excerpt from Acta Medica Scandinavia, Vol. 208, pp. 45-48 in certain of its printed advertisements, including Exhibit I.

CX3-1, 8f, and 10

Finally a weight loss compound that delivers exactly what it promises. But don't take our word for it. The results are medically documented. Published in Acta Medica Scandinavia (Volume 208, pages 45-48), this amazing study was uncovered by a team of U.S. researchers during a computer search of Excerpta Medica and Medicine (2 major medical data bases). What follows is a word for word excerpt from the actual medical abstract ...

"A highly significant decrease in body weight (62.9 + 2.1 vs. 60.4 + 2.4 kg. p is less than 0.0005, paired comparison) was seen in subjects receiving cyamopsis tetragonolobus (INTERCAL-SX) whereas body weight remained constant in the other two groups **IT IS CONCLUDED THAT THE DAILY INGESTION OF 15 MG. sic OF INTERCAL-SX RESULTS IN PERMANENT WEIGHT-LOSS...**"

III. The Advertising Representations (P.S. Docket No. 19/162)

Respondents' advertising materials, including product inserts accompanying reorder solicitations, make the representations alleged in subparagraphs 8(a), (b), (c), (d), (e), and (f) of the Complaint.

Specific reasons for these findings are as follows:

(a) Ingestion of Metabolite-2050 will cause significant weight loss in virtually all users.

The theme and central message of Respondents' advertisements is "Weight Loss]" See headline of CX3-17 p. 2, CX3-19. In CX3-24, a full-page advertisement in the July 1984 Cosmopolitan, the weight loss theme is expressed in the headline as "THE ULTIMATE CURE FOR FAT." The promise of "significant" weight loss is found in CX3-17, p. 1. when you need to lose 15 pounds or more, take METABOLITE-2050 . . .

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The text below that headline contains two references to the prospective customer's need to lose more than 15 and up to 40 pounds. In that paragraph, and again in the last paragraph on page 1 where it is in bold print, are references to "tough weight-loss problems." The same references are repeated in the package insert material, (CX3-23b and 31b), which also includes reorder forms, (CX3-23c and 31c). In the centered and boxed print on page 2 of CX3-17 and in CX3-19 is a reference to "highly significant decrease in body weight." The ordinary reader would understand "significant" in its usual sense rather than as it is technically used in a statistical sense. That usual meaning is "important, of consequence" Random House Dictionary of the English Language (1967) or "having meaning, full of import, weighty, notable" Webster's Third New International Dictionary (1968).

In the lower portion of the boxed text and in bold print is the language,

The research RESULTS ARE STAGGERING . . .

EVERYONE LOST SUBSTANTIAL WEIGHT PERMANENTLY.

On page 1 of CX3-17 at bottom center is the subheading

"I lost 31 pounds so far without even dieting]"

The message that the user will lose significant amounts of weight is repeated twice in CX3-32, a two-page advertisement in the September 1984 Playgirl. Under the large headline of "EAT ALL YOU WANT AND STILL LOSE WEIGHT," the text tells the reader,

There has truly been a major breakthrough in the science of dramatic and permanent weight loss. Science has produced a new, medically-documented weight loss compound specifically for those who need to lose a large amount of weight . . ."

Under "THE ULTIMATE CURE FOR FAT" headline in CX3-24 appears,

If you need to LOSE WEIGHT, and we mean LOTS OF WEIGHT - 10 pounds, 15 pounds, 20 pounds, 30 pounds, 50 pounds and more - . . .

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In CX3-32, as in CX3-24, the photograph of a slender woman wearing extremely large shorts emphasizes "significant" weight loss by the use of Metabolite-2050. The "before" and "after" photographs on page 1 of CX3-17 also represent that significant amounts of weight will be lost by taking Metabolite-2050.

That everyone will experience the promised weight loss with Metabolite is represented by the bold subheading, "FACT: EVERYONE LOST WEIGHT: TESTS PROVE 100% SUCCESS," followed by language which repeats and reinforces that message.(CX3-11 p.2, CX3-17 p. 2, CX3-19, CX3-24, CX3-32 p.2).

(b) Ingestion of Metabolite 2050 will cause significant weight loss without willpower, calorie restricted diets or exercise.

The advertisement at CX3-17 emphasizes:

AUTOMATIC WEIGHT-LOSS

NO calorie counting]

NO dieting]

NO food restrictions]

NO expensive fat clinics]

NO exercise]

In the same advertisement, the product is described to as "The powerful Scandinavian SUPERPILL]" -- an indication that the pill alone is responsible for an automatic weight loss. In the text near the middle of page 1, the message is repeated:

METABOLITE-2050 works by itself, without dieting, without calorie counting, without special foods, without powdered mixes, without strenuous exercise, without anything else at all. For the first time, we can truly say there is now a compound that will produce AUTOMATIC WEIGHT-LOSS.

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The automatic, i.e., effortless, achievement of weight loss is repeated in one sub-headline:

FACT: "EAT AS MUCH AS YOU WANT AND STILL

LOSE POUNDS & INCHES OF EXCESS FAT]

The Randee N. testimonial in CX3-17 says "you don't have to change your life style at all." On page 2 of that advertisement, the message is repeated:

WHAT DOES THIS MEAN IN ENGLISH? Now you can eat all you want and still lose weight, without will power and without dieting, automatically.

The same message is repeated in the product inserts, CX3-23b and 31b.

CX3-24 and 32 also represent weight loss without effort or diet. The headlines read, "EAT AS MUCH AS YOU WANT AND STILL LOSE WEIGHT] NEVER DIET AGAIN]" This is followed in CX3-24 by the subheadings:

NO CALORIE COUNTING.

NO STRENUOUS EXERCISE]

NO MORE WILLPOWER]§

NO MORE DIETING]

(c) Ingestion of Metabolite-2050 prevents foods from being converted into stored fat.

CX3-11 reads at page 2:

FACT: THE SECRET IS THE FORMULA METABOLITE-2050 has definitely been determined to increase satiety through its binding action to ingested food stuffs. WHAT DOES THIS MEAN IN ENGLISH? Now you can eat all you want and still lose weight ..."

The nearly identical message appears in the package insert received with the Metabolite ordered from CX3-11 (CX3-16, p. 2). In other

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advertising materials, Respondents add just after "ingested food stuffs:"

... thereby altering gastric emptying time, decreasing the normal caloric absorption rate and in effect lowering total caloric capacity (CX3-17 p. 1, 3-19, 3-23b).

In other advertisements, Respondents represent in a sub-headline:

<http://www.usps.com/judicial/1985deci/19-104dd.htm>

6/8/2004

FACT: METABOLITE-2050 RENDERS FAT CALORIE FREE]

(CX3-24, 3-32).

(d) The weight loss claims for Metabolite-2050 are supported by the results of scientifically sound clinical studies.

This proposed finding was not disputed in Respondents' July 8 submission. The May 20, 1985 Order required each party to reply to the opposing party's proposed findings. The parties were advised that unless an opposing party's proposed finding was specifically denied with supporting citations and an alternate finding, it would be deemed admitted. Respondents' comment, "no objection," is consequently deemed an admission. Therefore, I find that this representation was made. This finding is also based upon quotations from advertisements set forth in pages 24 and 25 of Complainant's proposed findings.

(e) Respondents have accurately reproduced an excerpt from Acta Medica Scandinavia, Vol. 208, pp 45-48 in certain of its printed advertisements, including Exhibit 1.

This proposed finding also was not disputed in Respondents' July 8 submission. Respondents' only comment similarly was "no objection." Therefore, the finding is deemed admitted and I find that this representation was made. This finding is also based upon a quotation from advertisements set forth in page 26 of Complainant's proposed findings.

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(f) An obese person who takes Metabolite-2050 may reasonably expect to lose weight while continuing to eat all he or she wants.

This proposed finding also was not disputed in Respondents' July 8 submission. Respondents' only comment was "no objection." Therefore, the finding is deemed admitted and I find that the representation was made. This finding is also based upon quotations from advertisements set forth in page 27 of Complainant's proposed findings.

IV. Qualifications of the Scientific Witnesses

Medical doctors William R. Ayers, Albert I. Mendeloff, and Richard C. Eastman testified for Complainant. Medical doctor Thomas M. S. Wolever and Stephen C. Woods, Ph.D., testified for Respondents.

Dr. William R. Ayers

Dr. William R. Ayers is Associate Professor of Internal Medicine and Associate Dean for undergraduate medical education at the Georgetown University Medical School, Washington, D.C. (Tr. 2194). He is certified in internal medicine (Tr. 2195), a fellow in the American College of Physicians (Tr. 2198), and co-founder and former director of the Diet Management Clinic at the Georgetown University Hospital (Tr. 2199-2200). He has published articles on the management of obesity and on the use of computers in medicine (Tr.2224, CX3-65). I found Dr. Ayers to be a credible witness. He demonstrated great expertise concerning principles of weight loss and diet management. He also testified logically in his analysis of scientific studies. Dr. Ayers' testimony in Docket No. 19/182, which was heard together with these cases, indicated weaknesses and

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misunderstandings with regard to peptide chemistry. However, Dr. Ayers' testimony demonstrated a good understanding about the state of scientific knowledge concerning guar.

Dr. Albert I. Mendeloff

Dr. Albert I. Mendeloff is Professor of Medicine at the Johns Hopkins University School of Medicine, Baltimore, Maryland (Tr. 2858). He is a gastroenterologist, a physician who specializes in digestive diseases and disorders of the digestive system. He is a fellow in gastroenterology, past president of the American Gastro enterological Association (Tr. 2859), Governor of the American College of Physicians for the State of Maryland (Tr. 2852) and editor of the American Journal of Clinical Nutrition (Tr. 2864). His research and practice interests encompass nutritional disorders, absorption and digestion, dietary fiber, diabetes and obesity (Tr. 2865-66). Respondents stated that Dr. Mendeloff "is eminently well qualified to testify and evaluate the studies" (Tr. 2867), and described him as "an expert's expert" who is "one of the world's greatest authorities on guar" (Tr. 2844). Dr. Mendeloff demonstrated great expertise concerning the product at issue in these cases. I found him to be an extremely credible and reliable witness. He also testified knowledgeably and persuasively about weight loss concepts and scientific studies.

Respondents accused Dr. Mendeloff of being untruthful and biased. They first argued that he had misrepresented a guar study that he conducted. Later they contended that he was biased because: (1) he was involved in a competing mail order business, (2) he may have incorrectly believed that Respondents delayed payment of his

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witness fee and, (3) he made negative comments to Dr. Wolever about Respondents. None of these accusations led me to conclude that Dr. Mendeloff testified untruthfully.

Dr. Mendeloff testified that he conducted a study using a grant from the United States Department of Agriculture for the purpose of determining guar's safety. Guar was administered in the form of bars made by the National Biscuit Company. Placebo bars which tasted exactly the same were also developed and administered. He stated that these were "fairly high calorie bars." At the end of the six month study, no differences in subjects' body weights were noted (Tr. 3090-94). He stated that this demonstrated how tough it is to make people lose weight, and that the subjects kept eating "even though they had all these extra calories we provided them" (Tr. 3093). Respondents contended that Dr. Mendeloff's co-researcher, Dr. Michael McIvor, contradicted several of Dr. Mendeloff's statements about the study in a recently taped telephone interview. Respondents were not permitted to introduce the recording of the conversation or the testimony of their interviewer, Mr. Lester, to prove the truth of Dr. McIvor's statements, but they were permitted to call Dr. McIvor as a witness (Tr. 3199-3201, 3261-62). Dr. McIvor agreed to testify (Tr. 3351), but Respondents subsequently decided not to call him as a witness (Lee H. Harter's February 25 mailgram). Thus Respondents never substantiated their accusation that Dr. Mendeloff did not testify credibly about the study.

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Respondents also argued that Dr. Mendeloff was biased, because according to Mr. Friedlander, "We have been informed that Dr. Mendeloff is selling medication through the mail in direct competition with me" (Tr. 4937). Mr. Friedlander appeared to refer to a "mail order diet" allegedly distributed by the

American Digestive Disease Society, a non-profit organization with which Dr. Mendeloff is associated (Tr. 4937-39, 4944, 4956-57, 5066-67). I found this accusation to be too far-fetched to constitute proof of bias (Tr. 4938, 4940). Dr. Mendeloff's association with the sale or distribution of diets by the American Digestive Disease Society does not place him in direct competition with Respondents, nor does it provide him a motive to testify falsely about Respondents' products and medical and scientific matters.

In a motion to strike testimonies of Drs. Ayers and Mendeloff filed June 12, 1985, Respondents also argued that because of a post script in a September 13, 1984 letter by Ms. McFeeley to Dr. Mendeloff referring to a "payment problem," which Respondents' contended referred to a delay in their payment of Dr. Mendeloff's witness fee through no fault of theirs, Dr. Mendeloff became biased against Respondents. This accusation also seems absurd. I do not believe that a man of Dr. Mendeloff's stature would testify falsely because of a delay in payment of his bill.

The final accusation of bias relates to Dr. Wolever's testimony. Dr. Wolever testified that he telephoned Dr. Mendeloff on April 9, 1985, the evening after Dr. Wolever's first day of testimony in this hearing. Dr. Wolever stated that Dr. Mendeloff

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said that Respondents were crooks who, after one mail box was closed down, moved to another city and opened another one (Tr. 5606). Although this testimony indicates Dr. Mendeloff's negative view of Respondents as of April 9, Dr. Wolever's statements do not destroy Dr. Mendeloff's credibility. Dr. Mendeloff completed his testimony almost three weeks before this conversation with Dr. Wolever. Assuming the accuracy of Dr. Wolever's testimony, it is not clear whether Dr. Mendeloff's negative opinion formed by April 9 preceded any of his testimony, or that these views effected his testimony. It would not be surprising after the many incidents in which Respondents verbally attacked Dr. Mendeloff during his testimony, that Dr. Mendeloff subsequently formed a negative impression of Respondents.

Dr. Richard C. Eastman

Dr. Richard C. Eastman is Associate Professor of Medicine at the Georgetown University Medical School, and chief of the Division of Endocrinology and Metabolism, an area which includes the treatment of obesity. Dr. Eastman is consultant to Georgetown's Diet Management and Eating Disorders Program. He also consults directly with patients, some of whom have obesity problems. He is director for clinical research for the diabetes unit. He is a board certified internist (Tr. 2043-45, CX3-67). Dr. Eastman has impressive credentials, having published approximately 25 articles. I found Dr. Eastman to be highly knowledgeable about weight loss principles and about peptide chemistry. He testified in a sincere, forthright manner and carefully considered the questions in an effort to be helpful and truthful. I found him to be an extremely reliable witness although he did not testify specifically about guar.

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Dr. Thomas M. S. Wolever

Dr. Thomas Wolever is a licensed physician in England and in Ontario, Canada (Tr. 5405-06). He is currently working toward a Ph.D. in the Department of Nutritional Sciences at the University of Toronto. His doctoral research involves nutrition in the treatment of diabetes and lipid problems (Tr. 5404). Dr. Wolever has excellent credentials and substantial expertise with regard to guar. Dr. Wolever was an extremely interesting and highly informative witness. However, on several critical issues, I found his testimony less reliable than that of Dr. Mendeloff. Dr. Mendeloff testified consistently despite

lengthy cross-examination. Although Dr. Wolever demonstrated candor in condemning Respondents' advertising language, his testimony at other times was unbelievable and contradicted by his subsequent testimony.

Dr. Stephen C. Woods

Dr. Stephen C. Woods is Professor of Psychology, chairman of the Department of Psychology, and Adjunct Professor of Medicine at the University of Washington. Dr. Woods holds the Ph.D. in physiology, biophysics, and psychology. He has worked in the field of endocrinology since the late 1960s and has authored more than 100 scientific articles, the majority of which deal with metabolism, food intake, and peptide hormones. Dr. Woods is the National Science Foundation's expert on food intake. He serves on the editorial boards of two peer review journals, *American Journal of Physiology* and *Behavioral Neurobiology*. He is organizer of the 1986 International Congress of Physiology of Food and Food Intake (Tr. 5113-15, RX3-36). Dr. Woods did not testify about guar. He

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testified mainly about a product involved in another case, but some of his testimony related to relevant issues concerning scientific method. I found his credentials to be impressive. V. Definition of Terms and Background Findings

Dr. Ayers stated, and Respondents accepted the definition, that obesity is the state of being 15 percent or more over the ideal weight for one's height, age and sex as defined by tables published periodically by, among others, the Metropolitan Life Insurance Company (Tr. 2201-02, Respondents' July 8, 1985 submission, p. 8, para 44).

As Dr. Ayers and Dr. Mendeloff testified, obesity is a complex problem that is not simple to treat. Nutrition, energy balance, exercise and behavior are important aspects of the problem. (Tr. 2202-03, 2268-69, 2873-76). Dr. Wolever also characterized obesity as a complex problem (Tr. 5463). To lose weight, a person must create an energy or calorie deficit so that the body will use stored energy or fat to meet its current energy needs (Tr. 2203, 3134, 3684). Satiety in humans is the sense of fullness that normally leads to cessation of eating. Dr. Ayers gave this definition (Tr. 4762-63), and Dr. Woods agreed that the definition was reasonable (Tr. 5215). Dr. Eastman's similar definition was, "the sense of having had enough to eat, being full" (Tr. 2092). Satiety signals that cause a lean person to stop eating are not equally effective for obese persons. Dr. Ayers testified that satiety does not necessarily cause obese people to eat less, that there is no necessary relationship between increased satiety and weight loss,

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and that the normal satiety signals do not apply in obese people (Tr. 3381, 4128). When Dr. Woods was asked whether he believed "that producing the feeling of satiety in an obese person leads inevitably to weight loss for that person," he replied, "Certainly not" (Tr. 5289-90). Dr. Wolever agreed that just because a substance produces satiety does not necessarily mean that the substance also produces weight loss (Tr. 5462-63, 5415, 5557). Dr. Mendeloff emphasized that many patients who say they feel full in hunger-satiety ratings continue to eat, ignoring the feeling of fullness (Tr. 3841, 3880).

As scientific experts for both sides testified, to establish a claim that a substance will be effective to achieve a particular result, the claim must be established by sound scientific evidence (Tr. 2079-82, 2273, 3068, 5283, 5434, 5550-51). Dr. Ayers said that efficacy claims for Anorex-CCK, a product involved in the companion case, must be treated as false in the absence of information to support them

(Tr. 2972-74). Dr. Woods said that until a substance is tested using the mode of administration for which claims are made, there is no way to know how that substance will work (Tr. 5283). He stated that, in the absence of data, a claim or hypo thesis is an open question; there is simply no information (Tr. 5197-98). Dr. Wolever also indicated that data are required in order to support a medical opinion (Tr. 5434-35, 5550-51).

Formation of a scientific or medical consensus requires that results of studies be disseminated among members of the scientific community and be reviewed by others working in the field. Presentations of data at meetings and conferences lend themselves to that

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function as do having papers reviewed by experts in the field prior to their publication in peer reviewed journals (Tr. 2270, 2956-57, 3072). Persons who perform work and who follow work in a field are in positions to be aware of a consensus in that field.

VI. The Truth or Falsity of the Representations

Intercal-SX and Metabolite-2050 each consists of tablets of cyamopsis tetragonolobus (CX3-5, 3-15, 3-29). The only difference between Intercal-SX and Metabolite-2050 tablets, other than their names, seems to be the quantities of liquids which the user is told to take with tablets when ingesting three daily doses. Test purchases of Intercal-SX and Metabolite-2050 each contained 1,500 mg of cyamopsis tetragonolobus per tablet (CX3-5, 3-15). A later test purchase of Metabolite-2050 contained 750 mg of cyamopsis tetragonolobus per tablet but required the user to take twice the number of tablets (CX3-29).

Cyamopsis tetragonolobus is the latin name for guar, a product made from seeds of the cluster plant. Guar is a dietary fiber. A dietary fiber is the portion of food obtained from plants which is not digested by the enzymes of the gastrointestinal tract (RX3-40, p. 1). When guar is mixed with water it swells and becomes gelatinous. It is used as a thickening agent for such foods as ice cream and salad dressings. It is also used to thicken skin creams and lotions, for baking to give better loaf quality to bread, and in oil wells to thicken sludge (Tr. 2878-79, 3073, 3075-76, 5413). Guar is grown and commonly used in India (Tr. 5414, 2880). Dr. Wolever testified that guar "is a very old part of the diet. People have been eating guar for many hundreds or even thousands of years. It's a staple" (Tr. 5414). Although guar is tasteless, when it

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combines with saliva in the mouth, it quickly forms a gel, swells and becomes unpleasant and bitter tasting. Like other fibers, guar adds bulk to the intestinal tract. It is believed that guar and other fibers may be helpful in treating diabetes since they have been shown to lower blood sugar levels (Tr. 2206, 2880, RX3-40, pp.1-2). Guar also slows gastric emptying and lowers cholesterol levels (Tr. 3850-52, RX3-40, p. 2). Guar was discussed at an international fiber conference held in Washington, D.C. in the Spring of 1984 and attended by Drs. Mendeloff and Wolever (Tr. 5596).

On February 15, the fourth day of the hearing, Respondents presented a new issue. Respondents stated that they wished to fill all existing orders for Intercal-SX and Metabolite-2050 with lej guar, a granulated form of guar manufactured by the Lej Pharmaceutical House in Sweden (Tr. 2901-03, 3010). Mr. Friedlander explained:

"In the ads and the coupons and orders that are being held, it says a three week supply of

Metabolite-2050. If I had my mail, I would supply them with a three week supply of Metabolite-2050. No one is going to be able to tell me that these people know what they are going to get when they order the product other than a three week supply of Metabolite-2050" (Tr. 2908-09).

Mr. Harter said that lej guar would be taken in amounts of 20 grams per day in two 10 gram doses. The guar in tablet form provided only 15 grams per day. Mr. Harter stated that Respondents would no longer sell guar in tablet form (Tr. 3013). The parties considered a consent agreement with respect to guar tablets, but were unable to reach agreement (Tr. 3049, 5452).

It is proper to determine falsity issues with respect to both the guar tablets and the guar granules within these proceedings.

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With respect to guar in tablet form, United States v. W. T. Grant Co., 345 U.S. 629, 632 (1953) instructs that "voluntary cessation of allegedly illegal conduct does not deprive the tribunal of power to hear and determine the case, i.e., does not make the case moot A controversy may remain to be settled in such circumstances ... The defendant is free to return to his old ways. This, together with a public interest in having the legality of the practices settled, militates against a mootness conclusion" Citations to other cases omitted. The parties agreed to litigate the truth or falsity issues and presented evidence regarding the lej guar products, and the Postal Service decisions prohibiting the issuance of advisory opinions do not bar decisions regarding these products. The decisions -- Paul Harvey, P.S. Docket No. 8/10 (P.S.D. on Appl. for Mod. of Mail Stop Order, August 29, 1980) and George Ernst, Jr., P.S. Docket No. 13/88 (P.S.D. in Motion to Revoke False Representation Orders, May 1, 1984) -- apply to requests for opinions where advertising representations have not been formulated and orders have not been received. In the present cases, there are existing advertisements and orders which Respondents desire to implement with lej guar products.

Although Respondents allege that lej guar represents an improvement over guar in tablet form, I find that there is no difference between these forms of guar in their effects upon weight loss. Dr. Mendeloff testified that guar may vary in grades of purity, particle size, palatability, concentration, and effects of temperature, but these variations do not effect the metabolism of food or nutrient

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absorption (Tr. 3075-77). With respect to the differences in effect between the guar tablets and lej guar granules, Dr. Mendeloff explained:

The first effect of guar, as it's customarily used, is in contact with water or "liquous" components so that granules would be in the mouth, subject to immediate swelling on contact with the secretions of saliva and the natural moisture that's in the mouth. Therefore, if you started swallowing guar as granules in the mouth, it would start swelling up. It might be unpleasant, because it's sticky stuff and it's hard to swallow. Therefore, the use of a capsule would mean that the material would not begin to swell until it reached the stomach, when the capsule dissolves and the material inside then goes out into the stomach secretions and begins to swell at that point. So the difference I would say has nothing to do with its actions in the stomach. It would have to do primarily with whether you want to avoid actions in the mouth, which is not really what you are trying to produce (Tr. 3073).

Dr. Wolever, Respondents' only witness concerning guar, wavered on this point. He stated that "possibly

the type of guar and the way it is given may be important" (Tr. 5563) and "Guar is not guar is not guar" (Tr. 5547), but on cross-examination Dr. Wolever could not support the conclusion that the form of guar would effect its weight loss properties. He testified:

Q. When you said the formulation is important, what exactly do you mean?

A. I mean whether the guar is the type of presentation, in other words whether it is a tablet, a capsule, mini capsule, granulated, whatever, powder, and how it is taken with respect to meals. In other words, do you mix it on your food, do you take it before the meal, after the meal, is it incorporated into the food and so on.

Q. Which is better for the purposes of producing weight loss?

A. That I don't know because this sort of experience is the sort of experience you get and from this data I would say the lej guar seems to be the one that is most effective (Tr. 5549-50)

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The data to which Dr. Wolever referred is a guar study by Dr. Marcin Krotkiewski of Sweden, the only known study using lej guar (CX3-64).

When pressed on the subject of formulation, Dr. Wolever testified:

Q. So you think if powdered or granulated guar is mixed with water and drunk down immediately before a meal it is likely to have more effect on weight loss than administered some other way?

A. I have no comment to make there, I don't know.

Q. You stated before formulation and administration were important. I am trying to find out what formulation and what mode of administration will produce weight loss.

A. I am telling you there has not been enough study (Tr. 5550-51).

There is very little scientific evidence relating to guar's effect upon weight loss. Most studies with respect to guar relate to its potential use for the treatment of diabetes and the treatment of heart disease (Tr. 3862, 5425).

Dr. Wolever testified that he knew of only one study which had specifically used guar to produce weight loss and had shown it to do so. That was a 1975 study reported by Evans and Miller entitled "Bulking Agents In The Treatment of Obesity" (RX3-21; Tr. 5462, 5543). Evans and Miller conducted a two-week study in which guar and methylcellulose were each given to 11 subjects for one week. They concluded that guar and methylcellulose were equally effective to produce weight loss. But reported weight losses with both substances were small and the two week time period was extremely short. The report concluded, "The indication that these agents are more effective in obese subjects than non-obese subjects is

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interesting and needs further investigation" (RX3-21, p. 203). Dr. Mendeloff said that he report "indicated a pious hope that this would be a very good way of reducing weight" (Tr. 4925).

In a 1980 Finnish study of guar's effect on cholesterol levels, the study that Respondents emphasized and quoted from in many of their advertisements (CX3-1, 3-8(f), 3-10, 3-11, 3-17, p. 2, 3-17), the investigators found no change in cholesterol levels, but noted that subjects lost weight (CX3-59). The weight loss was statistically significant but not clinically significant, being only 5.5 lbs in four months (Tr. 2882, 3287-88, 5493). Several of the report's authors indicated that the observed weight loss could possibly be explained by seasonal variations in diet and/or inadequate dietary instructions (CX3-60, p. 114-15). Drs. Ayers, Mendeloff and Wolever agreed that the 1980 study was not designed to reveal whether guar caused the weight loss (Tr. 3289-90, 2881-82, 5495-96).

Groups of researchers, including some of those involved in the 1980 study, conducted three follow-up studies using guar (CX3-60, 61, 62). None of these studies found significant weight loss with guar administration. A 1983 report of a study of 12 obese hypercholesterolemics indicated that subjects actually gained weight while on guar treatment, though not a statistically significant amount (CX3-60, p. 114). One group of Finnish investigators concluded, "it seems to us that guar gum alone cannot control body weight, but could probably be of importance as a part of a more comprehensive weight-control programme" (CX3-60, p. 115).

The only known study of lejel guar's effect on body weight, and the one upon which Respondents rely to support efficacy claims for

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their products, was reported in the British Journal of Nutrition in 1984. It is entitled "Effect of Guar Gum on Body Weight, Hunger Ratings and Metabolism in Obese Subjects" and was written by Dr. Marcin Krotkiewski, a Swedish scientist (CX3-64).

The report involved two studies -- experiment 1 and experiment 2. In experiment 1, nine obese female subjects were studied. They were recruited to the obesity outpatient clinic for weight reduction. Subjects were given 10 grams of lejel guar twice daily for eight weeks. The study was designed to evaluate guar's effects on blood glucose levels. Cholesterol and triglyceride levels and body weight were also measured. The mean weight loss for the nine subjects was about 1.1 pounds per week. Although this is a small weight loss, it is considered statistically significant (Complainant's proposed finding no. 71).

As Dr. Krotkiewski reported, "Since the obese patients in Expt 1 lost weight (see Table 3) and several patients spontaneously reported an increased satiety during guar gum treatment a second experiment was carried out" (CX3-64, p. 99). For Experiment 2, 21 obese subjects were recruited from the obesity outpatient clinic. Patients were given either 10 grams of lejel guar or 10 grams of wheat bran twice daily mixed in water. The experiment was designed to last 10 weeks with the subjects taking guar and wheat bran during alternating weeks. Subjects were weighed weekly and were asked to rate their hunger on a scale of one to nine. All subjects continued in the study for 6.6 weeks but then 14 subjects discontinued hunger ratings, and weight loss statistics were thereafter reported for

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only nine subjects in one table (Table 5) and for seven in another (Table 4). As Dr. Krotkiewski reported, the mean body weights were significantly less after 10 weeks (P. 102). The subjects lost an average of approximately 1.5 pounds per week (Tables 4 and 5, p.103). Dr. Krotkiewski concluded:

The results of the present study clearly demonstrate that guar gum taken in conjunction with meals leads to a reduction in hunger as compared with wheat bran taken in the same way. This effect seems to be

long-lasting and could still be demonstrated after a 10-week period.

The study acknowledged, "Previous studies have usually reported that guar gum treatment did not significantly influence body-weight, although this has been found in some investigations" (P. 104).

As the witnesses testified, although the Krotkiewski study of lej guar reported weight loss, there are a number of problems with the study. First, the two experiments involved very small numbers of subjects. Dr. Mendeloff testified that although this study's P value of .05 is highly significant in statistics (Tr. 2894) many would consider a seven-subject experiment with an .05 level of significance insufficiently rigorous from a statistical viewpoint (Tr. 3082, 3848). To the same effect, Dr. Wolever testified "it is not the P value that gives me caution, it is the smaller number of people that gives me caution" (Tr. 5633).

The Krotkiewski report presented other problems. Experiment 1 had no control group. Therefore, it was not a blind study. Another concern is the study's failure to explain why between 12 and 14 of the 21 subjects did not complete Experiment 2. Both Drs. Ayers (Tr. 3373, 3510-19) and Mendeloff (Tr. 3078) felt that this greatly reduced the study's value. I agree. Did they drop out because they

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achieved poor results and become discouraged? Dr. Mendeloff acknowledged that it is not unusual for subjects to drop out. However, he stated "But to have two-thirds of the people drop out is really a serious matter. And the fact that there's no explanation here makes it extremely difficult to understand what's going on here" (Tr. 3078). Dr. Wolever agreed that the reasons why they discontinued the study should have been explained. That would have been good scientific practice (Tr. 5502, 5505).

Drs. Ayers, Mendeloff and Wolever agreed that the Krotkiewski study was not designed to show the mechanism of action, whether guar caused the weight loss. Rather, the study was designed to look at hunger (Tr. 3479, 3080, 5460, 5509, 5512). Dr. Wolever also acknowledged that reduced hunger is not necessarily the reason why the patients lost weight; it is merely a plausible explanation (Tr. 5415).

Drs. Ayers and Mendeloff pointed out that Experiment 2 involved two subjects who lost much more weight than the other five. Without these two, the group weight loss would have been much less (Tr. 3374-76, 3081-82, Table 4). Also, Drs. Ayers and Mendeloff observed that subjects had been selected from new referrals to an obesity clinic. Thus, it would have been important to know what they had been eating and whether they were already losing weight (Tr. 3498, 4930-35, 4990-93). Dr. Mendeloff also testified that wheat bran has not been shown to cause weight loss. Weight loss observed during the bran treatment in Experiment 2 was not of significant statistical difference from that reported during guar treatment (Tr. 5009)

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Another weakness in the Krotkiewski study was its failure to monitor subjects' diets and exercise. A study should always control for other variables which could effect its results. Such important variables for a weight loss study include diet and exercise (Eastman Tr. 2079-80, 2089, 2141, 2149; Ayers 3308, 3479; Mendeloff 3125-26, 4930-31; Woods 5297). In Experiment 1, the subjects "were asked not to alter their normal diet or energy intake during the trial period." However, it is not clear whether they followed this direction. The report also indicated that, "Diet records (4d) before and during guar gum treatment suggested that no qualitative difference in dietary habits occurred" (P. 99). However, qualitative refers only to kinds of foods, as contrasted with amounts of food. Therefore, it is not clear whether there were quantitative changes in diet (Tr. 3371-72, 5512-13, 5594-95). Also the study did not

indicate whether subjects' exercise patterns were determined to make sure that after the study began they did not increase their exercise. Experiment 2 was completely silent about diet and exercise, making it unclear whether these important factors were controlled in that experiment.

Dr. Mendeloff testified that, of course, the medical community is not going to accept just one study of this type. The study would require replication by an independent source, "at least one other study, to reproduce this, before, I think, anyone would take it very seriously" (Tr. 3070-71). Dr. Ayers testified that "findings ... must be replicated in the hands of someone else so that any possible bias can be excluded ..." (Tr. 2270, 2301). Dr. Eastman explained that a single group's findings might be subjected to unknown biases and that findings would have to be confirmed before they would be

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widely accepted by the scientific community (Tr. 2140). Dr. Woods also advocates replication for unexpected findings. He stated, "when they give me - bring me back findings that I think are unexpected, I have them do the study again." When asked to explain why he would require replication, Dr. Woods said "because I'm a skeptic. And I would like to see if it comes out the same way. You have tremendous statistical power if you get the same results in two independent replications" (Tr. 5310). Dr. Wolever stated that "One paper alone on anything is not enough to convince the scientific community that anything works." He agreed that replication would be required to establish these results (Tr. 5561-62).

With regard to the Krotkiewski study, Dr. Wolever testified as follows: He telephoned Dr. Krotkiewski a few days before he testified and learned that Dr. Krotkiewski now puts virtually everybody in his obesity clinic on guar. Dr. Krotkiewski told Dr. Wolever that he has over 200 patients in his obesity clinic whom he has studied for 50 weeks using guar. He reported that as a result of the patients' use of guar, they are more compliant with the weight loss program, lose more weight, and still feel less hungry even after a year (Tr. 5415-16). By "compliant," Dr. Wolever thought that Dr. Krotkiewski meant continuing in the obesity clinic rather than dropping out (Tr. 5455). Dr. Wolever also testified that Dr. Krotkiewski's patients are not necessarily specifically instructed on diets. Therefore, a subject may or may not be on a diet during the study (Tr. 5457-58). Dr. Wolever said that Dr. Krotkiewski's findings would soon be published (Tr. 5416). Dr. Wolever stated that he felt a lot happier about testifying in this

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proceeding after having talked to Dr. Krotkiewski about Dr. Krotkiewski's additional work. Dr. Wolever said that if he only had the one study of a few patients CX3-64 to go on he would be a lot less happy about saying the things he has said at the hearing (Tr. 5593).

Soon after Dr. Wolever testified, Complainant recalled Dr. Ayers as a rebuttal witness. Dr. Ayers testified as follows: He telephoned Dr. Krotkiewski after being informed of Dr. Wolever's testimony. Dr. Krotkiewski confirmed that he had done subsequent work with guar, that a paper describing some of his work had been presented at the International Fiber Conference in Washington, DC in the spring of 1984 and that Dr. Ayers could most easily obtain a copy of the paper from Dr. George Vahouny, a co-director of the fiber conference, at the George Washington University in Washington, D.C. (Tr. 5918-19). Dr. Krotkiewski told Dr. Ayers that patients had better compliance with the program when they used guar and that the program included a 1000 calorie-a-day diet (Tr. 5923-23, 5964). After the telephone conversation, Dr. Ayers called Dr. Vahouny and obtained a copy of the Krotkiewski paper (Tr. 5917-19). The paper confirmed that in the Krotkiewski program guar helped patients comply with their 1000 calorie-a-day diets (CX3-73).

After introductory statements, the paper discussed the study at CX3-64 and then discussed Dr. Krotkiewski's subsequent work, beginning with the following language:

An additional study was made of seven patients on a low calorie regimen supplemented with guar gum. One patient succeeded in losing 62 kg over a period of one year. (The other six lost an average of 22.5 kg \pm SD) (CX3-73, p. 7) [Emphasis added].

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he paper continued:

After the completion of the above studies, 68 patients routinely obtained guar gum as a supplement to their 800 to 1000 Kcal diet recommendation. Of those who followed the programme (and had a check-up every five weeks), 58% reported good tolerance and an appetite-suppressing effect. Only 67% of those initially included in the study followed the treatment after eight months, but of these 74% belonged to the guar users. Sixty-nine percent reported a persistent appetite-suppressing effect and 61% a laxative effect of the guar (CX3-73, p. 8) [Emphasis added].

This language specifically contradicts Dr. Wolever's testimony about his telephone conversation with Dr. Krotkiewski. Dr. Wolever testified:

Q. In the follow-up work that you and he discussed on the phone, do you know whether those patients who had been taking the guar, as you said, for 50 weeks had been given a diet to follow, a diet plan?

A. No. He says that they are specifically -- they are not instructed to keep -- they are just instructed to keep their regular diet and encouraged to keep their regular activities.

Q. When you say "he says," do you mean in this paper?

A. No. Over the telephone, he stated to me that his patients are not instructed specifically on diets necessarily. Some of them go on to diets, and some of them don't. So it's not necessary for the patients to go on to specific diets. They can get weight loss just by maintaining their normal everyday life and not making any special efforts (Tr. 5457-58).

After Dr. Ayers testified on rebuttal, Respondents requested and were given additional time to present the testimony of either Dr. Krotkiewski, Dr. Wolever or a Dr. Kristokis as a surrebuttal witness (Tr. 6126-27). However, Respondents subsequently decided not to present surrebuttal testimony. In the absence of any contradictory

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evidence, I find that CX3-73 is an authentic report of Dr. Krotkiewski and I have no reason to question the truthfulness of the statements contained in the report. Therefore, I find that Dr. Wolever's testimony in this critical area is inaccurate.

The follow-up report confirms Dr. Krotkiewski's concluding statement in CX3-64:

In summary, the present results document some effect of granulated guar gum on carbohydrate and lipid metabolism in obese individuals. These effects would appear of particular importance in obesity considering the known associations with diabetes and lipid disorders. In addition, guar gum reduces

hunger when taken with meals and may thus be an important adjunct to other treatments of obesity. [Emphasis added].

Dr. Wolever was Respondents' only scientific witness with respect to guar. On direct examination Dr. Wolever was asked if the representations referred to in subparagraphs 8(a), (b), (c), and (d) of Docket No. 19/104 and subparagraphs 8(a), (b), (c), (d), and (f) of Docket No. 19/162 were true or false. He testified that all these representations were true (Tr. 5427-29). However, these conclusions were contradicted by the testimonies of Drs. Mendeloff and Ayers, the weight at the credible evidence and some of Dr. Wolever's own testimony. I find that the representations alleged in Paragraphs 8 of the Complaints in Docket Nos. 19/104 and 19/162 are false for the following reasons:

(a) Ingestion of Intecal-SX (or Metabolite-2050) will cause significant weight loss in virtually all users.

Dr. Wolever at first supported Respondents on this issue, testifying that "virtually every obese person has lost weight just 46taking guar." However, this testimony was contradicted by Dr. Wolever's later testimony and by other evidence. Later, Dr. Wolever acknowledged that (1) there is conflicting evidence as to whether everyone who takes guar loses weight (2) that a "good proportion" of persons who take guar will lose weight, and (3) that a majority or a high majority of persons who take guar will lose weight (Tr. 5558-59, 5549, 5592). I find Dr. Mendeloff's conclusions to be more plausible. Dr. Mendeloff stated that his review of the scientific literature for various forms of guar revealed inconsistent weight loss results and that only about 25 percent of the people reported in guar studies lost weight (Tr. 3961, 3988, 5031). Dr. Mendeloff concluded that "some people lose weight and most people don't" on guar administration (Tr. 4924-25). The results of the very few studies of guar's effects on weight loss are inconsistent. Three of the four Finnish studies showed no significant weight loss while taking guar; one showed weight gain. In the one Finnish study where there was weight loss (CX3-59) the weight loss was statistically significant but not clinically significant. In the Evans and Miller study the weight loss also was small. Dr. Krotkiewski's statement in CX3-64 also supports Dr. Mendeloff's conclusion. Dr. Krotkiewski stated, "Previous studies have usually reported that guar gum treatment did not significantly influence body weight, although this has been found in some investigations" (P. 104). The Krotkiewski study, in view of its small sample, unexplained drop outs, and the other problems discussed, and without replication, does not overcome the other evidence that guar will not cause significant weight loss in virtually all users.

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Guar does appear to cause a feeling of fullness and satiety and may cause weight loss in some users. Dr. Mendeloff explained that almost all dietary fibers that have been tested, including carrots, cabbage and a great number of foods, produce the effect of increased satiety (Tr. 3880). However, as the scientific experts agreed, satiety signals are not as effective for obese people and satiety does not necessarily cause obese people to eat less and lose weight (Tr. 3381, 3880, 4128, 5289-90, 5462-63, 5415).

(b) Ingestion of Intecal-SX (or Metabolite-2050) will cause significant weight loss without willpower, calorie restricted diets or exercise.

Dr. Mendeloff testified that the consensus of informed medical opinion is that this representation is false (Tr. 3096). The evidence supports that conclusion. Several of the authors of the Finnish studies concluded, "it seems to us that guar gum alone can not control body weight, but could probably be of importance as part of a more comprehensive weight loss programme" (CX 3-60, P.115). Dr. Krotkiewski agreed, stating that guar "may thus be an important adjunct to other treatments of obesity," such as the 800 to 1,000 calorie diet that Dr. Krotkiewski supplements with guar (CX3-64, 3-73, p. 8).

Dr. Wolever, in complaining about exaggerations found in Respondents' advertising materials stated that it would be more accurate to describe guar as "an aid to slimming." "In other words, used as a part of a calorie controlled diet and in the program of diet and exercise" although he then qualified his testimony by stating, "The fact that they can lose weight and even if they don't try to diet and don't alter their diet, that may be true" (Tr. 5556-57, CX3-40, p. 2).

(c) Ingestion of Intercal-SX (or Metabolite-2050) prevents foods from being converted into stored fat.

Dr. Mendeloff stated his opinion that this representation is false and that his opinion is consistent with the consensus of informed medical opinion (Tr. 3096). I agree. Dr. Mendeloff testified that guar has no effect on the metabolism of food. Guar's only effect is to cause the lining of the small intestine to be covered by a thickened layer which overlies every absorbing cell. Guar has no effect on the amount of nutrients absorbed, but does influence their rate of absorption (Tr. 3077). Dr. Wolever did not disagree with these assertions, and I find them to be accurate and to reflect the consensus of informed medical opinion.

At the hearing Respondents contended that an increase in fecal fat supports their representation that guar prevents food from being converted into stored fat (Tr. 3935-36) and offered scientific articles which they contended supported this argument (Tr. 3938-40). However, Respondents never indicated how the articles supported their position and the articles do not appear to support Respondents' claim. Moreover, the testimony of the expert witnesses indicates that the use of guar results in miniscule increase of fecal fat and I so find. In addition, the testimonies of Drs. Mendeloff and Wolever on this subject demonstrate why I found Dr. Mendeloff's testimony more reliable than that of Dr. Wolever where they differed. Dr. Mendeloff's testimony was clear and unequivocal despite many days of cross-examination. He stated, "The effect of guar on fecal excretion of most metabolites is minimal to nothing." When pressed on cross-examination with the question "Guar in large

doses, though, has been shown to increase fecal fat, not in all studies, but in some?" Dr. Mendeloff adhered to his previous testimony stating, "It is generally considered to be a trivial result" (Tr. 3861). In contrast, Dr. Wolever's initial testimony appeared misleading, and he later retracted some of that testimony. At first, Dr. Wolever stated that guar increases bile acid excretion in the stool and "this has implications in the way that fat itself is metabolized and absorbed" (Tr. 5422-24). Later he said, "Bile can be made from cholesterol, which can be made from stored fat, if you like, metabolically. So I guess that it could possibly come from stored fat" (Tr. 5463-64). Still later, Dr. Wolever admitted, "Well, bile acids are not fat, they don't get metabolized in the way of fat but they are fatty materials so there is not a great deal of calories there." He admitted that "we are talking about milligrams of fat" and agreed that one gram (1,000 milligrams) of fat equals only nine calories (Tr. 5571-72). Later when asked, "So if there were an alleged binding action on food that is ingested by guar in order to promote its excretion in the stool, it would be miniscule, if at all, would it not?" Dr. Wolever agreed, replying "I think from a physiological point of view, yes, it would be small" (Tr. 5572).

(d) The weight loss claims for Intercal-SX (or Metabolite-2050) are supported by the results of scientifically sound clinical studies.

Respondents did not dispute that this representation was made. The following are typical of Respondents' advertising language that made the representation:

INTERCAL-SX CERTIFIED GUARANTEE. The INTERCAL-SX Caloric "Neutralizing" compound has been proven in double-blind studies to create dramatic weight loss for all who used this unique formulation.

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MEDICALLY DOCUMENTED FACT: EVERYONE WHO USED INTERCAL-SX EXPERIENCED A SIGNIFICANT LOSS OF WEIGHT] (CX3-1, 3-8(f) and 3-10).

At last, the scientific community has developed what can only be called the "miracle" weight loss compound, a potent and powerful compound that is specifically designed for tough, adult weight loss problems... now there is a scientifically-developed,medically-verified answer to your adult weight loss problem -- (CX3-3c, 8-8d and 3-9).

FACT: EVERYONE LOST WEIGHT]

TESTS PROVE 100% SUCCESS]

Yes, that's right] Scientific documentation confirmed that EVERY PERSON who used METABOLITE-2050 LOST WEIGHT] The research RESULTS ARE STAGGERING. In a Scandinavian double-blind study, DOCTORS TESTED a number of overweight women and in the group that took METABOLITE-2050, EVERYONE LOST SUBSTANTIAL WEIGHT PERMANENTLY. This is not a marketing fantasy. This is a scientific fact documented by PUBLISHED MEDICAL FINDINGS from the Public Health Laboratory of Finland. This is the most DIRECT, unequivocal MEDICAL DOCUMENTATION of weight loss that can be published (CX3-11, 3-17).

In CX3-11, 3-17 and 3-32, a serious looking, bearded man in a white coat identified as Dr. G. K. Knowlton, stated:

After reviewing all the available European studies, I can say, without a doubt, that cyamopsis tetragonolobus (METABOLITE-2050) is the only product I have seen that has worked for everyone who has used it. . .

For the reasons that I state in this decision, Respondents' weight loss claims - subparagraphs 8(a), (b), and (c) of both Complaints and 8(f) of the Complaint in Docket No. 19/162 - are not supported by the results of scientifically sound scientific studies..

(e) Respondents have accurately reproduced an excerpt from Acta Medica Scandinavia, Vol. 208, pp. 45-48 in certain of its printed advertisements, including Exhibit 1.

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This representation is also false in both Docket Nos. 19/104 and 19/162. The advertisements for Intercal-SX in Docket No. 19/104 read:

But don't take our word for it. The results are medically documented. Published in Acta Medica Scandinavia (Volume 208, pages 45-48), this amazing study was uncovered by a team of U.S. researchers during a computer search of Excerpta Medica and Medicine (2 major medical data bases). What follows is a word for word excerpt from the actual medical abstract..."A highly significant decrease in body weight (62.9 ± 2.1 vs. 60.4 ± 2.2 kg.p - 0.0005, paired comparison) was seen in

subjects receiving cyamopsis tetragonolobus (INTERCAL-SXTM) whereas body weight remained constant in the other two groups. IT IS CONCLUDED THAT THE DAILY INGESTION OF 15MG, OF INTERCAL-SXTM RESULTS IN PERMANENT WEIGHT LOSS..." (CX3-1, 3-8(f), 3-10) [Emphasis added].

The advertisements for Metabolite-2050 in Docket No. 19/162 read:

Actual Excerpt from original Medical Abstract (Published in Vol. 208 of Acta Medica Scandinavica, pages 45-48). "A highly significant decrease in body weight (62.9 + 2.1 vs. 60.4 + 2.2 kg, p - 0.0005, paired comparison) was seen in subjects receiving cyamopsis tetragonolobus (METABOLITE-2050TM), whereas body weight remained constant in the other two groups. IT IS CONCLUDED THAT THE DAILY INGESTION OF 15MG. OF METABOLITE-2050TM RESULTS IN PERMANENT WEIGHT-LOSS..." (CX3-11, 3-17, p. 2, 3-19) Emphasis added.

The excerpt from the quoted report (CX3-59, p. 1) actually reads:

A highly significant decrease in body weight (62.9 + 2.1 vs. 60.4+ 2.2 kg, p - 0.0005 paired comparison) was seen in subjects receiving guar gum, whereas body weight remained constant in the other two groups. It is concluded that the daily ingestion of 15 g of guar gum results in a permanent weight loss. [Emphasis added].

Although most of the language in the report is quoted accurately in Respondents' advertisements, Respondents have substituted "cyamopsis tetragonolobus" and the names of their products for "guar gum." These substitutions render false Respondents' representations

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that "what follows is a word for word excerpt" and that each advertisement is an "actual excerpt." Furthermore, the substitutions convey the false impressions that Respondents' actual products were subjected to the reported test and that the report specifically concluded that the products themselves result in permanent weight loss.

(f) An obese person who takes Metabolite-2050 may reasonably expect to lose weight while continuing to eat all he or she wants (Docket No. 19/162).

This representation is false. As previously stated, to lose weight one must create an energy or calorie deficit so that the body will use stored energy or fat to meet its current energy needs (Tr. 2203, 3134, 3684). Although guar may cause satiety in some individuals, satiety does not necessarily cause overweight people to eat less (Tr. 3381, 4128). Thus Dr. Mendeloff stated, "There are plenty of people who tell you they are full while eating their fourth meal in five hours (Tr. 2889). Clearly a representation to such individuals that they can expect to lose weight while stuffing themselves with food is false. Dr. Wolever expressed this view on cross examination as follows:

Q. Which effect of the product is exaggerated and to what degree by this ad?

A. For instance, the statement "Eat as much as you want and still lose weight, never diet again," that seems to imply that people will be able to stuff themselves with ice cream and chocolate cake and all that sort of stuff and in fact they will be able to eat all the sorts of food that they like which are bad for them and lose weight (Tr. 5555).

Although guar may have weight loss attributes, the evidence is clear that it does not fulfill the exaggerated claims of Respondents' advertisements. Dr. Wolever expressed his disapproval

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of these advertisements. He testified in answer to Mr. Friedlander's questions:

Q. What do you think of the ads in general?

A. These ads?

Q. Yes.

A. I think they're sensational. They go along with the sort of ads that I usually see in the rag-mags for slimming products which generally I don't feel work. And this puts guar into a category, in my mind of material similar to that, which I find offensive, because I feel guar should have more respect than that (Tr. 5427). Dr. Wolever also stated, "Neither can I endorse the advertisements made as they seem to me to be sensational and able to be interpreted such that the effects of the product are exaggerated" (RX3-40, p. 2, Tr. 5553).

The issue is not whether guar has value. It is whether the public is being misled by untrue advertising claims.

As the Supreme Court stated in Leach v. Carlile, 258 U.S. 138, 139 (1922), "it is sufficient to say that the question really decided by the lower courts was, not that the substance which appellant was selling was entirely worthless as a medicine, as to which there were some conflict in the evidence, but that it was so far from being the panacea which he was advertising it through the mails to be, that by so advertising it he was perpetrating a fraud upon the public."

CONCLUSIONS OF LAW

1. Postal Service False Representation Orders do not violate the First Amendment of the Constitution. Donaldson v. Read Magazine, 333 U.S. 178 (1948); Lynch v. Blount, 330 F. Supp. 689

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(S.D.N.Y. 1971); Hollywood House International, Inc. v. Klassen, 508 F.2d 1276 (9th Cir. 1974); and United States Postal Service v. Beamish, 466 F.2d 804 (3d Cir. 1972). In the latter case, the Court held "Advertisers possess no constitutional right to disseminate false or misleading materials. Therefore, Congress has the power to prohibit such deceptions through appropriate legislation." p. 807. See also: Bolger v. Young's Drug Products Corp., 463 U.S. 60 (1983).

2. With the exception of 7770 West Oakland Park Boulevard, Landmark Building, Suite 210, Sunrise, Florida 33321-6729 as an address for W. G. Charles Company in Docket No. 19/104 and for Intra-Medic Formulations, Inc. in Docket No. 19/162, the Corporate Respondents solicit money through the mail in connection with their sales of Intercal-SX and Metabolite-2050 at the addresses listed in the captions of these proceedings.

3. An advertisement must be considered as a whole and its meaning will be determined in the light of its probable effect on persons of ordinary minds. Donaldson v. Read Magazine, Inc., *supra*; Vibra Brush

Corp. v. Schaffer, 152 F. Supp. 461 (S.D.N.Y. 1957). Rev'd on other grounds, 256 F.2d 681 (2d Cir. 1958).

4. The impression of promotional representations on the ordinary mind generally is a question for the judge to determine. Expert testimony on interpretation is not required, but it is within the discretion of the judge to permit such testimony. Vibra Brush Corp. v. Schaffer. The impression of advertising on the ordinary mind may be determined by the trier of fact solely on the basis of the advertising itself. Vibra Brush Corp. v. Schaffer; Delta Enterprises, P.S. 14/72 et al., (P.S.D. July 3, 1984).

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5. Express misrepresentations are not required. It is the net impression that the advertisement as a whole is likely to make upon individuals to whom it is directed that is important. Even if a solicitation is so worded as to not make an express representation, but is artfully designed to mislead those responding to it, the false representation statute is applicable. G. J. Howard Co. v. Cassidy, 162 F. Supp. 568 (E.D.N.Y. 1958); See also, Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, 425 U.S. 748 (1976), quoting United States v. 95 Barrels of Vinegar, 265 U.S. 438, 443 (1924): "It is not difficult to choose statements, designs and devices which will not deceive." In Vibra Brush Corp. v. Schaffer, *supra*, the Court stated:

It is not each separate word or a clause here and there of an advertisement which determines its force, but the totality of its contents and the impression of the entire advertisement upon the general populace. p. 465. Similarly, in American Image Corp. v. United States Postal Service, 370 F. Supp. 964 (S.D.N.Y. 1974) the Court held: "The cases are clear that such advertisements are to be viewed not with a lawyer's eye to 'fine spun distinctions' but with an eye to their over-all effect on the average reader."

6. False representations may also be made in order verification letters and package insert materials since these may be relied upon in connection with reorders. Iso-Tensor Plan, P.S. Docket No. 3/30 (P.S.D. May 23, 1975).

7. Where an advertisement is ambiguous or capable of more than one meaning, if one of those meanings is false, the advertisement will be held to be misleading. Rhodes Pharmacal Co., Inc. v.

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Federal Trade Commission, 208 F.2d 382, 387 (7th Cir. 1953); Ralph J. Galliano, P.S. Docket No. 19/15, (P.S.D. p. 9, May 2, 1985); Bruce Roberts Co., P.O.D. Docket No. 3/78, (I.D., August 16, 1971); Moneymakers et al., P.S. Docket No. 16/1, (I.D., June 20, 1983).

8. Applying the foregoing standards, the average person who reads Respondents' advertisements would interpret them substantially as characterized in paragraphs 8 of the Complaints in Docket Nos. 19/104 and 19/162.

9. As expressed in Chaachou v. American Central Insurance Co., 241 F.2d 889, 893 (5th Cir. 1957), a representation is material if it would "... cause the other party to do other than that which would have been done had the truth been told." Applying the Chaachou test, the representations are material because they have the effect of inducing individuals to remit money through the mail to purchase Intercal-SX and Metabolite-2050.

10. A statement of contents on a product label is presumptive evidence of the product's ingredients.

Sister Fannie Howard, P.S. Docket No. 1/101 (I.D. July 21, 1972). In fact, even in cases of conflicting evidence, ingredients listed on product labels may be relied upon as correct. Carter-Ross Labs, P.S. Docket No. 5/163 (I.D. July 25, 1977); Emil-John Research, P.S. Docket No. 5/162 (I.D. July 21, 1977).

11. Complainant has established through qualified expert testimony that the informed consensus of scientific and medical opinion is that Respondents' representations are false. Where Complainant shows that the representations in issue are not accepted as true by such a consensus, this establishes a prima facie case

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that the representations are false. Cosvetic Laboratories, P.S. Docket No. 8/160 (P.S.D. July 22, 1982). Once Complainant presents a prima facie case of falsity, the burden of going forward with evidence to rebut this showing (though not the burden of proof which always remains with Complainant) moves to Respondents who must adduce evidence either that the consensus does not exist or that the claim of effectiveness is true despite the lack of acceptance by the medical community. Peak Laboratories, Inc. v. United States Postal Service, 556 F. 2nd 1387 (5th Cir. 1977); Frank E. Bush, Inc. v. United States Postal Service, 84 Civ. 8756 (LBS) (S.D.N.Y. 1985); Cosvetic Laboratories, supra. Respondents have failed to rebut Complainant's prima facie case in either of these ways. Accordingly, the representations alleged in subparagraphs 8(a), (b), (c), (d) and (e) in Docket No. 19/104 and 8(a), (b), (c), (d), (e) and (f) in Docket No. 19/162 are materially false as a matter of law.

12. Respondents relied upon Reilly v. Pinkus, 338 U.S. 269 (1949) frequently throughout the hearing (e.g. Tr. 2041-42, 2815-20). Respondents appear to believe that Reilly stands for the proposition that if, in a case brought pursuant to 39 U.S.C. § 3005, Respondent produces evidence tending to show that their products perform as claimed, the Postal Service's case must necessarily fail. Reilly does not change the standard of evidence from a preponderance to some higher standard as Respondents suggest. Reilly's dictum cautioned the Postal Service to avoid crushing new or developing ideas. Reilly did not tell the agency to avoid

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enforcement actions where unproved ideas are promoted as established fact. Reilly stated:

In the science of medicine, as in other sciences, experimentation is the spur of progress. It would amount to condemnation of new ideas without a trial to give the Postmaster General power to condemn new ideas as fraudulent solely because some cling to traditional opinions with unquestioning tenacity P. 274.

The Court in Reilly court was concerned with placing a "limitation upon findings of fraud under the mail statutes when the charges concern medical practices in fields where knowledge has not yet been crystalized in the crucible of experience." Knowledge in the areas of weight loss and fiber has been sufficiently well scrutinized that one may state the consensus with respect to several scientific facts: One cannot lose weight without adjustment of caloric balance. Guar appears to cause satiety in some people but not virtually all people. The reported weight loss with guar alone and no diet regimen is generally not clinically significant. Satiety does not necessarily lead to weight loss. There is evidence, however, that guar assists persons to comply with reduced calorie diets, with resultant weight loss. Had Respondents produced evidence of properly conducted replicated tests showing that their product in tablet or granule form performed as claimed, this case would have been subject to the cautions of the Reilly Court. However, no such "minority school of thought" was established by Respondents' evidence.

13. A promise to refund if a customer is dissatisfied will not dispel the effect of false advertisements. Farley v. Heininger, 105 F.2d 79, 84 (D.C. Cir. 1939); Borg-Johnson Electronics, Inc., v. Christenberry, 169 F. Supp. 746, 751 (S.D.N.Y. 1959).

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14. The Corporate Respondents in this proceeding are conducting a scheme for obtaining money or property through the mails by means of materially false representations within the meaning of 39 U.S. Code § 3005 through their sales of Intercal-SX and Metabolite-2050.

15. Mitchell K. Friedlander formulates, directs and controls the policies of the corporate Respondents. Therefore, it is necessary that Cease and Desist Orders include Mitchell K. Friedlander. Because of the significant involvement of Harris Friedlander and Michael Meade in the business activities of the corporate Respondents, it is necessary that Cease and Desist Orders also include Harris Friedlander and Michael Meade. See: January 28, 1985 Decision and Order on Motion to Dismiss; Federal Trade Commission v. Standard Education Society, 302 U.S. 112 (1937); Benrus Watch Company v. F.T.C., 352 F.2d 313, (8th Cir. 1965).

Accordingly, False Representation Orders and Cease and Desist Orders are issued herewith.

FOR IMMEDIATE RELEASE: August 14, 1985

Tab 91

COURT ISSUES TEMPORARY RESTRAINING ORDER AGAINST
MAIL-ORDER COMPANIES FOR MISREPRESENTING
DIET PRODUCTS AND BALDNESS "CURES"

FTC Alleges Ad Claims Were False

A federal court in Florida yesterday issued a temporary restraining order (TRO) halting four mail-order companies from misrepresenting their weight-control and baldness-cure products. The Federal Trade Commission charged the companies' claims for the products were false and deceptive.

The Commission also asked the court to issue a permanent injunction and to order the companies to pay refunds to consumers. The TRO and FTC complaint name Intra-Medic Formulations Inc. and its wholly owned subsidiaries, The Robertson-Taylor Co. Inc., W.G. Charles Co. Inc. and Connor-Freeman Laboratories Inc. Also named is Mitchell K. Friedlander, allegedly sole shareholder and president of Intra-Medic and a director of all of the companies.

The Commission charged the companies falsely and deceptively represented in ads for their Medi-Tec 90 baldness cure that:

- the product will cure baldness or cause new hair to grow;
- photographs in the ads depict the progressive regrowth of hair by a user of the product; and
- tests verify Medi-Tec 90 is effective in curing baldness and causing new hair to grow.

The Commission also charged that ads for the weight-control products Lipogene GH, Lipogene GHX, Intercal SX, Metabolite 2050 and Anorex CCK falsely and deceptively claimed that:

- the products allow people to lose weight without dieting or exercise; and
- scientific and medical evidence confirms the products are effective for enabling users to lose weight without dieting or exercise.

The companies had no reasonable basis for most of the weight-control or baldness-cure claims, the Commission charged.

The FTC filed the suit in the U.S. District Court for the Southern District of Florida. The companies are based, and Friedlander resides, in Ft. Lauderdale. The FTC's Atlanta Regional Office handled the investigation.

(More)

Copies of the FTC's complaint are available from the FTC's Public Reference Branch, Room 130, 6th St. and Pennsylvania Ave. N.W., Washington, D.C. 20580; 202-523-3598; TTY 202-523-3638. News media copies are available from the Office of Public

Affairs, Room 496, same address; 202-523-1892.

#

MEDIA CONTACT: Susan Ticknor, Office of Public Affairs,
202-523-1892

STAFF CONTACT: Cynthia Smith, Atlanta Regional Office,
404-881-4836

(FTC File No. 832 3154)

(IntraMedic)

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FEDERAL TRADE

002

MAR 03 1986

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

CASE NO. 85-2819-CIV-NESBITT

Tab 92

FEDERAL TRADE COMMISSION,

Plaintiff,

vs.

FINDINGS OF FACT AND
CONCLUSIONS OF LAW

INTRA-MEDIC FORMULATIONS,
INC., THE ROBERTSON-TAYLOR
COMPANY, INC., W.G. CHARLES
COMPANY, INC., and CONNOR-
FREEMAN LABORATORIES, INC.,
corporations, and MITCHELL
K. FRIEDLANDER, individually
and as an officer of the
defendant corporations,

Defendants.

FILED by _____ D.C.
FEB 23 1986
ROBERT M. ...

THIS CAUSE came before this Court for a non-jury trial on January 15, 16, 17, 21, 22 and 23, 1986. The Court, having heard the testimony of the witnesses, having considered the evidence and having made determination of credibility of the witnesses presented, enters the following findings of fact and conclusions of law:

FINDINGS OF FACT

I. NATURE OF THE ACTION

1. This is an action by Federal Trade Commission (FTC) which alleges that Intra-Medic Formulations, Inc., the Robertson-Taylor Company, Inc., W.G. Charles Company, Inc., Connor-Freeman Laboratories, Inc. and Mitchell K. Friedlander, individually (Defendants) have violated Sections 5 and 12 of the

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FEDERAL TRADE

003

Federal Trade Commission Act, 15 U.S.C. §§45(a) and 52, by falsely and deceptively advertising five purported weight loss products and one purported baldness cure.

2. FTC has requested equitable relief: (1) enjoining Defendants from falsely or deceptively advertising any food, drug or cosmetic product, and from making efficacy claims for any such product unless Defendants have two well-controlled double-blinded studies of the product being advertised, demonstrating that the product is efficacious as advertised; and (2) providing consumer redress in the form of restitution for those people who have already purchased one or more of Defendants' products.

II. JURISDICTION AND VENUE

3. The basis for federal jurisdiction is 28 U.S.C. §§1331, 1337, 1345 and 1355, and 15 U.S.C. §§45(a) and 53(b).

4. Venue in the Southern District of Florida is proper under 28 U.S.C. §§1391 and 1395, and 15 U.S.C. §53(b).

III. THE PARTIES

5. Defendant Intra-Medic Formulations, Inc. ("Intra-Medic") is a Florida corporation with its principal office and place of business located at 1110 West Sunrise Boulevard, Fort Lauderdale, Florida 33311. Intra-Medic acts as a holding company for its wholly-owned subsidiaries, including the Robertson-Taylor Company, Inc. ("Robertson-Taylor") The W.G. Charles Company, Inc. ("W.G. Charles") and Connor-Freeman Laboratories, Inc. ("Connor-Freeman"). Intra-Medic and its subsidiaries are engaged in the nationwide advertising and sale

by telephone and mail order of hair care, diet, and other health and beauty preparations. Intra-Medic dominates and controls the acts and practices of Robertson-Taylor, W.G. Charles and Connor-Freeman.

6. Defendant Robertson-Taylor is a wholly-owned subsidiary of Intra-Medic. Robertson-Taylor is a Florida corporation with its principal office and place of business at 1110 West Sunrise Boulevard, Fort Lauderdale, Florida 33311. Among the products advertised and sold by Robertson-Taylor are Medi-Tec 90, a baldness cure preparation, and the weight loss products Lipogene GH, Lipogene GHX, and Metabolite 2050.

7. Defendant W.G. Charles is a wholly-owned subsidiary of Intra-Medic. W.G. Charles is a Florida corporation with its principal office and place of business at 1110 West Sunrise Boulevard, Fort Lauderdale, Florida 33311. W.G. Charles advertises and sells Intercal SX, a diet and weight loss product.

8. Defendant Connor-Freeman is a wholly-owned subsidiary of Intra-Medic. Connor-Freeman is a Florida corporation with its principal office and place of business at 1110 West Sunrise Boulevard, Fort Lauderdale, Florida 33311. Connor-Freeman advertises and sells Anorex-CCK, a diet and weight loss product.

9. At all times relevant herein, Defendants have maintained a substantial course of trade, including the advertising, promoting, offering for sale and sale of food, drugs, devices and cosmetics in or affecting commerce, as "commerce," "food," "drug," and "cosmetic" are defined in the FTC Act, 15 U.S.C. §§41 et seq.

10. Defendant corporations had no operations, staff, financing or system of accounting distinct in any way from each other, other than the products sold by each, or from their parent, Intra-Medic Formulations, Inc.

11. Defendant Mitchell K. Friedlander ("Friedlander") resides within the Southern District of Florida in Fort Lauderdale, Florida. Friedlander is the sole shareholder, President and Director of Intra-Medic and is also the President and Director of Robertson-Taylor, W.G. Charles and Connor-Freeman. At all times relevant herein, Friedlander, individually or in concert with others, has formulated, directed and controlled the policies, acts and practices of Intra-Medic, Robertson-Taylor, W.G. Charles and Connor-Freeman.

12. Each of the corporate Defendants is under the common control and ownership of Mitchell K. Friedlander.

IV. THE WEIGHT LOSS PRODUCTS - LIPOGENE

13. Defendants were advertising and offering for sale or distribution Lipogene GH as of October 21, 1983 and Lipogene GHX as of May 29, 1984.

14. In their advertisements, Defendants made certain representations about Lipogene GHX and Lipogene GH regarding the efficacy of these products.

15. Defendants' advertisements represent directly and by implication that Lipogene GHX and Lipogene GH enable any person to lose weight without exercising or restricting calorie intake, and consumers could reasonably interpret the advertisements as making that representation.

16. Defendants' advertisements represent directly and by implication that scientific and medical evidence confirms the effectiveness of Lipogene GHX and Lipogene GH in enabling any person to lose weight without exercising or restricting caloric intake, and consumers could reasonably interpret the advertisements as making that representation.

17. These representations by the Defendants regarding Lipogene GHX and Lipogene GH are material.

18. At the time they began advertising Lipogene GHX and Lipogene GH, Defendants had not consulted with any medical or scientific experts to determine whether or not the claims they planned to make about the product in their advertising were true. Nor had Defendants conducted or authorized anyone else to conduct tests as to whether the products were efficacious as advertised.

19. At the time they began advertising Lipogene GHX and Lipogene GH, Defendants knew of no study in which those products or their constituent ingredients had been tested and shown to produce weight loss or a slimming effect in humans or animals.

19. At some time after Defendants began advertising Lipogene GHX and Lipogene GH, they compiled a group of articles that purportedly substantiated the claims of efficacy that Defendants were making about Lipogene GHX and Lipogene GH.

21. Dr. Merimee testified as an expert witness that neither the articles compiled by the Defendants, nor the general body of literature on growth hormone supports the efficacy claims in Defendants' advertisements for the Lipogene products.

22. Dr. Stephen Woods testified for the Defendants as an expert in the area of peptides and their role in food intake. Dr. Woods has had extremely limited experience working with humans in clinical investigations and has never been involved in measuring growth hormone levels in humans.

23. Defendants could not have relied on Dr. Woods' opinion to develop efficacy claims about Lipogene GHX and Lipogene GH because they elicited his opinion long after they began advertising the products.

24. Dr. Woods' opinion that Lipogene GHX and Lipogene GH might cause a "fat-burning" effect is wholly theoretical.

25. Even Dr. Woods expressed doubt that Lipogene GHX and Lipogene GH would cause actual weight loss because, assuming his theory of fat-burning was true, fat would be replaced by muscle, muscle weighs more than fat, and the person might have a net weight gain.

26. Dr. Woods based his belief that Lipogene GHX and Lipogene GH should work in theory on two scientific studies and one review of medical literature. The first study relied on by Dr. Woods purportedly showed that when 15-20 year-old males ingested the ingredients contained in Lipogene GHX and Lipogene GH, their growth hormone levels rose dramatically.

27. Dr. Merimee testified that this study was seriously flawed and would be regarded as worthless by any person with experience in the growth hormone field. In Dr. Merimee's own studies in which he gave these same amino acids to humans by an oral route, no significant rise in growth hormone was seen.

28. The second study relied upon by Dr. Woods examined the reactions of genetically obese mice to intravenous infusion of arginine and determined that genetically obese mice gained weight more slowly than did lean mice; the study did not show a weight loss in either set of mice.

29. Because of special traits of rodents, results obtained from studies involving mice injected with arginine and measures for growth hormone reaction are not likely to be analogous to results obtained in humans.

30. While Dr. Woods was permitted to give expert testimony about clinical research and growth hormone, because of his limited practical experience in both these areas, particularly when viewed in comparison to the clinical experience with growth hormone of Dr. Thomas Merimee, that testimony is not as authoritative as the testimony of Dr. Merimee on the subjects of clinical weight loss studies and growth hormone.

31. Dr. Merimee testified that neither Lipogene GHX nor Lipogene GH will dissolve excess fat, cause a person to lose weight while sleeping, or cause a person to lose weight without exercising or restricting caloric intake.

32. Both Drs. Merimee and Wood testified that, to date, no studies exist that demonstrate that Lipogene GHX or Lipogene GH will produce weight loss or a slimming effect in humans or animals.

33. Defendants have never had a reasonable basis for making the efficacy claims contained in their Lipogene GHX and Lipogene

GH advertisements, nor for making representations that scientific or medical evidence confirmed that Lipogene GHX or Lipogene GH were efficacious as advertised.

34. The efficacy claims made by Defendants in their advertisements for Lipogene GHX and Lipogene GH are materially misleading and false.

35. Defendants' representations, that medical and scientific evidence proves that Lipogene GHX and Lipogene GH are efficacious as advertised, are materially misleading and false.

V. THE WEIGHT LOSS PRODUCTS - ANOREX-CCK

36. Anorex-CCK is taken orally in tablet form and contains 350 mg. of bovine tissue extract, and approximately 210 mg. of carboxymethylcellulose, 210 mg. of guar gum, 210 mg. of vegetable bran and 10 mg. of caffeine per oral tablet.

37. Defendants began advertising Anorex-CCK in September 1984 and were still advertising it on December 30, 1984.

38. The Defendants' advertisements made certain representations as to the efficacy of Anorex-CCK.

39. Advertisements for Anorex-CCK also contain purported testimonials "about the awesome weight loss power of Anorex-CCK" attributed to "satisfied customers" but do not disclose that each testimonial was written by an employee or an accountant of Defendants.

40. Defendants' advertisements represent directly and by implication that Anorex-CCK enables any person to lose weight

without exercising or restricting caloric intake, and consumers could reasonably interpret the advertisements as making that representation.

41. Defendants' advertisements represent directly and by implication that scientific and medical evidence confirms the effectiveness of Anorex-CCK in enabling any person to lose weight without exercising or restricting caloric intake, and consumers could reasonably interpret the advertisements as making that representation.

42. The representations made in Defendants' advertising, that Anorex-CCK will enable any person to lose weight without exercising or restricting caloric intake, and that medical and scientific evidence confirms that Anorex-CCK will enable any person to lose weight without exercising or restricting caloric intake, are material.

43. In the fall of 1984, the Defendant prepared a list of references to medical literature concerning CCK that was intended, along with a study done by a company called Gen Trac, Inc. ("Gen Trac study"), to be substantiation for Defendants' weight loss claims concerning Anorex-CCK.

44. The Gen Trac study is not a well-controlled clinical investigation in that the study suffers from serious flaws in research design that make its results unreliable. Specifically, subjects were not randomly assigned, investigators were not blinded and investigators had a financial stake in the outcome of the study.

45. At the time they began advertising Anorex-CCK, Defendants had consulted the Gen Trac investigators and Dr. James Gibbs about the product. Dr. Gibbs told Defendants at that time that he had some concerns about the safety and efficacy of the product.

46. At some later time, while Defendants were advertising and selling Anorex, Dr. Gibbs provided at Defendants' request a more comprehensive opinion in which he voiced five major concerns, namely that: he did not believe CCK would work when administered orally; he believed there might not be CCK in the product; he lacked confidence in the Gen Trac study because it did not have adequate controls, and because it had not been publicly scrutinized or replicated; he thought certain advertising claims were untrue; and he was worried that the product might not be safe.

47. Dr. Gibbs, in explaining his doubts about Defendants' products, directed Defendant Friedlander to an article written by West and Woods (Defendants' expert) in which the researchers found that, although the individual meal sizes of laboratory animals decreased when they were injected with CCK prior to every feeding, the animals' overall daily food intake remained constant because the animals compensated by eating more frequent meals. Defendant Friedlander read that article.

48. There is no published research to support the advertised claim that "Laboratory Animals Injected With CCK Literally Starved Themselves To Death!"

49. Dr. Gibbs authored a research paper (American Journal of Clinical Nutrition, May 30, 1977 pp. 758-761) cited by Defendants in their advertisement as concluding that "the awesome weight loss powers of CCK are dose dependent;" according to Dr. Gibbs, however, the paper cited did not consider and drew no conclusions about weight loss effects either of CCK itself or the product, Anorex.

50. Defendants' advertisements for Anorex-CCK attribute the purported weight loss properties of the product to a substance called "cholecystokinin," which is abbreviated "CCK." CCK is referred to over 10 times in each of the advertisements for Anorex-CCK.

51. There is no published research that attributes weight loss to orally administered CCK. The purported weight loss properties of Anorex-CCK cannot be attributed to cholecystokinin.

52. The medical literature referenced by Defendants and the study done by Gen Trac do not constitute a reasonable basis for the weight loss claims made by Defendants.

53. Defendants have never had a reasonable basis for making the efficacy claims contained in their Anorex-CCK advertisements, nor for making representations that scientific or medical evidence confirmed that Anorex-CCK was efficacious as advertised.

54. Defendants' advertising claims, that Anorex-CCK enables any person to lose weight without exercising or restricting calorie intake, are materially misleading and false.

55. Defendants' representations that scientific and medical evidence confirms that Anorex-CCK is efficacious as advertised, are materially misleading and false.

VI. THE WEIGHT LOSS PRODUCTS - METABOLITE 2050 AND INTERCAL SX

56. Metabolite 2050 and Intercal SX ("Intercal") each contain 750 mg of guar gum per oral tablet, with a recommended daily consumption of guar gum being 15 g. per day. Metabolite and Intercal are identical products.

57. Defendants began advertising Metabolite 2050 in the early fall of 1983 and Intercal at some point subsequent to September, 1983.

58. In their advertisements, Defendants have made certain representations about ~~Metabolite 2050~~ and Intercal SX regarding the efficacy of these products.

59. Defendants' advertisements represent directly and by implication that Metabolite 2050 and Intercal enable any person to lose weight without exercising or restricting calorie intake, and consumers could reasonably interpret the advertisements as making that representation.

60. Defendants' advertisements represent directly and by implication that scientific and medical evidence confirms the effectiveness of Metabolite 2050 and Intercal in enabling any person to lose weight without exercising or restricting caloric intake, and consumers could reasonably interpret the advertisements as making that representation.

61. The representations made in Defendants' advertisements, that Metabolite 2050 and Intercal would enable any person to lose weight without exercising or restricting caloric intake, and that scientific and medical evidence confirms the effectiveness of Metabolite 2050 and Intercal in enabling any person to lose weight without exercising or restricting caloric intake, are material.

62. At the time they began advertising Metabolite 2050 and Intercal, Defendants had not consulted with any medical or scientific experts or conducted tests to determine whether or not the claims they were to make about the products in their advertising were true.

63. Medical studies that Defendant Friedlander had seen prior to publishing his advertisements did not show that 100% of Metabolite 2050 users, Intercal users, or guar users, had lost weight.

64. In the spring of 1984, some time after Defendants began advertising Metabolite 2050, they compiled a list of references to medical articles that purportedly substantiated the claims of efficacy that Defendants were making about their guar products; these articles were reviewed by Dr. Albert Mendeloff.

65. Neither the references compiled by Defendants, nor the general body of literature on guar, support the efficacy claims made by Defendants about Metabolite 2050 or Intercal in their advertising.

66. Defendants have never had a reasonable basis for making the efficacy claims contained in their Metabolite and Intercal advertisements, nor for making representations that scientific or medical evidence confirmed that Metabolite or Intercal were efficacious as advertised.

67. The efficacy claims made by Defendants in their advertisements for Metabolite 2050 and Intercal are materially misleading and false.

68. Defendants' representations, that medical and scientific evidence confirms that Metabolite 2050 and Intercal are efficacious as advertised, are materially misleading and false.

VII. THE BALDNESS CURE PRODUCT: MEDI-TEC 90

69. From approximately December, 1981 until October, 1985, Defendants made certain representations regarding the efficacy of their baldness cure product, Medi-Tec 90.

70. Defendants' advertisements represent directly and by implication that Medi-Tec 90 will cure baldness and cause new hair to grow on a balding scalp and consumers could reasonably interpret them as making those representations.

71. Defendants' advertisements represent directly and by implication that scientific evidence confirms that Medi-Tec 90 will cure baldness and cause new hair to grow on a balding scalp.

72. The representations made in Defendants' advertising, that Medi-Tec 90 will cure baldness and cause new hair to grow on

a balding scalp and that scientific evidence confirms that Medi-Tec 90 will cure baldness and cause new hair to grow on a balding scalp, are material.

73. On February 7, 1984, Defendants identified two studies dated 1974 and 1978 by Kai Setala, M.D., and Illona Schreck-Purola, M.D. of Finland as all documents relied upon to support claims that Medi-Tec regrows hair on a balding scalp.

74. The 1974 and 1978 studies of Doctors Setala and Schreck-Purola are not well-controlled, clinical investigations in that the studies suffer from serious flaws in research design, including the following: the researchers were not blinded in either study; there were no control groups in either study; neither study reports the results of individual subjects to allow independent evaluation; and, in the 1978 study, 11 out of 24 subjects were excluded from the reported results without adequate explanation.

75. The 1974 and 1978 studies of Doctors Setala and Schreck-Purola do not constitute a reasonable basis for the Medi-Tec 90 advertising claims.

76. Defendants have identified polysorbate 60 or 80, niacin and biotin as all of the ingredients that contribute to the purported efficacy of Medi-Tec 90.

77. There is no evidence in the published medical literature that topically applied polysorbate, niacin, or biotin is efficacious for the treatment of baldness.

78. Defendants have never had a reasonable basis for making the efficacy claims contained in their Medi-Tec 90 advertisements, nor for making representations that scientific or medical evidence confirmed that Medi-Tec 90 was efficacious as advertised.

79. Defendants' representations that Medi-Tec 90 will cure baldness or cause new hair to grow on a balding scalp are materially misleading and false.

80. Defendants' representations that scientific evidence confirms that Medi-Tec 90 will cure baldness or cause new hair to grow on a balding scalp are materially misleading and false.

VIII. FRAUD

81. Defendant Friedlander was responsible for drafting and approving the final version of all advertisements used by the corporate Defendants in the sale of the products at issue in the case.

82. Beth Zuckerkorn, an employee of Defendants, worked closely with Defendant Friedlander and got his approval on every advertisement before placing it for publication.

83. Defendants included in their advertisements for Metabolite 2050 "before-and-after" pictures and a testimonial of Randee Nadler, despite the fact that Beth Zuckerkorn knew Randee Nadler had not lost the weight shown in the advertisement from taking Metabolite and that Ms. Zuckerkorn had fabricated the testimonial.

84. Defendants used photographs of Albert Donato in advertisements for Medi-Tec 90, knowing that the photographs were all taken on the same day, and yet representing in the advertisements that the photographs depicted the progressive regrowth of hair due to Medi-Tec 90.

85. Defendants used photographs of Sal Santangelo in advertisements for Medi-Tec 90, knowing that at least two of the photographs were taken by their photographer on a single night in a photography studio, with Defendant Friedlander supervising the application of black dye to Mr. Santangelo's scalp in stages to make it appear as if his hair was regrowing, and yet representing in the advertisements that, "The photos shown are not studio photos. They were taken by an actual client at home. The poor reproduction on this page is due to that fact."

86. Defendants, through their employed consultant Louis Rinaldi, solicited the opinion of Dr. Jack Hegenauer about the product Metabolite 2050 and were told by Dr. Hegenauer that he believed many of the statements made in their Metabolite advertisements were false or misleading, including claims that the product was "fast acting," that it "eliminated dieting, calorie counting and strenuous exercise," that it caused "dramatic and permanent weight loss," that it caused "large amounts" of weight loss, and that "scientific documentation has confirmed that everyone...who used Metabolite 2050 formulation lost weight."

87. Defendant Friedlander read but then otherwise ignored Dr. Hegenauer's critique of the Metabolite advertisement copy and told Louis Rinaldi to do the same.

88. Defendant Friedlander was fully aware prior to marketing Medi-Tec 90 that Dr. Henry Earl Jones, a dermatologist and Chairman of the Department of Dermatology at Emory University School of Medicine, had been consulted by Louis Rinaldi about the adequacy of the 1974 study of Doctors Setala and Schreck-Puroola and had been told by Dr. Jones in 1978 and 1979 that the study was too seriously flawed to support any efficacy claims that might be made for the hair regrowth product.

89. Each of the testimonials listed in the Anorex-CCK advertisements was written by an employee or agent of Defendants. The fact of their connection to Defendants is not disclosed in the advertisements nor is the fact mentioned that three of the addresses given in the advertisement (showing them to be from places all across the United States) were birth places rather than the present Florida address of each of those persons.

90. Defendants represented in advertisements for Anorex-CCK that N. J. Lester was "Chief CCK Researcher, A.R.C. Research Center" and used Mr. Lester's testimonial in the advertisement, never mentioning that Mr. Lester was Defendants' employee or that he had no science background.

91. Defendants included a testimonial in advertisements for Metabolite 2050 attributed to Dr. G. K. Knowlton, in which he asserts that, after reviewing all the available European studies,

he could not see any way that Metabolite 2050 could fail, but not mentioning that Dr. Knowlton was a chiropractor, and not a doctor of medicine.

92. Throughout some period of time during which Medi-Tec 90 was being advertised and sold, customers could only obtain a refund within 30 days after purchasing the product although Defendants stressed that it would take anywhere between 2 and 6 weeks to see hair regrowth.

93. Despite the representations made in Defendants' advertisements that Lipogene GH and Metabolite 2050 would enable any person to lose weight automatically, Defendants had specific form letters on their computer to send to people telling them that the product did not work for everyone because of "metabolic individuality." Thus, Defendants were fully aware that their claims for these products were false.

94. Defendants knew that customers were not successfully losing weight when using Lipogene GH and Metabolite 2050 yet continued to advertise the products as causing automatic, infallible weight loss.

95. Defendants either intentionally misrepresented, recklessly disregarded the truth, or intentionally avoided the truth while having an awareness of a high probability of fraud when making claims of efficacy and of scientific confirmation of efficacy of the products at issue in this lawsuit.

96. Defendants fraudulently misrepresented each of the products at issue in this lawsuit.

CONCLUSIONS OF LAW

1. The District Court for the Southern District of Florida has jurisdiction over this matter pursuant to 28 U.S.C. §§1331, 1337, 1345 and 1355 and 15 U.S.C. §§45(a) and 53(b).
2. Venue in this District is proper under 28 U.S.C. §§1391 and 1395, and 15 U.S.C. §53(b).
3. Defendants' advertising, promoting, offering for sale, and sale of Medi-Tec 90, Lipogene GH, Lipogene GHX, Metabolite 2050, Intercal SX, and Anorex-CCK ("the six products") have been in and affecting commerce as "commerce" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. §44. See FTC v. Simeon Management Corp., 532 F.2d 708, 711 (9th Cir. 1976).
4. Each of the six products at issue in this suit is a food, drug or cosmetic as these terms are defined in Section 15 of the FTC Act, 15 U.S.C. §§55(b), (c) and (e).
5. Defendants' advertisements for each of the six products were for the purpose of inducing or likely to induce the purchase of those products as required by Section 12 of the FTC Act, 15 U.S.C. §52.
6. With regard to each of the six products, Defendants lacked a reasonable basis for making the claims of effectiveness that appear in their advertisements at the time those advertisements were published. Moreover, the claims of effectiveness made in the advertisements are false.
7. Lack of a reasonable basis for advertising claims and falsity of advertising claims are independent legal theories, either one of which is sufficient for a determination that

Defendants' advertisements are misleading. FTC v. Pharmtech Research, Inc., 575 F.Supp. 294; National Dynamic Corp., 82 F.T.C. 488, 550 n. 10 (1973), aff'd in part, remanded on other grounds, 492 F.2d 1333 (2d Cir.), cert. denied 419 U.S. 993 (1974); Thompson Medical Co., 3 Trade Reg.Rep. (CCH) ¶ 22,214 at 23,160 (November 23, 1984), appeal pending, No.85-1047 (D.C. Cir., pet for review filed 1/18/85).

8. Defendants' advertisements for each of the six products are misleading in a material way and are "false advertisements," as defined by Section 15(a) of the FTC Act, 15 U.S.C. §55(A).

9. A violation of Section 12 of the FTC Act, 15 U.S.C. §52, is defined by statute also to be a violation of Section 5 of the FTC Act, 15 U.S.C. §45(a).

10. Defendants' advertisements violate Section 5 of the FTC Act, 15 U.S.C. §45(a). See International Harvester Company, 14 F.T.C. 949, 1056 (1984).

11. Defendants' advertisements for the six products are false and deceptive and violative of Sections 5 and 12 of the FTC Act, 15 U.S.C. §§45(a) and 52.

12. This Court is authorized by Section 13(b) of the FTC Act, 15 U.S.C. §53(b), to enjoin Defendants permanently from violating the Act.

13. Defendant Friedlander has engaged in wide-scale deception and fraud, using Defendant corporations as vehicles for that deception and fraud, and making him individually liable for all of the violations enumerated herein.

14. Defendant Friedlander and each of the corporate Defendants are jointly and severally liable for the violations of Sections 5 and 12 of the FTC Act, 15 U.S.C. §§45 and 52. FTC v. Kitco of Nevada, Inc., 612 F.Supp. 1282, 1292 (D. Minn. 985); FTC v. H. N. Singer Inc., 1982-83 Trade Cas. (CCH) ¶ 65,01 at 70,618-19 (N.D. Cal. 1982); FTC v. International Diamond Corp., 1983-2 Trade Cas. (CCH) ¶ 65,725 at 69,707-08 (N.D. Cal. 1983).

15. There is a reasonable likelihood of future violations of the FTC Act by Defendants, which justifies the imposition of the injunctive relief sought by Plaintiff against each of the Defendants, corporate and individual. United States v. W. T. Grant Co., 345 U.S. 629, 633 (1953); CFTC v. Hunt, 591 F.2d 1211, 1220 (7th Cir.), cert. denied, 438 U.S. 905 (1978); SEC v. Manor Nursing Centers, Inc., 458 F.2d 1082, 1100-02 (2d Cir. 1972).

16. The Court, exercising its discretion, declines to award consumer redress in this cause.

DONE AND ORDERED at Miami, Dade County, Florida this 28^B day of February, 1986.



LENORE C. NESSITT
U.S. DISTRICT JUDGE

cc: Chris Coulliou, Esq.
Amy Gershenfeld Donnellio, Esq.
Mitchell Friedlander

08/09/03 TUE 10:33 FAX 202 328 3585

FEDERAL TRADE

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FEDERAL TRADE COMMISSION,
Plaintiff,

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

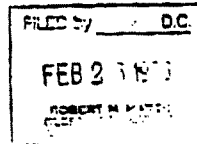
CASE NO. 85-2819-Civ-Nesbitt

vs.

INTRA-MEDIC FORMULATIONS,
INC., THE ROBERTSON-TAYLOR
COMPANY, INC., W.G. CHARLES
COMPANY, INC., and CONNOR-
FREEMAN LABORATORIES, INC.,
corporations, and MITCHELL
K. FRIEDLANDER, individually
and as an officer of the
defendant corporations,

FINAL JUDGMENT

Defendants.



THIS CAUSE came before the Court for non-jury trial on January 15, ~~16, 17,~~ 21, 22 and 23, 1986, and the Court having entered Findings of Fact and Conclusions of Law on this matter, in accordance with those Findings of Fact and Conclusions of Law, it is hereby

ORDERED AND ADJUDGED that pursuant to Section 13(b) of the FTC Act, 15 U.S.C. 53(b), Mitchell K. Friedlander, individually and as an officer of the defendant corporations, Intra-Medic Formulations, Inc., The Robertson-Taylor Company, inc., W.G. Charles, Company, Inc., and Connor-Freeman Laboratories, Inc., their employees, agents, representatives, and all those acting in concert with them in connection with the advertising, marketing or selling, are presently and hereafter enjoined from disseminating or causing to be disseminated in or affecting commerce, directly or through any device, any representation or misrepresentation, directly or by implication,

(1) that the use of Lipogene GH, Lipogene GHX, Intercal SX,

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FEDERAL TRADE

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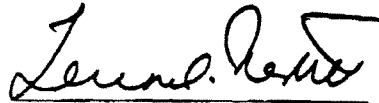
Metabolite 2050, Anorex-CCK or any other product will enable any person to lose weight without exercising or restricting caloric intake;

(2) that scientific and/or medical evidence confirms the effectiveness of Lipogene GN, Lipogene GHX, Metabolite 2050, Intercal SX, Anorex-CCK or any other product for enabling a person to lose weight without exercising or restricting caloric intake;

(3) that the use of Medi-Tec 90 or any other product will cure baldness or cause new hair to grow;

(4) that tests verify the effectiveness of Medi-Tec 90 or any other product for curing baldness or causing new hair to grow.

DONE AND ORDERED at Miami, Dade County, Florida this 28
day of February, 1986.



LENORE C. NESBITT
U.S. DISTRICT JUDGE

cc: Chris Coulliou, Esq.
Amy Gershenfeld Donella, Esq.
Mitchell K. Friedlander

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

| | |
|-----------------------------------|---|
| <hr/> | |
| In the Matter of |) |
| |) |
| DYNAMIC HEALTH OF FLORIDA, LLC, |) |
| CHHABRA GROUP, LLC, |) |
| DBS LABORATORIES, LLC, |) |
| limited liability companies, |) |
| VINEET K. CHHABRA, |) |
| a/k/a VINCENT K. CHHABRA |) |
| individually and as an officer of |) |
| Dynamic Health of Florida, LLC, |) |
| and Chhabra Group, LLC, and |) |
| |) |
| JONATHAN BARASH, |) |
| individually and as an officer of |) |
| DBS Laboratories, LLC. |) |
| <hr/> | |

Tab 93

DOCKET NO.

COMPLAINT

The Federal Trade Commission, having reason to believe that Dynamic Health of Florida, LLC, Chhabra Group, LLC, DBS Laboratories, LLC, Vineet K. Chhabra a/k/a Vincent K. Chhabra, and Jonathan Barash (collectively, "respondents"), have violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent Dynamic Health of Florida, LLC ("Dynamic Health") is a Florida limited liability company with offices located at 1455 North Park Dr., Weston, Florida.
2. Respondent Chhabra Group, LLC ("Chhabra Group") is a Florida limited liability company located at 1455 North Park Dr., Weston, Florida.
3. Respondent DBS Laboratories, LLC ("DBS Laboratories") is a Florida limited liability company with offices located at 1485 North Park Dr., Weston, Florida.
4. Respondent Vineet K. Chhabra a/k/a Vincent K. Chhabra is an officer of Dynamic Health and Chhabra Group. Individually, or in concert with others, he has formulated, directed, participated in, or controlled the acts or practices of Dynamic Health and Chhabra Group, including the acts and practices alleged in this complaint. His principal office or place of

business is 1455 North Park Dr., Weston, Florida.

5. Respondent Jonathan Barash is an owner and officer of DBS Laboratories, LLC and has participated in its day to day operations. Individually, or in concert with others, he has formulated, directed, participated in, or controlled the acts or practices of DBS Laboratories LLC, including the acts or practices challenged in the complaint. His principal office or place of business is 6599 NW 97th Drive, Parkland, Florida 33076.

6. Respondents have advertised, labeled, offered for sale, sold, and distributed products to the public, including Pedia Loss, a weight loss supplement, and Fabulously Feminine, a female sexual enhancement supplement. Pedia Loss and Fabulously Feminine are either a "food" or a "drug" within the meaning of Sections 12 and 15 of the Federal Trade Commission Act, 15 U.S.C. §§ 52 and 55.

7. The acts and practices of respondents alleged in this complaint have been in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act.

PEDIA LOSS

8. Respondents have disseminated or caused to be disseminated advertisements for Pedia Loss through various Internet websites, including www.pediafloss.com, www.dynamichealthproducts.com, and www.dbslabs.com, as well as print advertising in Cosmopolitan magazine. According to the product labels, Pedia Loss contains, among other ingredients, fructose, inulin, glutamine, lecithin, citric acid, and hydroxycitric acid (HCA). Advertisements for Pedia Loss products include, but are not necessarily limited to, the attached Exhibits A through C. The advertisements contain the following statements, among others:

a. **Pedia Loss**

* * *

Child obesity is a growing problem in North America. Pedia Loss is an appetite suppressant for children 6 years and older. Allow children to enjoy their favorite foods without gaining weight. This revolutionary new formula slows the absorption of carbohydrates, allowing more to be burned for energy and less to be stored as fat. This highly effective and natural dietary supplement comes in berry-flavored chewable tablets for easy consumption. In conjunction with a proper diet and exercise program, Pedia Loss can keep your child from becoming a statistic.

Please consult your healthcare provider before giving Pedia Loss to your child.

* * *

This synergistic formula was designed to aide in a child's glucose metabolism. Since many of their favorite foods are rich in carbohydrates but very low in dietary fiber, their digestive tracts and insulin never function properly. Now with Pedia Loss children can still enjoy their favorite food but with the help of Inulin their bodies with [sic] slow down the absorption of carbohydrate, allowing more to be burned for energy and less to be stored as fat, and give a great source of soluble fiber. In addition to this highly advanced ingredient, we have included supplemental amounts of both glutamine and FOS, which have both been proven to drastically improve intestinal health. Finally this product contains a highly effective compound called HCA. This compound has been shown to safely burn fat without any form of stimulants.

(Exhibit A: web page from www.dynamichealthproducts.com)

b. Pedia Loss is highly effective for children 6 years of age and older. Children can still enjoy their favorite food in moderation while slowing the absorption of carbohydrates, allowing more to be burned for energy and less to be stored as fat. For best results use in conjunction with an exercise program and a low fat low calorie diet. Please consult your healthcare provider before giving this product for your child.

(Exhibit B: product label)

c. **Child Obesity**

an american [sic] reality

According to the Centers for Disease Control and Prevention, childhood obesity is a growing problem in the U.S., with one in ten pre-schoolers considered clinically obese. Pedia Loss addresses this growing health care issue in children 6 years of age and older. Children can still enjoy their favorite foods in moderation, while slowing the absorption of carbohydrates. The use of Pedia Loss enables more carbs to be burned for energy and less to be stored as fat. This highly effective and natural dietary supplement comes in berry-flavored chewable tablets that will appeal to children. Best of all is the feeling of strength and confidence they'll

experience by overcoming childhood weight problems. . . .

(Exhibit C: ad in Cosmopolitan Magazine)

9. Through the means described in Paragraph 8, respondents have represented, expressly or by implication, that:

- a. Pedia Loss causes weight loss in overweight or obese children ages 6 and over, and
- b. When taken by overweight or obese children ages 6 and over, Pedia Loss causes weight loss by suppressing appetite, increasing fat burning, and slowing carbohydrate absorption.

10. Through the means described in Paragraph 8, respondents have represented, expressly or by implication, that they possessed and relied upon a reasonable basis that substantiated the representations set forth in Paragraph 9, at the time the representations were made.

11. In truth and in fact, respondents did not possess and rely upon a reasonable basis that substantiated the representations set forth in Paragraph 9, at the time the representations were made. Therefore, the representation set forth in Paragraph 10 was, and is, false or misleading.

FABULOUSLY FEMININE

12. Respondents have disseminated or caused to be disseminated advertisements for Fabulously Feminine through various Internet websites, including www.usaprescription.com, www.dbslabs.com, and www.medprescribe.com, as well as print ads in various newspaper publications. According to the product labels, Fabulously Feminine contains L-arginine, ginseng, damiana leaf, ginkgo biloba leaf, and horny goat weed, among other ingredients. Advertisements for Fabulously Feminine products include, but are not necessarily limited to, the attached Exhibits D through F. The advertisements contain the following statements, among others:

- a. **Fabulously Feminine**
Do you crave more from sexual intimacy? Rev up your sex drive with FABULOUSLY FEMININE. All-natural FABULOUSLY FEMININE can help you build the stamina you need to make your sexual experiences more intense and lasting. . . It's all a matter of stimulating blood flow and increasing sensitivity, and FABULOUSLY FEMININE'S herbal and amino acid formula accomplishes this naturally, yet powerfully. . . .

* * *

PRODUCT INFORMATION

Fabulously Feminine is a safe, natural way to enhance sexual desire, satisfaction and enjoyment. The ingredients in Fabulously Feminine, when taken daily with a multivitamin, have been shown in a double-blind, placebo-controlled Stanford University study to enhance satisfaction with sex life, the level of sexual desire and frequency of sexual encounters.

It is estimated that 43% of women experience a loss of sexualvitality at some time in their lives. External factors such as stress and fatigue may contribute to the decline in sexual interest. .

(Exhibit D : web page from
www.usaprescription.com)

b. It is not unusual for men and women, young or old, to lose desire, arousal and overall satisfaction in the bedroom. Let **DBS Laboratories** give you the fuel you need to re-kindle the fire inside you.

LIBIDO ENHANCER
**FABULOUSLY
FEMININE**
Dietary Supplement

Millions of women are dealing with the same issues you are. Put your confidence and your relationship in the hands of **Fabulously Feminine** – The safe, natural way to enhance sexual desire, satisfaction and enjoyment. A special libido enhancing formula designed specifically for women, **Fabulously Feminine** contains a proprietary blend of traditional libido enhancing herbs. Not being in the mood for sex is often times the result of poor stimulation; lack of energy, and hormonal imbalance. This product was specially formulated to address these issues. These all-natural ingredients are known to stimulate blood flow and increase sensitivity, making this product one of the most potent available on the market.

(Exhibit E: National Examiner
newspaper ad)

c. LIBIDO ENHANCER
FABULOUSLY™
FEMININE
Dietary Supplement
* * *

A scientific formula designed especially for women, **Fabulously Feminine** contains a proprietary blend of clinically proven ingredients for libido health. Not being in the mood for sex is oftentimes the result of poor stimulation, lack of energy, and hormonal imbalance. This product has been formulated to address these issues. . . .

(Exhibit F: National Enquirer newspaper ad)

13. Through the means described in Paragraph 12, respondents have represented, expressly or by implication, that clinical testing proves that Fabulously Feminine enhances a woman's satisfaction with her sex life and level of sexual desire.

14. In truth and in fact, clinical testing does not prove that Fabulously Feminine enhances a woman's satisfaction with her sex life and level of sexual desire. Therefore, the representation set forth in Paragraph 13 was, and is, false or misleading.

15. Through the means described in Paragraph 12, respondents have represented, expressly or by implication, that Fabulously Feminine will increase a woman's libido, sexual desire, and sexual satisfaction by stimulating blood flow and increasing sensitivity.

16. Through the means described in Paragraph 12, respondents have represented, expressly or by implication, that they possessed and relied upon a reasonable basis that substantiated the representation set forth in Paragraph 15, at the time the representation was made.

17. In truth and in fact, respondents did not possess and rely upon a reasonable basis that substantiated the representation set forth in Paragraph 15, at the time the representation was made. Therefore, the representation set forth in Paragraph 16 was, and is, false or misleading.

18. The acts and practices of respondents as alleged in this complaint constitute unfair or deceptive acts or practices in or affecting commerce in violation of Sections 5(a) and 12 of the Federal Trade Commission Act.

NOTICE

Proceedings on the charges asserted against Dynamic Health of Florida, LLC, Chhabra

Group, LLC, DBS Laboratories, LLC, limited liability companies, and Vineet K. Chhabra a/k/a Vincent K. Chhabra in this complaint will be held before an Administrative Law Judge (ALJ) of the Federal Trade Commission, under Part 3 of the Commission's Rules of Practice, 16 C.F.R. Part 3. A copy of Part 3 of the Rules is enclosed with this complaint.

You may file an answer to this complaint. Any such answer must be filed within 20 days after service of the complaint on you. If you contest the complaint's allegations of fact, your answer must concisely state the facts constituting each ground of defense, and must specifically admit, deny, explain, or disclaim knowledge of each fact alleged in the complaint. You will be deemed to have admitted any allegations of the complaint that you do not so answer.

If you elect not to contest the allegations of fact set forth in the complaint, your answer shall state that you admit all of the material allegations to be true. Such an answer will constitute a waiver of hearings as to the facts alleged in the complaint and, together with the complaint, will provide a record basis on which the ALJ will file an initial decision containing appropriate findings and conclusions and an appropriate order disposing of the proceeding. Such an answer may, however, reserve the right to submit proposed findings and conclusions and the right to appeal the initial decision to the Commission under Section 3.52 of the Commission's Rules of Practice.

If you do not answer within the specified time, you waive your right to appear and contest the allegations of the complaint. The ALJ is then authorized, without further notice to you, to find that the facts are as alleged in the complaint and to enter an initial decision and a cease and desist order.

The ALJ will schedule an initial prehearing scheduling conference to be held not later than 14 days after the answers are due. Unless otherwise directed by the ALJ, the scheduling conference and further proceedings will take place at the Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580. Rule 3.21(a) requires a meeting of the parties' counsel as early as practicable before the prehearing scheduling conference, and Rule 3.31(b) obligates counsel for each party, within 5 days of receiving a respondent's answer, to make certain initial disclosures without awaiting a formal discovery request.

A hearing on the complaint will begin on _____, 2004, at 10:00 A.M. in Room 532, or such other date as determined by the ALJ. At the hearing, you will have the right to contest the allegations of the complaint and to show cause why a cease and desist order should not be entered against you.

The following is the form of order which the Commission has reason to believe should issue if the facts are found to be as alleged in the complaint. If, however, the Commission should conclude from the record facts developed in any adjudicative proceedings in this matter that the proposed order provisions as to Dynamic Health of Florida, LLC, Chhabra Group, LLC, DBS

Laboratories, LLC, limited liability companies; and Vineet K. Chhabra a/k/a Vincent K. Chhabra, individually and as a director or officer of Dynamic Health of Florida, LLC and Chhabra Group, LLC might be inadequate to fully protect the consuming public, the Commission may order such other relief as it finds necessary or appropriate.

Moreover, the Commission has reason to believe that, if the facts are found as alleged in the complaint, it may be necessary and appropriate for the Commission to seek relief to redress injury to consumers, or other persons, partnerships or corporations, in the form of restitution and refunds for past, present, and future consumers and such other types of relief as are set forth in Section 19(b) of the Federal Trade Commission Act. The Commission will determine whether to apply to a court for such relief on the basis of the adjudicative proceedings in this matter and such other factors as are relevant to consider the necessity and appropriateness of such action.

ORDER

DEFINITIONS

For purposes of this Order, the following definitions shall apply:

A. Unless otherwise specified, "respondents" shall mean Dynamic Health of Florida, LLC, Chhabra Group, LLC, DBS Laboratories, LLC, limited liability companies, their successors and assigns and their officers; and Vineet K. Chhabra, a/k/a Vincent K. Chhabra, individually and as a director or officer of Dynamic Health of Florida, LLC and Chhabra Group, LLC, and each of the above's agents, representatives, and employees.

B. "Competent and reliable scientific evidence" shall mean tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.

C. "Pedia Loss" shall mean "Pedia Loss Dietary Supplement" and any other product containing one or more of the ingredients in the current product that is marketed for weight loss or control.

D. "Fabulously Feminine" shall mean "Fabulously Feminine Dietary Supplement" and any other product containing one or more of the ingredients in the current product that is marketed for sexual enhancement.

E. "Food," "drug," and "device" shall mean as "food," "drug," and "device" are defined in Section 15 of the Federal Trade Commission Act, 15 U.S.C. § 55.

F. "Covered product or service" shall mean any dietary supplement, food, drug, or device, and any health-related service or program promoting weight loss or sexual enhancement.

G. "Commerce" shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

H. "Endorsement" shall mean as defined in 16 C.F.R. § 255.0(b).

I. The term "including" in this Order shall mean "without limitation."

J. The terms "and" and "or" in this Order shall be construed conjunctively or disjunctively as necessary, to make the applicable phrase or sentence inclusive rather than exclusive.

I.

IT IS ORDERED that:

A. Respondents, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of Pedia Loss or any other covered product or service, shall not make any representation, in any manner, expressly or by implication, including through the use of endorsements or the product name, that:

1. Such product or service causes weight loss, suppresses appetite, increases fat burning, or slows carbohydrate absorption;
2. Such product or service causes weight loss in overweight or obese children ages 6 and over; or
3. Such product or service, when taken by overweight or obese children ages 6 and over, suppresses appetite, increases fat burning, or slows carbohydrate absorption,

unless, at the time the representation is made, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation; and

B. Respondents, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of Fabulously Feminine or any other covered product or service, shall not make any representation, in any manner, expressly or by implication, including through the use of endorsements or the product name, that such product or service will increase a woman's libido, sexual desire, or sexual satisfaction, unless, at the time the representation is made, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

II.

IT IS FURTHER ORDERED that respondents, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any covered product or service, in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, including through the use of endorsements or the product name, about the benefits, performance, or efficacy of such product or service, unless, at the time the representation is made, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

III.

IT IS FURTHER ORDERED that respondents, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any covered product or service, in or affecting commerce, shall not misrepresent, in any manner, directly or by implication, the existence, contents, validity, results, conclusions, or interpretations of any test or study.

IV.

IT IS FURTHER ORDERED that:

- A. Nothing in this Order shall prohibit respondents from making any representation for any drug that is permitted in labeling for such drug under any tentative final or final standard promulgated by the Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration; and
- B. Nothing in this Order shall prohibit respondents from making any representation for any product that is specifically permitted in labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990.

V.

IT IS FURTHER ORDERED that respondents Dynamic Health of Florida, LLC, Chhabra Group, LLC, DBS Laboratories, LLC and their successors and assigns, and respondent Vineet K. Chhabra shall, for five (5) years after the last date of dissemination of any representation covered by this order, maintain and upon request make available for inspection and copying:

- A. All advertisements and promotional materials containing the representation;

- B. All materials that were relied upon in disseminating the representation; and
- C. All tests, reports, studies, surveys, demonstrations, or other evidence in their possession or control that contradict, qualify, or call into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

VI.

IT IS FURTHER ORDERED that respondents Dynamic Health of Florida, LLC, Chhabra Group, LLC and DBS Laboratories, LLC and their successors and assigns, and respondent Vineet K. Chhabra shall deliver a copy of this order to all current and future principals, officers, directors, and managers, and to all current and future employees, agents, and representatives having responsibilities with respect to the subject matter of this order, and shall secure from each person a signed and dated statement acknowledging receipt of the order. Respondents shall deliver this order to current personnel within thirty (30) days after the date of service of this order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities.

VII.

IT IS FURTHER ORDERED that respondents Dynamic Health of Florida, LLC, Chhabra Group, LLC, and DBS Laboratories, LLC and their successors and assigns, and respondent Vineet K. Chhabra shall notify the Commission at least thirty (30) days prior to any change in the corporation that may affect compliance obligations arising under this order, including, but not limited to, a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor corporation; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in the corporate name or address. **Provided, however,** that, with respect to any proposed change in the corporation about which respondent learns less than thirty (30) days prior to the date such action is to take place, respondent shall notify the Commission as soon as is practicable after obtaining such knowledge. All notices required by this Part shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580. Attention: In the Matter of Dynamic Health of Florida, LLC.

VIII.

IT IS FURTHER ORDERED that respondent Vineet K. Chhabra, for a period of ten (10) years after the date of issuance of this order, shall notify the Commission of the

discontinuance of his current business or employment, or of his affiliation with any new business or employment. The notice shall include respondent's new business address and telephone number and a description of the nature of the business or employment and his duties and responsibilities.

IX.

IT IS FURTHER ORDERED that respondent Dynamic Health of Florida, LLC, Chhabra Group, LLC, and DBS Laboratories, LLC and their successors and assigns, and respondent Vineet K. Chhabra shall, within sixty (60) days after service of this order, and at such other times as the Federal Trade Commission may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which they have complied with this order.

X.

This order will terminate twenty (20) years from the date of its issuance, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; provided, however, that the filing of such a complaint will not affect the duration of:

- A. Any Part in this order that terminates in less than twenty (20) years;
- B. This order's application to any respondent that is not named as a defendant in such complaint; and
- C. This order if such complaint is filed after the order has terminated pursuant to this Part.

Provided, further, that if such complaint is dismissed or a federal court rules that the respondents did not violate any provision of the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order will terminate according to this Part as though the complaint had never been filed, except that the order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

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THEREFORE, the Federal Trade Commission this day of , 2004,
has issued this complaint against respondents.

By the Commission.

Donald S. Clark
Secretary

SEAL:

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

COMMISSIONERS: Timothy J. Muris, Chairman
Mozelle W. Thompson
Orson Swindle
Thomas B. Leary
Pamela Jones Harbour

Tab 94

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| In the Matter of |) |
| |) |
| DYNAMIC HEALTH OF FLORIDA, LLC, |) |
| CHHABRA GROUP, LLC, |) |
| DBS LABORATORIES, LLC, |) |
| limited liability companies, |) |
| |) |
| VINEET K. CHHABRA, |) |
| a/k/a VINCENT K. CHHABRA |) |
| individually and as an officer of |) |
| Dynamic Health of Florida, LLC, |) |
| and Chhabra Group, LLC, and |) |
| |) |
| JONATHAN BARASH, |) |
| individually and as an officer of |) |
| DBS Laboratories, LLC. |) |
| <hr/> |) |

DOCKET NO.
DECISION AND ORDER
AGAINST
JONATHAN BARASH

The Federal Trade Commission having initiated an investigation of certain acts and practices of respondent Jonathan Barash ("respondent") named in the caption hereof, and the respondent having been furnished thereafter with a copy of a draft of complaint which the Bureau of Consumer Protection proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge respondents with violation of the Federal Trade Commission Act; and

The respondent, his attorneys, and counsel for Federal Trade Commission having thereafter executed an agreement containing a consent order, an admission by the respondent of all the jurisdictional facts set forth in the aforesaid draft of complaint, a statement that the signing of said agreement is for settlement purposes only and does not constitute an admission by respondent that the law has been violated as alleged in such complaint, or that the facts as alleged in such complaint, other than jurisdictional facts, are true and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that the respondent has violated the said Act, and that complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such agreement on the public record for a period of thirty (30) days, now in further conformity with the procedure prescribed in § 2.34 of its Rules, the Commission hereby issues its complaint, makes the following jurisdictional findings and enters the following order:

1. Respondent Jonathan Barash is a minority owner and officer of DBS Laboratories, LLC and has participated in its day to day operations. Individually, or in concert with others, he has formulated, directed, participated in, or controlled the acts or practices of DBS Laboratories LLC, including the acts or practices challenged in the complaint. His principal office or place of business is 6599 NW 97th Drive, Parkland, Florida 33076.
2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the respondent, and the proceeding is in the public interest.

ORDER

DEFINITIONS

For purposes of this order, the following definitions shall apply:

- A. Unless otherwise specified, "respondent" shall mean Jonathan Barash individually and as an officer of DBS Laboratories, LLC, and his agents, representatives, and employees.
- B. "Competent and reliable scientific evidence" shall mean tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.
- C. "Pedia Loss" shall mean "Pedia Loss Dietary Supplement" and any other product containing one or more of the ingredients in the current product that is marketed for weight loss or control.
- D. "Fabulously Feminine" shall mean "Fabulously Feminine Dietary Supplement" and any other product containing one or more of the ingredients in the current product that is marketed for sexual enhancement.
- E. "Food," "drug," and "device" shall mean as "food," "drug," and "device" are defined in Section 15 of the Federal Trade Commission Act, 15 U.S.C. § 55.
- F. "Covered product or service" shall mean any dietary supplement, food, drug, or device, and any health-related service or program promoting weight loss or sexual enhancement.

G. "Commerce" shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

H. "Endorsement" shall mean as defined in 16 C.F.R. § 255.0(b).

I. The term "including" in this order shall mean "without limitation."

J. The terms "and" and "or" in this order shall be construed conjunctively or disjunctively as necessary, to make the applicable phrase or sentence inclusive rather than exclusive.

I.

IT IS ORDERED that:

A. Respondent, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of Pedia Loss or any other covered product or service, shall not make any representation, in any manner, expressly or by implication, including through the use of endorsements or the product name, that:

1. Such product or service causes weight loss, suppresses appetite, increases fat burning, or slows carbohydrate absorption;
2. Such product or service causes weight loss in overweight or obese children ages 6 and over; or
3. Such product or service, when taken by overweight or obese children ages 6 and over, suppresses appetite, increases fat burning, or slows carbohydrate absorption,

unless, at the time the representation is made, respondent possesses and relies upon competent and reliable scientific evidence that substantiates the representation; and

B. Respondent, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of Fabulously Feminine or any other covered product or service, shall not make any representation, in any manner, expressly or by implication, including through the use of endorsements or the product name, that such product or service will increase a woman's libido, sexual desire, or sexual satisfaction, unless, at the time the representation is made, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

II.

IT IS FURTHER ORDERED that respondent, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any covered product or service, in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, including through the use of endorsements or the product name, about the benefits, performance, or efficacy of such product or service, unless, at the time the representation is made, respondent possesses and relies upon competent and reliable scientific evidence that substantiates the representation.

III.

IT IS FURTHER ORDERED that respondent, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any covered product or service, in or affecting commerce, shall not misrepresent, in any manner, directly or by implication, the existence, contents, validity, results, conclusions, or interpretations of any test or study.

IV.

IT IS FURTHER ORDERED that:

A. Nothing in this order shall prohibit respondent from making any representation for any drug that is permitted in labeling for such drug under any tentative final or final standard promulgated by the Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration; and

B. Nothing in this order shall prohibit respondent from making any representation for any product that is specifically permitted in labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990.

V.

IT IS FURTHER ORDERED that respondent Jonathan Barash shall, for a period of three (3) years after the last date of dissemination of any representation covered by this order, maintain and upon request make available for inspection and copying:

1. All advertisements and promotional materials containing the representation;
2. All materials that were relied upon in disseminating the representation; and
3. All tests, reports, studies, surveys, demonstrations, or other evidence in

their possession or control that contradict, qualify, or call into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations;

VI.

IT IS FURTHER ORDERED that respondent Jonathan Barash shall deliver a copy of this order to all current and future principals, officers, directors, and managers, and to all current and future employees, agents, and representatives having responsibilities with respect to the subject matter of this order, and shall secure from each person a signed and dated statement acknowledging receipt of the order. Respondent shall deliver this order to current personnel within thirty (30) days after the date of service of this order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities.

VII.

IT IS FURTHER ORDERED that respondent Jonathan Barash, for a period of three (3) years after the date of issuance of this order, shall notify the Commission of the discontinuance of his current business or employment, or of his affiliation with any new business or employment. The notice shall include respondent's new business address and telephone number and a description of the nature of the business or employment and his duties and responsibilities. All notices required by this Part shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580. Attention: In the Matter of Dynamic Health of Florida, LLC.

VIII.

IT IS FURTHER ORDERED that respondent Jonathan Barash shall, within sixty (60) days after service of this order, and at such other times as the Federal Trade Commission may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which he has complied with this order.

IX.

This order will terminate twenty (20) years from the date of its issuance, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; provided, however, that the filing of such a complaint will not affect the duration of:

- A. Any Part in this order that terminates in less than twenty (20) years;

- B. This order's application to any respondent that is not named as a defendant in such complaint; and
- C. This order if such complaint is filed after the order has terminated pursuant to this Part.

Provided, further, that if such complaint is dismissed or a federal court rules that the respondent did not violate any provision of the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order will terminate according to this Part as though the complaint had never been filed, except that the order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission.

Donald S. Clark
Secretary

ISSUED:

SEAL

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

Tab 95

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| In the Matter of | / | |
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| |) | |
| DYNAMIC HEALTH OF FLORIDA, LLC, |) | |
| CHHABRA GROUP, LLC, |) | FILE NO. 042-3002 |
| DBS LABORATORIES, LLC, |) | |
| limited liability companies, |) | AGREEMENT CONTAINING |
| |) | CONSENT ORDER AGAINST |
| VINEET K. CHHABRA, |) | JONATHAN BARASH |
| a/k/a VINCENT K. CHHABRA |) | |
| individually and as an officer of |) | |
| Dynamic Health of Florida, LLC, |) | |
| and Chhabra Group, LLC, and |) | |
| |) | |
| JONATHAN BARASH, |) | |
| individually and as an officer of |) | |
| DBS Laboratories, LLC. |) | |
| |) | |

The Federal Trade Commission has conducted an investigation of certain acts and practices of Jonathan Barash ("proposed respondent"). Proposed respondent, having been represented by counsel, is willing to enter into an agreement containing a consent order resolving the allegations contained in the attached draft complaint. Therefore,

IT IS HEREBY AGREED by and between Jonathan Barash and counsel for the Federal Trade Commission that:

1. Respondent Jonathan Barash is a minority owner and officer of DBS Laboratories, LLC and has participated in its day to day operations. Individually, or in concert with others, he has formulated, directed, participated in, or controlled the acts, or practices of DBS Laboratories LLC, including the acts or practices challenged in the complaint. His principal office or place of business is 6599 NW 97th Drive, Parkland, Florida 33076.
2. Proposed respondent admits all the jurisdictional facts set forth in the draft complaint.
3. Proposed respondent waives:
 - a. Any further procedural steps;
 - b. The requirement that the Commission's decision contain a statement of findings of

fact and conclusions of law; and

- c. All rights to seek judicial review or otherwise to challenge or contest the validity of the order entered pursuant to this agreement.

4. This agreement shall not become part of the public record of the proceeding unless and until it is accepted by the Commission. If this agreement is accepted by the Commission, it, together with the draft complaint, will be placed on the public record for a period of thirty (30) days and information about it publicly released. The Commission thereafter may either withdraw its acceptance of this agreement and so notify proposed respondent, in which event it will take such action as it may consider appropriate, or issue and serve its complaint (in such form as the circumstances may require) and decision in disposition of the proceeding.

5. This agreement is for settlement purposes only and does not constitute an admission by proposed respondent that the law has been violated as alleged in the draft complaint, or that the facts as alleged in the draft complaint, other than the jurisdictional facts, are true.

6. This agreement contemplates that, if it is accepted by the Commission, and if such acceptance is not subsequently withdrawn by the Commission pursuant to the provisions of Section 2.34 of the Commission's Rules, the Commission may, without further notice to proposed respondent, (1) issue its complaint corresponding in form and substance with the attached draft complaint and its decision containing the following order in disposition of the proceeding, and (2) make information about it public. When so entered, the order shall have the same force and effect and may be altered, modified, or set aside in the same manner and within the same time provided by statute for other orders. The order shall become final upon service. Delivery of the complaint and the decision and order to proposed respondent's address as stated in this agreement by any means specified in Section 4.4(a) of the Commission's Rules shall constitute service. Proposed respondent waives any right he may have to any other manner of service. The complaint may be used in construing the terms of the order, and no agreement, understanding, representation, or interpretation not contained in the order or the agreement may be used to vary or contradict the terms of the order.

7. Proposed respondent has read the draft complaint and consent order. He understands that he may be liable for civil penalties in the amount provided by law and other appropriate relief for each violation of the order after it becomes final.

ORDER

DEFINITIONS

For purposes of this order, the following definitions shall apply:

- A. Unless otherwise specified, "respondent" shall mean Jonathan Barash individually and as an officer of DBS Laboratories, LLC, and his agents, representatives, and employees.
- B. "Competent and reliable scientific evidence" shall mean tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.
- C. "Pedia Loss" shall mean "Pedia Loss Dietary Supplement" and any other product containing one or more of the ingredients in the current product that is marketed for weight loss or control.
- D. "Fabulously Feminine" shall mean "Fabulously Feminine Dietary Supplement" and any other product containing one or more of the ingredients in the current product that is marketed for sexual enhancement.
- E. "Food," "drug," and "device" shall mean as "food," "drug," and "device" are defined in Section 15 of the Federal Trade Commission Act, 15 U.S.C. § 55.
- F. "Covered product or service" shall mean any dietary supplement, food, drug, or device, and any health-related service or program promoting weight loss or sexual enhancement.
- G. "Commerce" shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.
- H. "Endorsement" shall mean as defined in 16 C.F.R. § 255.0(b).
- I. The term "including" in this order shall mean "without limitation."
- J. The terms "and" and "or" in this order shall be construed conjunctively or disjunctively as necessary, to make the applicable phrase or sentence inclusive rather than exclusive.

I.**IT IS ORDERED** that:

A. Respondent, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of Pedia Loss or any other covered product or service, shall not make any representation, in any manner, expressly or by implication, including through the use of endorsements or the product name, that:

1. Such product or service causes weight loss, suppresses appetite, increases fat burning, or slows carbohydrate absorption;
2. Such product or service causes weight loss in overweight or obese children ages 6 and over; or
3. Such product or service, when taken by overweight or obese children ages 6 and over, suppresses appetite, increases fat burning, or slows carbohydrate absorption,

unless, at the time the representation is made, respondent possesses and relies upon competent and reliable scientific evidence that substantiates the representation; and

B. Respondent, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of Fabulously Feminine or any other covered product or service, shall not make any representation, in any manner, expressly or by implication, including through the use of endorsements or the product name, that such product or service will increase a woman's libido, sexual desire, or sexual satisfaction, unless, at the time the representation is made, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

II.

IT IS FURTHER ORDERED that respondent, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any covered product or service, in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, including through the use of endorsements or the product name, about the benefits, performance, or efficacy of such product or service, unless, at the time the representation is made, respondent possesses and relies upon competent and reliable scientific evidence that substantiates the representation.

III.

IT IS FURTHER ORDERED that respondent, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any covered product or service, in or affecting commerce, shall not misrepresent, in any manner, directly or by implication, the existence, contents, validity, results, conclusions, or interpretations of any test or study.

IV.

IT IS FURTHER ORDERED that:

A. Nothing in this order shall prohibit respondent from making any representation for any drug that is permitted in labeling for such drug under any tentative final or final standard promulgated by the Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration; and

B. Nothing in this order shall prohibit respondent from making any representation for any product that is specifically permitted in labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990.

V.

IT IS FURTHER ORDERED that respondent Jonathan Barash shall, for a period of three (3) years after the last date of dissemination of any representation covered by this order, maintain and upon request make available for inspection and copying:

- A. All advertisements and promotional materials containing the representation;
- B. All materials that were relied upon in disseminating the representation; and
- C. All tests, reports, studies, surveys, demonstrations, or other evidence in their possession or control that contradict, qualify, or call into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

VI.

IT IS FURTHER ORDERED that respondent Jonathan Barash shall deliver a copy of this order to all current and future principals, officers, directors, and managers, and to all current and future employees, agents, and representatives having responsibilities with respect to the subject matter of this order, and shall secure from each person a signed and dated statement acknowledging receipt of the order. Respondent shall deliver this order to current personnel

within thirty (30) days after the date of service of this order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities.

VII.

IT IS FURTHER ORDERED that respondent Jonathan Barash, for a period of three (3) years after the date of issuance of this order, shall notify the Commission of the discontinuance of his current business or employment, or of his affiliation with any new business or employment. The notice shall include respondent's new business address and telephone number and a description of the nature of the business or employment and his duties and responsibilities. All notices required by this Part shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580. Attention: In the Matter of Dynamic Health of Florida, LLC.

VIII.

IT IS FURTHER ORDERED that respondent Jonathan Barash shall, within sixty (60) days after service of this order, and at such other times as the Federal Trade Commission may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which he has complied with this order.

IX.

This order will terminate twenty (20) years from the date of its issuance, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; provided, however, that the filing of such a complaint will not affect the duration of:

- A. Any Part in this order that terminates in less than twenty (20) years;
- B. This order's application to any respondent that is not named as a defendant in such complaint; and
- C. This order if such complaint is filed after the order has terminated pursuant to this Part.

Provided, further, that if such complaint is dismissed or a federal court rules that the respondent did not violate any provision of the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order will terminate according to this Part as though the complaint had never been filed, except that the order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

Signed this _____ day of _____ 2004.

JANET EVANS
SYDNEY KNIGHT
Counsel for the
FEDERAL TRADE COMMISSION

JONATHAN BARASH

DEBRA BASS, ESQ.

ANTONIO C. MARTINEZ, II, ESQ.
MARTINEZ BASS & ASSOCIATES
601 Pennsylvania Avenue, N.W.
Washington, DC 20004
Attorneys for Respondent

APPROVED:

MARY K. ENGLE
Associate Director
Division of Advertising Practices

J. HOWARD BEALES, III
Director
Bureau of Consumer Protection

**Analysis of Proposed Consent Order
to Aid Public Comment**

Tab 96

The Federal Trade Commission has accepted, subject to final approval, an agreement containing a consent order from Jonathan Barash ("proposed respondent"). Proposed respondent collaborated with others in the marketing of a purported children's weight loss product called "Pedia Loss," and a purported female libido enhancer called "Fabulously Feminine."

The proposed consent order has been placed on the public record for thirty (30) days for reception of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement in light of and the any comments received and will decide whether it should withdraw from the agreement and take other appropriate action or make final the agreement's proposed order.

The Commission's complaint charges that proposed respondents advertising for Pedia Loss made unsubstantiated claims that (1) Pedia Loss causes weight loss in overweight or obese children ages 6 and over, and (2) when taken by overweight or obese children ages 6 and over, Pedia Loss causes weight loss by suppressing appetite, increasing fat burning, and slowing carbohydrate absorption. The Commission's complaint also charges that proposed respondent advertisements for Fabulously Feminine falsely represented that clinical testing proves that Fabulously Feminine enhances a woman's satisfaction with her sex life and level of sexual desire. In addition, the complaint challenges the unsubstantiated claim that Fabulously Feminine will increase a woman's libido, sexual desire, and sexual satisfaction by stimulating blood flow and increasing sensitivity.

Part I A of the proposed order pertains to Pedia Loss. It requires that proposed respondent possess and rely on competent and reliable scientific evidence to support claims that Pedia Loss or any other covered product or service causes weight loss, suppresses appetite, increases fat burning, or slows carbohydrate absorption; causes weight loss in overweight or obese children ages 6 and over; or causes weight loss by suppressing appetite, increasing fat burning, or slowing carbohydrate absorption, when taken by overweight or obese children ages 6 and over; or is safe or has no side effects. Part IB of the order pertains to Fabulously Feminine. It requires that proposed respondent possess and rely on competent and reliable scientific evidence to support claims that Fabulously Feminine or any other covered product or service will increase a woman's libido, sexual desire, or sexual satisfaction.

Part II of the proposed order requires that proposed respondent possess and rely on competent and reliable scientific evidence to support benefits, performance, or efficacy claims for covered products or services defined as any dietary supplement, food, drug, or device, and any health-related service or program promoting weight loss or sexual enhancement.

Part III of the proposed order prohibits proposed respondent from misrepresenting the existence, contents, validity, results, conclusions, or interpretations of any test or studies. Part IV of the proposed order permits proposed respondents to make certain claims for drugs or dietary

supplements, that are permitted in labeling under laws and/or regulations administered by the U.S. Food and Drug Administration.

The remainder of the proposed order contains standard requirements that proposed respondent maintain advertising and any materials relied upon as substantiation for any representation covered by substantiation requirements under the order; distribute copies of the order to certain company officials and employees; notify the Commission of any change in the business entity that may affect compliance obligations under the order; and file one or more reports detailing their compliance with the order. Part IX of the proposed order is a provision whereby the order, absent certain circumstances, terminates twenty years from the date of issuance.

This proposed order, if issued in final form, will resolve the claims alleged in the complaint against the named respondent. It is not the Commission's intent that acceptance of this consent agreement and issuance of a final decision and order will release any claims against any unnamed persons or entities associated with the conduct described in the complaint.

The purpose of this analysis is to facilitate public comment on the proposed order, and is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

002-3300

Tab 97

_____)
 In the Matter of)
)
 BASIC RESEARCH, L.L.C.,)
 a limited liability corporation,)
)
 A.G. WATERHOUSE, L.L.C.,)
 a limited liability corporation,)
)
 KLEIN-BECKER USA, L.L.C.,)
 a limited liability corporation,)
)
 NUTRASPORT, L.L.C.,)
 a limited liability corporation,)
)
 SOVAGE DERMALOGIC LABORATORIES, L.L.C.,)
 a limited liability corporation,)
)
 BAN, L.L.C.,)
 a limited liability corporation, also doing)
 business as BASIC RESEARCH, L.L.C.,)
 OLD BASIC RESEARCH, L.L.C.,)
 BASIC RESEARCH, A.G. WATERHOUSE,)
 KLEIN-BECKER USA, NUTRA SPORT, and)
 SOVAGE DERMALOGIC LABORATORIES,)
)
 DENNIS GAY,)
 individually and as an officer)
 of the limited liability corporations,)
)
 DANIEL B. MOWREY,)
 also doing business as)
 AMERICAN PHYTOTHERAPY RESEARCH)
 LABORATORY, and)
)
 MITCHELL K. FRIEDLANDER)
 _____)

DOCKET NO. 9318

COMPLAINT

The Federal Trade Commission, having reason to believe that Basic Research, L.L.C., a limited liability corporation also doing business as A.G. Waterhouse; Klein-Becker usa, L.L.C., a limited liability corporation; Nutrasport, L.L.C., a limited liability corporation; Sovage Dermalogic Laboratories, L.L.C.; BAN, L.L.C., a limited liability corporation; Dennis Gay, individually and as an officer of the limited liability corporations; Daniel B. Mowrey, also doing business as American Phytotherapy Research Laboratory; and Mitchell K. Friedlander have violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent Basic Research, L.L.C., is a Utah limited liability corporation with its principal office or place of business at 5742 W. Harold Gatty Dr., Salt Lake City, Utah 84116.
2. Respondent A.G. Waterhouse, L.L.C., is a Wyoming limited liability corporation with its principal office or place of business at 5742 W. Harold Gatty Dr., Salt Lake City, Utah 84116.
3. Respondent Klein-Becker usa, L.L.C., is a Utah limited liability corporation with its principal office or place of business at 5742 W. Harold Gatty Dr., Salt Lake City, Utah 84116.
4. Respondent Nutrasport, L.L.C., is a Utah limited liability corporation with its principal office or place of business at 5742 W. Harold Gatty Dr., Salt Lake City, Utah 84116.
5. Respondent Sovage Dermalogic Laboratories, L.L.C., is a Utah limited liability corporation with its principal office or place of business at 5742 W. Harold Gatty Dr., Salt Lake City, Utah 84116.
6. Respondent BAN, L.L.C., is a Utah limited liability corporation with its principal office or place of business at 5742 W. Harold Gatty Dr., Salt Lake City, Utah 84116. Respondent also has done business as Basic Research, L.L.C.; Old Basic Research, L.L.C.; Basic Research; A.G. Waterhouse; Klein-Becker usa; Nutra Sport; and Sovage Dermalogic Laboratories. Respondents Basic Research L.L.C.; Klein-Becker usa, L.L.C.; Nutrasport, L.L.C.; and Sovage Dermalogic Laboratories, L.L.C. are successors in interest to BAN, L.L.C. with respect to acts or practices alleged in this complaint that preceded the incorporation of respondents Basic Research L.L.C.; Klein-Becker usa, L.L.C.; Nutrasport, L.L.C.; and Sovage Dermalogic Laboratories, L.L.C.
7. Respondent Dennis Gay is an officer of the limited liability corporations. Individually or in concert with others, he formulates, directs, controls, or participates in the acts or practices of the limited liability corporations alleged in this complaint. His principal place of business is the same as that of the limited liability corporations.
8. Respondent Daniel B. Mowrey is an individual also doing business as American Phytotherapy Research Laboratory. Mowrey develops and endorses products for the limited liability corporations and participates in the acts or practices of the limited liability corporations

alleged in this complaint. Mowrey's principal office or place of business is located at 5742 W. Harold Gatty Dr., Salt Lake City, Utah 84116.

9. Respondent Mitchell K. Friedlander is an individual whose principal office or place of business is the same as that of Mowrey. Friedlander has developed products marketed by the limited liability corporations and participates in the acts or practices of the limited liability corporations alleged in this complaint.

10. Respondents have operated a common business enterprise while engaging in the deceptive acts and practices alleged below and are therefore jointly and severally liable for said acts and practices.

11. Respondents have manufactured, advertised, labeled, offered for sale, sold, and/or distributed products to the public, including but not limited to:

- A. Dermalin-APg, a topical "penetrating gel," containing aminophylline and other ingredients, that has typically sold for \$135.00/8 oz. bottle;
- B. Cutting Gel, a topical "penetrating gel," containing aminophylline and other ingredients, that has typically sold for \$89.00/4 oz. bottle;
- C. Tummy Flattening Gel, a topical gel "concentrate," containing aminophylline and other ingredients, that has typically sold for \$119.00/4 oz. tube;
- D. Leptoprin, a "weight control compound" capsule, containing ephedrine, caffeine, aspirin and other ingredients, that has typically sold for \$153.00 for a 180-tablet bottle (30-day supply); and
- E. Anorex, a "weight control compound" capsule, containing ephedrine, caffeine, aspirin and other ingredients, that has typically sold for \$153.00 for a 180-tablet bottle (30-day supply); and
- F. PediaLean, a "weight control compound" capsule, containing glucomannan and other ingredients, that has typically sold for \$79.00 for a 120-capsule bottle (20 to 30-day supply).

These products have been advertised on Basic Research's Internet websites; in newspapers and tabloids; in magazines; and/or in television commercials. Dermalin-APg, Cutting Gel, Tummy Flattening Gel, Leptoprin, Anorex, and PediaLean are "foods," and/or "drugs" within the meaning of Sections 12 and 15 of the Federal Trade Commission Act.

12. The acts and practices of respondents alleged in this complaint have been in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act.

Dermalin-APg, Cutting Gel, and Tummy Flattening Gel Products for Fat Loss

13. Respondents have disseminated or have caused to be disseminated advertisements and labeling for Dermalin-APg, Cutting Gel, and Tummy Flattening Gel, including but not necessarily limited to the attached exhibits A - G. Dermalin-APg advertisements have appeared in magazines such as Cosmopolitan, Redbook, Energy Times, Let's Live, and Muscle & Fitness Hers. Cutting Gel advertisements have appeared in magazines such as Muscle & Fitness Physical, and Let's Live. Tummy Flattening Gel advertisements have appeared in magazines such as Cosmopolitan and Redbook. Advertisements for these products contain the following statements:

A. Exhibit A - Dermalin-APg Magazine Advertisement

**"Dermalin-APG: The next generation fat emulsifier
Penetrating Gel Emulsifies Fat On Contact
Dissolves Deep-Stored Body Fat Wherever Applied."**

"Dermalin-APg's unique transdermal 'gel' formulation releases fat stores from any problem area. . . . [W]hen the gel is applied to the tummy, waist or hips, a dramatic reduction of stored body fat occurs."

"The Miracle of Dermalin-APg

Dermalin APg permits you to spot reduce. Put it on around your thighs - slimmer thighs. Over thirty and getting thick around the middle? Just apply Dermalin APg's transdermal gel to your waist or tummy and watch them shrink in size within a matter of days."

B. Exhibit B - Dermalin-APg Website <www.dermalin.com>

**"Dermalin-APG: The next generation transdermal fat emulsifying gel
BUY ONLINE NOW! or call 1-888-340-1628 Ext. KBWEB
Penetrating Gel Emulsifies Fat On Contact
Dissolves Deep-Stored Body Fat Wherever Applied."**

"Dermalin-APg's unique transdermal gel formulation releases fat stores from any problem area. . . . [W]hen the gel is applied to the tummy, waist or hips, a dramatic reduction of stored body fat occurs

The Miracle of Dermalin-APg

Dermalin APg permits you to spot reduce. Put Dermalin-APg on your thigh, it goes to work directly on your thigh. Over thirty and getting thick around the middle? Just apply Dermalin APg's transdermal gel to your waist or tummy and watch them shrink in size within a matter of days."

C. Exhibit C - Cutting Gel Product Packaging

"CUTTING GEL's patented, transdermal gel formulation has been specifically designed to reduce resistant surface body fat wherever applied. . . . Apply CUTTING GEL to your glutes, biceps, triceps, or lats, and the fat literally melts away, leaving pure, ripped muscle behind! And let's not forget, if you're a man over 40 and have a problem with 'love handles' (or a woman developing a 'pre-menopausal tummy'), you can't live without CUTTING GEL!

You apply CUTTING GEL topically, directly to the specific areas that need extra definition. CUTTING GEL penetrates the skin and goes to work directly on stubborn fat cells, literally **forcing** them to release fat into the bloodstream to be burned as energy. Now you can finally get rid of that last concealing layer of ugly fat and get really cut!" (emphasis in original).

D. Exhibit D - Cutting Gel Magazine Advertisement

"FACT/ CUTTING GEL Gets Rid of Surface Body Fat!

Finally, there's Cutting Gel, a unique, patented, transdermal gel that penetrates deep into the skin and dissolves stubborn body fat on contact. That's right! A clinically proven, transdermal gel that dissolves surface body fat wherever applied! It's called Cutting Gel, and it's finally available in the United States in full clinical strength, without a prescription, and without annoying doctor's visits." (emphasis in original).

"Apply CUTTING GEL to your glutes, biceps, triceps, or lats, and the fat literally melts away, leaving pure, ripped muscle behind! And let's not forget, if you're a man over 40 and have a problem with 'love handles,' you can't live without CUTTING GEL!

"FACT/ Clinically Proven, Full-Strength, Patented Formula!"

"Put Cutting Gel in a culture dish with fat cells and you can literally watch them deflate – similar to sticking a pin in a balloon."

Dr. Daniel B. Mowrey" (emphasis in original)

"Dissolves Surface Body Fat on Contact!

Published Clinical Trials Prove CUTTING GEL's Power!"

E. Exhibit E - Cutting Gel Website <www.cuttinggel.com>

“the future of fat-burning”

FACT CUTTING GEL Gets Rid of Surface Body Fat!

Finally, there's Cutting Gel, a unique, patented, transdermal gel that penetrates deep into the skin and dissolves stubborn body fat on contact. That's right! A clinically proven, transdermal gel that dissolves surface body fat wherever applied! It's called Cutting Gel, and it's finally available in the United States in full clinical strength, without a prescription, and without annoying doctor's visits.”

“Apply CUTTING GEL to your glutes, biceps, triceps, or lats, and the fat literally melts away, leaving pure, ripped muscle behind! And let's not forget, if you're a man over 40 and have a problem with 'love handles' you can't live without Cutting Gel!”

“All of us want flat, washboard stomachs, firm buns, and tight, smooth thighs. But no matter how many pills we swallow, or how much we sweat all over our Stairmaster, we will can't get rid of that extra layer of body fat covering up the results of all our pain and hard work. That is until now!”

“Just apply Cutting Gel directly to any resistant pocket of surface body fat (the fat around your abs, thighs, hips, or buttocks) and Cutting Gel's transdermal formulation penetrates the skin, mobilizing stored fat and leaving only lean, sexy curves behind!”

F. Exhibit F - Tummy Flattening Gel Magazine Advertisement

“New Product Update from Savage Dermalogic Laboratories

**PATENTED TOPICAL GEL
REDUCES TUMMY FAT!**

“This new, highly concentrated formula allows for precise, targeted delivery... making it the first true spot-reducing gel capable of effective reduction of dense abdominal fat.”

Dr. Nathalie Chevreau, PhD, RD, Director of Women's Health, Savage Dermalogic Laboratories”
(emphasis in original)

“CLINICALLY PROVEN

How It Works – The Science

It is well documented that when beta adrenergic stimulants such as Epidril are added to a culture dish with adipose (fat) cells, the cells deflate as they release their stored fat – very similar to the way a balloon deflates when stuck with a pin. The evidence is conclusive. Epidril has been verified by two published clinical trials and has been awarded a United States Patent [No. 4,525,359].”

“The ‘Fine Print’

As with all Epidril formulations, there are two caveats. First, because Sovage Tummy Flattening Gel works by forcing stored fat out of abdominal fat cells and into the bloodstream to be burned as energy, you have to help burn off the released fat by exercising or decreasing caloric intake so circulating fat is not redeposited. Second, you might be tempted to use more than the recommended dosage of Sovage Tummy Flattening Gel. Don’t...there is simply no way for your body to deal with that much released fat.

See Visible Results in Approximately 19 Days, Guaranteed!

Use Sovage Tummy Flattening Gel as directed, and you will begin to see dramatic, visible results in approximately 19 days.”

“NOTE: Many of our clients who have considered liposuction surgery use Sovage Tummy Flattening Gel first, as a kind of ‘test-drive’ before committing to a possibly dangerous surgical solution.”

G. Exhibit G - Tummy Flattening Gel Website <www.sovage.com>

“New Product Update from Sovage Dermalogic Laboratories

**PATENTED TOPICAL GEL
REDUCES TUMMY FAT!**

‘This new, highly concentrated formula allows for precise targeted delivery... making it the first true spot-reducing gel capable of effective reduction of dense abdominal fat.’

Dr. Nathalie Chevreau, PhD, RD, Director of Women’s Health, Sovage Dermalogic Laboratories”
(emphasis in original)

“The evidence is conclusive. Epidril has been verified by two published clinical trials and has been awarded dual United States Patents [Nos. 4,525,359 and 4,588,724].”

“The Power of Sovage Tummy Flattening Gel

The ultimate power of Sovage Tummy Flattening Gel results from a patent-pending process that allows precise delivery of its **ultra-concentrated** Epidril base formulation to resistant areas of dense abdominal fat – selectively accelerating the breakdown of regional fat cells. Sovage Tummy Flattening Gel is a quick-penetrating gel so thick, concentrated, and smooth some people call it a ‘fat burning paste.’” (emphasis in original)

“[T]he quickest way to capture a perfectly sculpted midsection is with the new, area-specific, clinically proven, super-concentrated Sovage Tummy Flattening Gel.”

14. Through the means described in Paragraph 13, respondents have represented, expressly or by implication, that Dermalin-APg causes rapid and visibly obvious fat loss in areas of the body to which it is applied.
15. Through the means described in Paragraph 13, respondents have represented, expressly or by implication, that they possessed and relied upon a reasonable basis that substantiated the representation set forth in Paragraph 14, at the time the representation was made.
16. In truth and in fact, respondents did not possess and rely upon a reasonable basis that substantiated the representation set forth in Paragraph 14 at the time the representation was made. Therefore, the representation set forth in Paragraph 15 was, and is, false or misleading.
17. Through the means described in Paragraph 13, respondents have represented, expressly or by implication, that Cutting Gel causes rapid and visibly obvious fat loss in areas of the body to which it is applied.
18. Through the means described in Paragraph 13, respondents have represented, expressly or by implication, that they possessed and relied upon a reasonable basis that substantiated the representation set forth in Paragraph 17, at the time the representation was made.
19. In truth and in fact, respondents did not possess and rely upon a reasonable basis that substantiated the representation set forth in Paragraph 17 at the time the representation was made. Therefore, the representation set forth in Paragraph 18 was, and is, false or misleading.
20. Through the means described in Paragraph 13, respondents have represented, expressly or by implication, that Tummy Flattening Gel causes rapid and visibly obvious fat loss in areas of the body to which it is applied.
21. Through the means described in Paragraph 13, respondents have represented, expressly or by implication, that they possessed and relied upon a reasonable basis that substantiated the representation set forth in Paragraph 20 at the time the representation was made.

22. In truth and in fact, respondents did not possess and rely upon a reasonable basis that substantiated the representation set forth in Paragraph 20 at the time the representation was made. Therefore, the representation set forth in Paragraph 21 was, and is, false or misleading.

23. Through the means described in Paragraph 13, respondents have represented, expressly or by implication, that published, clinical testing proves that Cutting Gel causes rapid and visibly obvious fat loss in areas of the body to which it is applied.

24. In truth and in fact, published, clinical testing does not prove that Cutting Gel causes rapid and visibly obvious fat loss in areas of the body to which it is applied. Therefore, the representation set forth in Paragraph 23 was, and is, false or misleading.

25. Through the means described in Paragraph 13, respondents have represented, expressly or by implication, that published, clinical testing proves that Tummy Flattening Gel causes rapid and visibly obvious fat loss in areas of the body to which it is applied.

26. In truth and in fact, published, clinical testing does not prove that Tummy Flattening Gel causes rapid and visibly obvious fat loss in areas of the body to which it is applied. Therefore, the representation set forth in Paragraph 25 was, and is, false or misleading.

Leptoprin and Anorex Products for Weight and Fat Loss in "the Significantly Overweight"

27. Respondents have disseminated or have caused to be disseminated advertisements and labeling for Leptoprin and Anorex, including but not necessarily limited to the attached Exhibits H - J. These advertisements contain the following statements and depictions:

A. Exhibit H - Leptoprin 120-Second Television Commercial (transcript attached as Exhibit H-1)

ON SCREEN: \$153 a bottle

FEMALE ANNOUNCER: When is a diet pill worth \$153 a bottle?

**ON SCREEN: When You Need to Lose More than 20 pounds...
Developed for the Significantly Overweight.**

FEMALE ANNOUNCER: When you're more than 20 pounds overweight and tired of wasting money on one ordinary diet pill after another and every diet plan has failed. Now, there's Leptoprin.

**ON SCREEN: (Scrolling on screen)
Specifically developed for the
significantly overweight,**

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backed by two United States patents, two published clinical trials, and an ironclad 100 percent money back guarantee. Leptoprin is simply the most powerful, clinically proven weight control compound available...
Period!
1-800-460-2990
www.leptoprin.com

MALE ANNOUNCER: Specifically developed for the significantly overweight, backed by two United States patents, two published clinical trials and an ironclad 100 percent money back guarantee. Leptoprin is simply the most powerful, clinically proven weight control compound available, period.

ON SCREEN: Before photo
203 lbs.
1-800-460-2990
www.leptoprin.com

RHONDA WILLIAMS: I've gone from 203 pounds down to 153 pounds.

ON SCREEN: LOST 50 LBS.
Results May Not Be Typical
Rhonda Williams
Titusville, Florida
1-800-460-2990
www.leptoprin.com

RHONDA WILLIAMS: I went from a size 18 down to a size 7 dress. If you had told me that I would have dropped 50 pounds, I would never have believed it. And now look at me.

ON SCREEN: 1-800-460-2990
www.leptoprin.com

FEMALE ANNOUNCER: If you're one of those people who constantly worry about five or six vanity pounds, Leptoprin is not for you. Leptoprin is much too expensive and much too powerful for the casual dieter. But if you're one of the millions of Americans who are 20, 30, 50 pounds or more overweight, you need Leptoprin.

ON SCREEN: Before photo
404 lbs.
1-800-460-2990

www.leptoprin.com

TONY TRUPIANO: You don't have to be fat.

**ON SCREEN: LOST 147 LBS.
Results May Not Be Typical
Tony Trupiano
Detroit, Michigan
1-800-460-2990
www.leptoprin.com**

TONY TRUPIANO: Eight months ago I wore these pants at 404 pounds. I've lost 147. I'm actually going to frame these pants and put them on my wall. I am.

**ON SCREEN: Before photo
235 lbs.
Amy Richardson
St. Louis, Missouri
1-800-460-2990
www.leptoprin.com**

AMY RICHARDSON: I'm currently down to 175.

**ON SCREEN: LOST 60 LBS.
Results May Not Be Typical
Amy Richardson
St. Louis, Missouri
1-800-460-2990
www.leptoprin.com**

* * *

MALE ANNOUNCER: So, when is a diet pill worth \$153 a bottle? When it works, really works.

**ON SCREEN: LOST 60 LBS.
1-800-460-2990
www.leptoprin.com**

AMY RICHARDSON: It's like you're a new person.

**ON SCREEN: LOST 147 LBS.
1-800-460-2990
www.leptoprin.com**

TONY TRUPIANO: It's been an amazing journey.

**ON SCREEN: LOST 50 LBS.
1-800-460-2990
www.leptoprin.com**

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RHONDA WILLIAMS: It works.

B. Exhibit I - Leptoprin Website <www.leptoprin.com>**"LEPTOPRIN**

The Ultimate Weight Loss Compound For The Significantly Overweight... More Than 20 Pounds Overweight or A Body Mass Index (BMI) Greater Than 27"

"Unless a weight-control compound addresses the genetic factor – and helps you overcome your genetic predisposition to obesity – your attempts at weight loss become no more than an exercise in futility (and a waste of time and money).

But now there's Leptoprin – the first weight-control compound designed to mitigate the profound effect that variations in the human genetic code have on the storage, use, and disposition of body fat.

Leptoprin is an extremely powerful anorectic agent and is not intended for use by the casual dieter who is merely attempting to shed five or ten 'vanity' pounds. However, if substantial, excess body fat is adversely affecting your health and self-esteem, then it's time for you to discover Leptoprin – the first comprehensive weight-loss compound designed specifically to overcome your genetic predisposition.

Leptoprin: The Result of an Extraordinary Collaboration

Leptoprin (or more correctly, its patent-protected core compound, Leptoprin) is the result of an extraordinary collaborative effort between Dr. Daniel B. Mowrey, Director of Scientific Affairs, APRL (American Phytotherapy Research Laboratory), Salt Lake City, Utah, and Dr. Edward G. Fey, University of Massachusetts Medical Center, Worcester, Massachusetts. Though working independently, both doctors were keenly aware of the growing body of evidence linking obesity to certain genetic 'markers.' In September of 1998, Drs. Mowrey and Fey discovered each had access to compatible patents for variant methods of regulating obesity. As they familiarized themselves with each others' work, it became clear that combining the patented formulations could overcome genetic anomalies responsible for significant overweight."

"Leptoprin: Now Available in The United States Without A Prescription

In a report dated February 19, 2000, Dr. Mowrey stated 'Although Leptoprin is much too powerful for the 'casual dieter,' the ability of Leptoprin to help people overcome the genetic implications of obesity leads me to believe Leptoprin, and its base formulation Leptoprin, is the most effective means of providing considerable benefit to that vast population of American men and women who are significantly overweight. That is, until science develops a reliable means of altering the genetic code.' If You're Significantly Overweight, You Need Leptoprin. If you're significantly overweight (more than 20 lbs. of excess body weight and/or a BMI greater than 30), there is only one weight-control compound specifically designed for you... it's Leptoprin. Patent-protected, clinically

established, and guaranteed to help you become the thinner, healthier, and more active person you've always wanted to be." (Ellipses in original)

C. Exhibit J - Anorex Website <www.anorex.com>

"To begin, if you are one of those people who constantly worry about 5 or 6 simple 'vanity' pounds, Anorex is not for you. But if you're one of the millions of Americans who are significantly overweight (more than 20 lbs. of excess body weight and/or a BMI [body mass index] greater than 30) there is no longer any way to deny that ordinary diet pills and so-called 'fat burners' (if they work at all) so often fail to help the significantly overweight. . . .

But now there's Anorex – the first weight-control compound designed to mitigate the profound effect that variations in the human genetic code have on the storage, use, and disposition of body fat. Anorex is an extremely powerful anorectic agent and is not intended for use by the casual dieter who is merely attempting to shed five or ten 'vanity' pounds. However, if substantial, excess body fat is adversely affecting your health and self-esteem, then it's time for you to discover Anorex – the first comprehensive weight-loss compound designed specifically to overcome your genetic predisposition.

Anorex: The Result of an Extraordinary Collaboration

Anorex (or more correctly, its patent-protected core compound, Leptoprin) is the result of an extraordinary collaborative effort between Dr. Daniel B. Mowrey, Director of Scientific Affairs, APRL (American Phytotherapy Research Laboratory), Salt Lake City, Utah, and Dr. Edward G. Fey, University of Massachusetts Medical Center, Worcester, Massachusetts. Though working independently, both doctors were keenly aware of the growing body of evidence linking obesity to certain genetic 'markers.' In September of 1998, Drs. Mowrey and Fey discovered each had access to compatible patents for variant methods of regulating obesity. As they familiarized themselves with each others' work, it became clear that combining the patented formulations could overcome genetic anomalies responsible for significant overweight."

"Although Anorex is much too powerful for the 'casual dieter' (someone concerned about losing 5 or 6 extra 'vanity pounds), its distinct ability to help overcome the genetic implications of obesity makes it the most effective means of providing considerable benefit to that vast population of American men and women who are significantly overweight.'

Dr. Daniel B. Mowrey,
Director Scientific Affairs
Klein-Becker usa

CAUTION: Anorex is Not a Toy. Anorex Should Not Be Used by the 'Casual Dieter'."

"If You're Significantly Overweight, You Need Anorex

If you're significantly overweight (more than 20 lbs. of excess body weight and/or a BMI greater than 30), there is only one weight-control compound specifically designed for you... it's Anorex. Patent-protected, clinically established, and guaranteed to help you become the thinner, healthier, and more active person you've always wanted to be."
(Ellipses in original)

28. Through the means described in Paragraph 27, respondents have represented, expressly or by implication, that:

- A. Leptoprin causes weight loss of more than 20 pounds, including as much as 50, 60, or 147 pounds, in significantly overweight users; and
- B. Leptoprin causes loss of substantial, excess fat in significantly overweight users.

29. Through the means described in Paragraph 27, respondents have represented, expressly or by implication, that they possessed and relied upon a reasonable basis that substantiated the representations set forth in Paragraph 28, at the time the representations were made.

30. In truth and in fact, respondents did not possess and rely upon a reasonable basis that substantiated the representations set forth in Paragraph 28 at the time the representations were made. Therefore, the representation set forth in Paragraph 29 was, and is, false or misleading.

31. Through the means described in Paragraph 27, respondents have represented, expressly or by implication, that:

- A. clinical testing proves that Leptoprin causes weight loss of more than 20 pounds, including as much as 50, 60, or 147 pounds, in significantly overweight users; and
- B. clinical testing proves that Leptoprin causes loss of substantial, excess fat in significantly overweight users.

32. In truth and in fact:

- A. clinical testing does not prove that Leptoprin causes weight loss of more than 20 pounds, including as much as 50, 60, or 147 pounds, in significantly overweight users; and
- B. clinical testing does not prove that Leptoprin causes loss of substantial, excess fat in significantly overweight users.

Therefore, the representations set forth in Paragraph 31 were, and are, false or misleading.

33. Through the means described in Paragraph 27, respondents have represented, expressly or by implication, that:

- A. Anorex causes weight loss of more than 20 pounds in significantly overweight users; and
- B. Anorex causes loss of substantial, excess fat in significantly overweight users.

34. Through the means described in Paragraph 27, respondents have represented, expressly or by implication, that they possessed and relied upon a reasonable basis that substantiated the representations set forth in Paragraph 33, at the time the representations were made.

35. In truth and in fact, respondents did not possess and rely upon a reasonable basis that substantiated the representations set forth in Paragraph 33 at the time the representations were made. Therefore, the representation set forth in Paragraph 34 was, and is, false or misleading.

PediaLean Product for Weight Loss in Children

36. Respondents have disseminated or have caused to be disseminated advertisements and labeling for PediaLean, including but not necessarily limited to the attached Exhibits K - L. PediaLean advertisements have appeared in magazines such as Redbook, Let's Live, and Healthy Living, and in tabloids such as Star and The Enquirer. Advertisements for PediaLean contain the following statements:

- A. Exhibit K - PediaLean Magazine Advertisement

“Now there's hope for you and your Overweight Child

At Last! A Clinically Proven, Safe & Effective, All-natural Weight Control Compound Designed, Tested and Developed Specifically for Children... Discovered in Europe and Now Available in America.

If you're the parent or grandparent of one of the more than 11 million overweight or obese school-aged children in the United States, you know the pain and embarrassment this growing 'Epidemic' can cause. But now, a revolutionary, all-natural weight control compound offers new hope. It's called PediaLean: the first and only clinically proven, safe, and effective weight-control compound designed for children and adolescents... and it's finally available in America exclusively from Klein-Becker usa.” (Emphasis and ellipses in original)

“Klein-Becker's proprietary micronization process guarantees that PediaLean is not only safe, but is the one and only weight-control compound designed, manufactured, and clinically proven safe and effective for use by overweight children and adolescents.

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Does PediaLean work? You bet it does! In a well-controlled double-blind clinical trial, each and every child who used PediaLean as directed lost a significant amount of excess body weight... a success rate of 100%.”

“Published Medical Studies Don’t Lie...Clinically Proven Safe and Effective
Children who used PediaLean along with a healthy, but not calorie-reduced diet and modest exercise lost an incredible 20% of their excess body weight. Those who followed the same diet and exercise program, but did not take PediaLean, failed to lose any significant excess weight at all. In other words, the only difference between success and failure was PediaLean. See the actual study at www.WeightLossForChildren.com.”
(Ellipses in original)

B. Exhibit L - PediaLean Website <www.pedialean.com>

“New Product Update by Klein-Becker usa

Weight Loss for Children

When Your Child Needs More Than Diet and Exercise.

European Breakthrough Gives Hope to You and Your Overweight Child!

If you’re the parent or grandparent of one of the more than 11 million overweight or obese school-aged children in the United States, you know the pain and embarrassment this growing ‘Epidemic’ can cause. But now, a revolutionary, all-natural weight control compound offers new hope. It’s called PediaLean: the first and only clinically proven, safe, and effective weight-control compound designed for children and adolescents... and it’s finally available in America exclusively from Klein-Becker usa.” (Ellipses in original)

“Klein-Becker’s proprietary micronization process guarantees that PediaLean is not only safe, but is the one and only weight-control compound designed, manufactured, and clinically proven safe and effective for use by overweight children and adolescents.

Does PediaLean work? You bet it does! In a well-controlled double-blind clinical trial, each and every child who used PediaLean as directed lost a significant amount of excess body weight... a success rate of 100%.” (Ellipses in original)

“Published Medical Studies Don’t Lie...Clinically Proven Safe and Effective”
(Ellipses in original)

“What does this mean in plain English?

Children who used PediaLean along with a healthy, but not calorie-restricted diet and modest exercise lost an incredible 20% of their excess body weight. Those who followed the same diet and exercise program, but did not take PediaLean, failed to lose any significant excess weight at all. In other words, the only difference between success and failure was PediaLean. (Individual results may vary.)”

37. Through the means described in Paragraph 36, respondents have represented, expressly or by implication, that PediaLean causes substantial weight loss in overweight or obese children.

38. Through the means described in Paragraph 36, respondents have represented, expressly or by implication, that they possessed and relied upon a reasonable basis that substantiated the representation set forth in Paragraph 37, at the time the representation was made.

39. In truth and in fact, respondents did not possess and rely upon a reasonable basis that substantiated the representation set forth in Paragraph 37 at the time the representation was made. Therefore, the representation set forth in Paragraph 38 was, and is, false or misleading.

40. Through the means described in Paragraph 36, respondents have represented, expressly or by implication, that clinical testing proves that PediaLean causes substantial weight loss in overweight or obese children.

41. In truth and in fact, clinical testing does not prove that PediaLean causes substantial weight loss in overweight or obese children. Therefore, the representation set forth in Paragraph 40 was, and is, false or misleading.

Expertise of Respondent Mowrey

42. Through the means described in Paragraph 27, respondents have represented, expressly or by implication, that respondent Mowrey is a medical doctor.

43. In truth and in fact, respondent Mowrey is not a medical doctor. Therefore, the representation set forth in Paragraph 42 was, and is, false or misleading.

44. The acts and practices of respondents as alleged in this complaint constitute unfair or deceptive acts or practices, and the making of false advertisements, in or affecting commerce in violation of Sections 5(a) and 12 of the Federal Trade Commission Act.

* * *

NOTICE

Notice is hereby give to each of the respondents hereinbefore named that the fifteenth day of September, 2004, at 10:00 a.m. o'clock, or such later date as determined by an Administrative Law Judge of the Federal Trade Commission, is hereby fixed as the time, and Room 532, Federal Trade Commission Building, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580 as the place when and where a hearing will be had before an Administrative Law Judge of the Federal Trade Commission, on the charges set forth in this complaint, at which time and place you will have the right under the Federal Trade Commission Act to appear and show cause why an order

should not be entered requiring you to cease and desist from the violations of law charged in this complaint.

You are notified that the opportunity is afforded you to file with the Commission an answer to this complaint on or before the twentieth (20th) day after service of it upon you. An answer in which the allegations of the complaint are contested shall contain a concise statement of the facts constituting each ground of defense; and specific admission, denial, or explanation of each fact alleged in the complaint or, if you are without knowledge thereof, a statement to that effect. Allegations of the complaint not thus answered shall be deemed to have been admitted.

If you elect not to contest the allegations of fact set forth in the complaint, the answer shall consist of a statement that you admit all of the material allegations to be true. Such an answer shall constitute a waiver of hearings as to the facts alleged in the complaint, and together with the complaint will provide a record basis on which the Administrative Law Judge shall file an initial decision containing appropriate findings and conclusions and an appropriate order disposing of the proceeding. In such answer you may, however, reserve the right to submit proposed findings and conclusions and the right to appeal the initial decision to the Commission under Section 3.52 of the Commission's Rules of Practice for Adjudicative Proceedings.

Failure to answer within the time above provided shall be deemed to constitute a waiver of your right to appear and contest the allegations of the complaint and shall authorize the Administrative Law Judge, without further notice to you, to find the facts to be as alleged in the complaint and to enter an initial decision containing such findings, appropriate conclusions and order.

The following is the form of order which the Commission has reason to believe should issue if the facts are found to be as alleged in the complaint. If, however, the Commission should conclude from record facts developed in any adjudicative proceedings in this matter that the proposed order provisions as to Basic Research, L.L.C., a limited liability corporation; A.G. Waterhouse, L.L.C., a limited liability corporation; Klein-Becker usa, L.L.C., a limited liability corporation; Nutrasport, L.L.C., a limited liability corporation; Sovage Dermalogic Laboratories, L.L.C.; BAN, L.L.C., a limited liability corporation; Dennis Gay, individually and as an officer of the limited liability corporations; Daniel B. Mowrey, also doing business as American Phytotherapy Research Laboratory; and Mitchell K. Friedlander, might be inadequate to fully protect the consuming public, the Commission may order such other relief as it finds necessary or appropriate, including corrective advertising or other affirmative disclosure.

Moreover, the Commission has reason to believe that, if the facts are found as alleged in the complaint, it may be necessary and appropriate for the Commission to seek relief to redress injury to consumers, or other persons, partnerships or corporations, in the form of restitution and refunds for past, present, and future consumers and such other types of relief as are set forth in Section 19(b) of the Federal Trade Commission Act. The Commission will determine whether to

apply to a court for such relief on the basis of the adjudicative proceedings in this matter and such other factors as are relevant to consider the necessity and appropriateness of such action.

ORDER

DEFINITIONS

For purposes of this order, the following definitions shall apply:

1. "Commerce" shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.
2. "Competent and reliable scientific evidence" shall mean tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.
3. "Covered product or service" shall mean any service, program, dietary supplement, food, drug, or device.
4. "Endorser" and "endorsement" shall mean as defined in 16 C.F.R. 2.55.0(b).
5. "Food," "drug," "device," and "cosmetic" shall mean as "food," "drug," "device," and "cosmetic" are defined in Section 15 of the Federal Trade Commission Act, 15 U.S.C. § 55.
6. Unless otherwise specified, "respondents" shall mean Basic Research, L.L.C.; A.G. Waterhouse, L.L.C.; Klein-Becker usa, L.L.C.; Nutrasport, L.L.C.; Sovage Dermalogic Laboratories, L.L.C.; BAN, L.L.C., and each of the above's successors and assigns, and their officers, agents, representatives, and employees; Dennis Gay, individually and as an officer of the limited liability corporations; Daniel B. Mowrey; and Mitchell K. Friedlander, and each of the above's agents, representatives, and employees.
7. "Substantially similar product" shall mean any product that is substantially similar in ingredients, composition, and properties.

I.

IT IS ORDERED that respondents, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of Dermalin-APg, Cutting Gel, Tummy Flattening Gel, Leptoprin, Anorex, PediaLean, or any other covered product or service, in or affecting

commerce, shall not represent, in any manner, expressly or by implication, including through the use of the names "Cutting Gel," "Tummy Flattening Gel," "Anorex" and "PediaLean," or through the use of endorsements, that such product causes weight or fat loss, unless, at the time the representation is made, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

II.

IT IS FURTHER ORDERED that respondents, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any covered product or service, in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, including through the use of endorsements, about the health or weight loss benefits, performance, safety, or efficacy of such product or service, unless, at the time the representation is made, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

III.

IT IS FURTHER ORDERED that respondents, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any product, service, or program in or affecting commerce, shall not misrepresent, in any manner, expressly or by implication, including through the use of endorsements, the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

IV.

IT IS FURTHER ORDERED that respondents, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of Leptoprin, Anorex, or any other product, service, or program in or affecting commerce, shall not misrepresent, in any manner, expressly or by implication, including through the use of endorsements:

- A. That respondent Daniel B. Mowrey is a medical doctor; or
- B. The profession, expertise, training, education, experience or qualifications of Mowrey or any other endorser.

V.

Nothing in this order shall prohibit respondents from making any representation for any drug that is permitted in labeling for such drug under any tentative final or final standard

promulgated by the Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration.

VI.

Nothing in this order shall prohibit respondents from making any representation for any product that is specifically permitted in labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990.

VII.

IT IS FURTHER ORDERED that respondents shall, for five (5) years after the last date of dissemination of any representation covered by this order, maintain and upon request make available to the Federal Trade Commission for inspection and copying:

- A. All advertisements and promotional materials containing the representation;
- B. All materials that were relied upon in disseminating the representation; and
- C. All tests, reports, studies, surveys, demonstrations, or other evidence in their possession or control that contradict, qualify, or call into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

VIII.

IT IS FURTHER ORDERED that respondents shall deliver a copy of this order to all current and future principals, officers, directors, and managers, and to all current and future employees, agents, and representatives having responsibilities with respect to the subject matter of this order, and shall secure from each such person a signed and dated statement acknowledging receipt of the order. Respondents shall deliver this order to current personnel within thirty (30) days after the date of service of this order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities.

IX.

IT IS FURTHER ORDERED that respondents Basic Research, L.L.C.; Klein-Becker usa, L.L.C.; Nutrasport, L.L.C.; Sovage Dermalogic Laboratories, L.L.C.; and BAN, L.L.C., and each of the above's successors and assigns, shall notify the Commission at least thirty (30) days prior to any change in the limited liability corporation(s) that may affect compliance obligations arising under this order, including but not limited to a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor corporation; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this

order; the proposed filing of a bankruptcy petition; or a change in the corporate name or address. Provided, however, that, with respect to any proposed change in the corporation about which respondent learns less than thirty (30) days prior to the date such action is to take place, respondent shall notify the Commission as soon as is practicable after obtaining such knowledge. All notices required by this Part shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580.

X.

IT IS FURTHER ORDERED that respondents Dennis Gay, Daniel B. Mowrey, and Mitchell K. Friedlander, for a period of ten (10) years after the date of issuance of this order, shall notify the Commission of the discontinuance of their current business or employment, or of their affiliation with any new business or employment. The notice shall include the respondent's new business address and telephone number and a description of the nature of the business or employment and his duties and responsibilities. All notices required by this Part shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580.

XI.

IT IS FURTHER ORDERED that respondents shall, within sixty (60) days after the date of service of this order, and at such other times as the Federal Trade Commission may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which they have complied with this order.

XII.

This order will terminate twenty (20) years from the date of its issuance, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; provided, however, that the filing of such a complaint will not affect the duration of:

- A. Any Part in this order that terminates in less than twenty (20) years;
- B. This order's application to any respondent that is not named as a defendant in such complaint; and
- C. This order if such complaint is filed after the order has terminated pursuant to this Part.

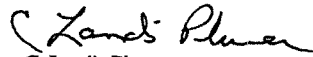
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Provided, further, that if such complaint is dismissed or a federal court rules that the respondent did not violate any provision of the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order will terminate according to this Part as though the complaint had never been filed, except that the order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

IN WITNESS WHEREOF, the Federal Trade Commission has caused this complaint to be signed by its Secretary and its official seal to be hereto affixed at Washington, D.C. this fifteenth day of June, 2004.

By the Commission.


C. Landis Plummer
Acting Secretary

SEAL:

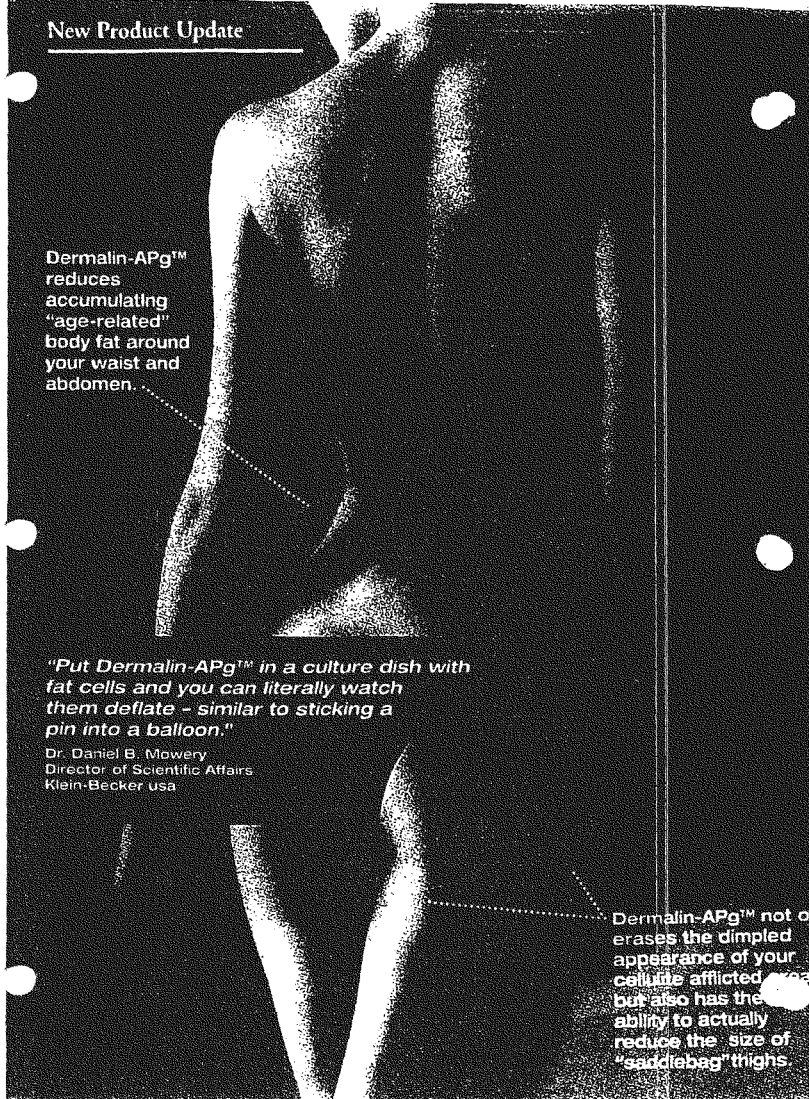
New Product Update

Dermalin-APg™
reduces
accumulating
"age-related"
body fat around
your waist and
abdomen.

*"Put Dermalin-APg™ in a culture dish with
fat cells and you can literally watch
them deflate - similar to sticking a
pin into a balloon."*

Dr. Daniel B. Mowery
Director of Scientific Affairs
Klein-Becker usa

Dermalin-APg™ not only
erases the dimpled
appearance of your
cellulite afflicted areas
but also has the
ability to actually
reduce the size of
"saddlebag" thighs.



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Dermalin-APg™: The next generation transdermal fat emulsifier

Penetrating Gel Emulsifies Fat On Contact

Dissolves Deep-Stored Body Fat Wherever Applied.

It was October, 1993, in Milwaukee, Wisconsin. More than 400 of the world's foremost weight loss scientists gathered to discuss the latest research at the annual meeting of the prestigious North American Association for the Study of Obesity. Ordinarily not too many people, outside this elite group of experts, would have cared.

But then something extraordinary happened. The results of a double-blind clinical trial were made public for the first time - a specially applied compound that could actually penetrate the skin and shrink a woman's thigh.

Because the paper was being presented by Drs. George Bray and Frank Greenway of the Pennington Biomedical Research Center, two of this country's most respected scientists, even the most skeptical attendee was in a hurry to get their hands on a sample of the active substance. And for good reason, the results of the study were undeniable.

The next day headlines around the world screamed: "Fitness...ers Discover 'Thigh-Shrinking Compound.'" News reports of a "Fat Loss Compound That Really Works!" and a "Miracle Substance That Melts Stubborn Fat On Contact!" filled the newspapers. No less than the Washington Post,

Fast Forward Seven Years...

"I call our formula a 'cellulite' cream is a misnomer," says Klein-Becker's Dr. Mowery. "Dermalin-APg's™ unique transdermal 'gel' formulation releases fat stores from any problem area. When the fat is released from the back of a woman's thigh, the dimpled appearance disappears because tension on the connective tissue is reduced as stored 'deposit' fat is released. However, when the gel is applied to the tummy, waist or hips, a dramatic reduction of stored body fat occurs, even though cellulite isn't an issue."

The Miracle of Dermalin-APg™

Dermalin APg™ permits you to spot reduce. Put it on your thighs - slimmer thighs. Over thirty and getting thick around the middle? Just apply Dermalin APg's™ transdermal gel to your waist or tummy and watch them shrink in size within a matter of days. You can even apply Dermalin-APg™ to your double chin. Wherever you've got those unsightly lumps and bumps, apply Dermalin-APg™ and they're gone.



So What's The Catch?

There are two. While Dermalin-APg™ forces the fat out of adipose tissue cells and into the blood stream to be used as energy, the fat doesn't just disappear. You have to help by increasing physical activity or decreasing caloric intake so the fat isn't redeposited.

Secondly, you can't rub Dermalin-APg™ all over your body at the same time. There is simply no way for your body to utilize all the newly released fat. Therefore, "choose your most problematic areas first," suggests Dr. Bruce Frome, a member of the Bray-Greenway team and co-administrator of the patented active formula. "Use the product until you get the desired results, then move on, one problem area at a time, until you've literally melted the fat and molded your body to a more pleasing shape."

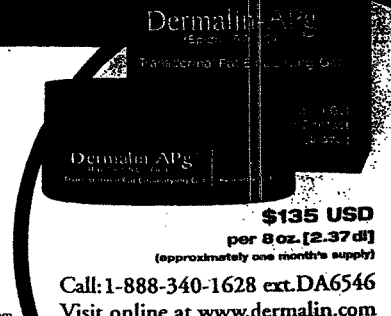
Shrink Hips, Thighs, Waist And Tummy... Even Your Double Chin.

dubbed it "The Dream Cream." **Could It All Be True?**

Frankly, this is where the real story begins. As with so many new discoveries, the most efficient dosage level and optimal delivery mechanism had yet to be determined. In other words, in 1993, the scientists had discovered a new fat-dissolving ingredient, but didn't have a stable, or effective base formula to make it work quickly on all parts of the body. In fact, that would take another seven years to perfect.

But that didn't stop the knockoff artists from crawling out of the woodwork. By early 1994, there were scores of advertisements for so-called "lumps" creams. Thousands of women flocked to cosmetic counters, plunking down millions, only to be disappointed. So-called cellulite creams became a joke.

Limited quantities make Dermalin APg™ difficult to find. Call your local supplement retailer or pharmacy for current availability. For additional information visit online at www.dermalin.com or call 1-888-340-1628 ext. DA6546



\$135 USD
per 8 oz. [2.37dl]
(approximately one month's supply)

Call: 1-888-340-1628 ext. DA6546
Visit online at www.dermalin.com



Klein-Becker USA

www.kleinbeckerusa.com



Exhibit B











Featured Products

Specialized Weight Control and Life Enhancement Formulations

Check Out Our Sport Nutrition Products!

| | |
|---|--|
| <p>Weight Control For Children</p>  <p>PediaLean™
Specifically Developed For the Weight Loss Needs of Children Ages 6-16</p> | <p>NEW • NEW • NEW</p>  <p>StriVectin-SD™
Penetrating Cream Repairs Existing Stretch Marks in Weeks</p> |
|---|--|

Specialized Weight Control Formulations

| | | | |
|---|---|---|---|
| <p>Transdermal Emulsifying Gel</p>  <p>Dermalin-APg™</p> | <p>Do You Need To Lose Over 20 lbs?</p>  <p>Anorex™</p> | <p>Are You Sensitive to Stimulants?</p>  <p>Anorex-SF™</p> | <p>Solution for Lower Body (Pear-Shaped) Adiposity?</p>  <p>Luprinol™</p> |
| <p>Prevent Breast Shrinkage Due To Weight-Loss</p>  <p>Mamrafin-ARa™</p> | <p>Provides Thyroid Support During Dieting</p>  <p>Thyrovarin™</p> | <p>Increased Oxygen Saturation – Increased Endurance</p>  <p>Oxydrene™</p> | <p>Increased Sex Drive For You and Your Partner</p>  <p>Testro el™</p> |

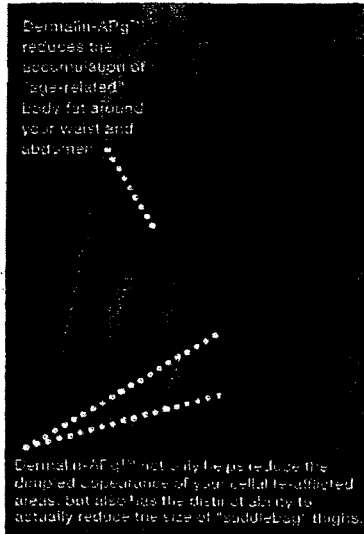
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Dermalin-APg

008
Page 1 of 2

Dermalin-APg™ The next-generation transdermal fat emulsifying gel



or call 1-888-340-1628 Ext. KBWEB

Penetrating Gel Emulsifies Fat On Contact

Dissolves Deep-Stored Body Fat
Wherever Applied.

It was October, 1993 in Milwaukee, Wisconsin. More than 400 of the world's foremost weight loss scientists gathered to discuss the latest research at the annual meeting of the prestigious North American Association for the Study of Obesity.

Ordinarily not too many people outside this elite group of experts would have cared. But then something extraordinary happened. The results of a double-blind clinical trial were made public for the first time — a topically applied compound that could actually penetrate the skin and shrink a woman's thigh.

Because the paper was being presented by two of this country's most respected scientists, even the most skeptical attendees were in a hurry to get their hands on a sample of the active substance. And for good reason — the results of the study were undeniable.

The very next day headlines around the world screamed: "Researchers Discover Thigh-Shrinking Compound." News reports of a "Fat Loss Compound That Really Works!" and a "Miracle Substance That Melts Stubborn Fat On Contact!" filled the airwaves. No less than the famed Washington Post dubbed it....."The Dream Cream."

Frankly, this is where the real story begins. As with so many new discoveries, the most efficient dosage level and optimal delivery mechanism had yet to be determined. In other words, in 1993, scientists had discovered a new fat-dissolving agent, but didn't have a stable or effective base formula to make it work quickly on all parts of the body. In fact, that would take another seven years to perfect.

But that didn't stop the knockoff artists from crawling out of the woodwork. By early 1994, there were scores of advertisements for so-called "cellulite" creams. Thousands of women flocked to cosmetic counters, plunking down millions, only to be disappointed. So-called cellulite creams became a joke.

Fast-Forward Seven Years...

"To call our formula a 'cellulite' cream is a misnomer," says Klein-Becker USA's Dr. Mowrey. "Dermalin-APg™'s unique transdermal gel formulation releases fat stores from any problem area. When the fat is released from the back of a woman's thigh, the dimpled appearance disappears because tension on the connective tissue is reduced as stored 'depot' fat is released. However, when the gel is applied to the tummy, waist or hips, a dramatic reduction of stored body fat occurs, even though cellulite isn't an issue."



Dermalin-APg



"Put Dermalin-APg™ in a culture dish with fat cells and you can literally watch them deflate – similar to sticking a pin into a balloon."

Dr. Daniel B. Mowrey, Director of Scientific Affairs Klein-Becker usa

The Miracle of Dermalin-APg™

Dermalin-APg™ permits you to spot reduce. Put Dermalin-APg™ on your thigh, it goes to work directly on your thigh. Over thirty and getting thick around the middle? Just apply Dermalin-APg's transdermal gel to your waist or tummy and watch them shrink in size within a matter of days. You can even apply Dermalin-APg™ to your double chin. Wherever you've got those unsightly lumps and bumps, apply Dermalin-APg and they're gone.

"At \$135.00 a bottle it better be good..."

So What's The Catch?

There are two. While Dermalin-APg™ forces the fat out of adipose tissue cells and into the bloodstream to be used as energy, the fat doesn't just disappear. You have to help by increasing physical activity or decreasing caloric intake so the fat isn't redeposited.

Secondly, you can't rub Dermalin-APg™ all over your body at the same time. There is simply no way for your body to utilize all the newly released fat. Therefore, as one member of the original research team suggests, "choose your most problematic area first ... use the product until you get the desired results, then move on, one problem area at a time, until you've literally melted the fat and molded your body to a more pleasing shape." We wholeheartedly agree.

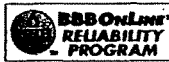
Money-Back Guarantee

Of course, Dermalin-APg™ comes with Klein-Becker's 100% Unconditional Money-Back Guarantee: if for any reason you are not totally satisfied with Dermalin-APg™, just return the empty bottle within 30 days for a full, prompt refund... no questions asked!

or call 1-888-340-1628 Ext. KBWEB

"Share Your Success Story"

Home | Lueminol | Anorex | Anorex-SE | Orlistat | TestoGel | Mamralin | Thyrozarin | PadiLean | SiroVascin



521

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Exhibit C

NUTRASPORT™

Epidril (10% Solution)

CUTTING GEL™

Transdermal

Muscle Defining

Compound

**Penetrating Gel
for the Visible Reduction
of Surface Body Fat**

*Protected by United States
Patents 4,525,859 and 4,588,724*

NET WT. 4 oz.

NUTRASPORT™

Before using CUTTING GEL on a regular basis, test CUTTING GEL on a small area of your forearm. If extreme redness/rash or itching occur, discontinue use and call our customer service department at: 1-800-698-5153.

- Apply CUTTING GEL once or twice daily (do not exceed two applications per 24 hour period).
- Focus on one targeted area at a time (i.e., abs, quads, triceps, etc.) until you achieve desired results.
- Use sparingly. An amount equal in size to a small marble should be sufficient to cover your entire abdominal region, both shoulders, or the back of one thigh.
- Vigorously rub CUTTING GEL into the target area for approximately 45 seconds or until CUTTING GEL is completely absorbed.

CUTTING GEL

- It is best to apply CUTTING GEL just before your workout.
- As CUTTING GEL begins to work within your chosen target area, you may experience a moderate feeling of warmth... this is normal.
- CUTTING GEL's Lecithin-based gel formulation may appear honey-like (sticky) at first glance... it is not.

Lecithin, Octyl Palmitate, Water, Aminophylline, Isopropylparaben, Isobutylparaben, Butylparaben, Fragrance.

For additional information see booklet inside box.

Produced under U.S. Patent Nos. 4,525,359 and 4,588,724.

Store at controlled room temperature 15°-30°C / 59°-86°F

www.cuttinggel.com
Call toll-free: 1-800-898-5153

CUTTING GEL's patented, transdermal gel formulation has been specifically designed to reduce resistant surface body fat wherever applied. Apply CUTTING GEL to your abs, and your abs get ripped. Apply CUTTING GEL to your quads, your quads get ripped. Apply CUTTING GEL to your glutes, biceps, triceps, or lats, and the fat literally melts away, leaving pure, ripped muscle behind! And let's not forget, if you're a man over 40 and have a problem with "love handles" (or a woman developing a "post-menopausal tummy"), you can't live without CUTTING GEL!

You apply CUTTING GEL topically, directly to the specific areas that need extra definition. CUTTING GEL penetrates the skin and goes to work directly on stubborn fat cells, literally forcing them to release fat into the bloodstream to be burned as energy. Now you can finally get rid of that last concealing layer of ugly fat and get really cut!

Distributed by **NUTRASPORT**

Provo UT 84604 • Phone: 1-800-898-5153
Manufactured in the U.S.A.

Exhibit D

When pills, powders,
and exercise just don't get
you ripped... you need

CUTTING GEL™

(Epidril™ 100% Solution)

Transdermal
Muscle Defining
Compound

- Ripped Abs
- Ripped Pecs
- Ripped Glutes
- Ripped Everything

*"Transdermal
muscle-defining gels...
the future of fat-burning"*

All of us want to look ripped. Ripped abs, ripped pecs, ripped glutes... ripped everything. But for most of us, no matter how many pills we swallow, how many powders we mix, or how much we sweat at the gym, we just can't get rid of that spongy layer of surface body fat... the hard to get rid of layer of excess body fat that keeps you looking weak and ordinary. That is until now!

FACT CUTTING GEL... Gets Rid of Surface Body Fat!

Finally, there's Cutting Gel™, a unique, patented, transdermal gel that penetrates deep into the skin and dissolves stubborn body fat on contact. That's right! A clinically proven, transdermal gel that dissolves surface body fat wherever applied! It's called Cutting Gel™, and it's finally available in the United States in full clinical strength, without a prescription, and without annoying doctor's visits.

FACT CUTTING GEL... Goes to Work Directly on Your Abs, Biceps, Glutes, Pecs, or Anywhere Else You Rub It In!

Cutting Gel's™ patented, transdermal gel formulation has been specifically designed to reduce resistant surface body fat wherever applied. Apply Cutting Gel™ to your abs, and your abs get ripped. Apply Cutting Gel™ to your quads, your quads get ripped. Apply Cutting Gel™ to your glutes, biceps, triceps, or lats, and the fat literally melts away, leaving pure, ripped muscle behind! And let's not forget, if you're a man over 40 and have a problem with "love handles," you can't live without Cutting Gel™!

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Dissolves Surface Body Fat On Contact!

So what's the catch?

There are two. First, because Cutting Gel™ releases stored fat into the bloodstream to be used as energy, you have to help burn that released fat by exercising or reducing caloric intake so that free fat isn't redeposited. Second, you can't rub Cutting Gel™ all over your body at the same time. There is simply no way for your body to deal with that much newly released fat. So, start with the one area you think needs the most help, and use Cutting Gel™ until you get the desired results (usually about ten days). Then move on, one target area at a time, until you get that cut, rock-hard, attention-grabbing look you want and deserve!

FACT Clinically Proven, Full-Strength, Patented Formula!

"Put Cutting Gel™ in a culture dish with fat cells and you can literally pinch them deflate - similar to sticking a pin into a balloon."

Dr. Daniel B. Mowrey

FACT Get CUTTING GEL™ today! You will see the difference (and so will everyone else)!

Produced under exclusive license U.S. Pat Nos. 4,525,359 and 4,588,724

1-800-376-3913

www.CuttingGel.com

Distributed Exclusively by **NUTRASPORT™**

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Epidriol™ (Epidriol)

CUTTING GEL™

Transdermal Muscle Defining Compound

Penetrating Gel for the Visible Reduction of Surface Body Fat

Patented by United States Patents 4,525,359 and 4,588,724

NET WT. 4oz.

NUTRASPORT™

\$89.00

CUTTING GEL

100% NATURAL

527

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Exhibit E

Contact Us
Money-Back Guarantee

| | | | | |
|-------------------------------------|--|--|---------------------------------------|----------------------------|
| The Patented ECA Stack™ | Cutting Gel™ | Oxy Pills™ | Testroxin™ | NITROV |
| The "Granddaddy" of All Fat-Burners | Fat Emulsifying Gel | Deep Tissue Muscle Oxygenator | Topical Androgen Gel | Nighttime f |
| | | | | |
| Patented
Proven
Powerful | Ripped Glutes
Ripped Abs
Ripped Everything | Increased Strength
Increased Endurance
Increased Stamina | Muscle Mass
Strength
Definition | Grow n
Ov n
Yo |
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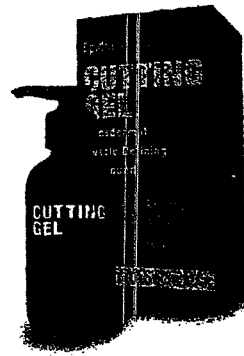


When pills, powders, and exercise just don't
get you ripped... get

CUTTING GEL™

[> Cutting Gel™ for Men](#)

[> Cutting Gel™ for Women](#)



[eca stack](#) | [cutting gel for men](#) | [cutting gel for women](#) | [oxy pills](#) | [testoxin](#) | [nitrovarin](#)
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When pills, powders, and exercise just don't
get you ripped... get

CUTTING GEL™

Or Call 1-800-996-3528
Ext. NSWEB

Transdermal Muscle Defining Compound

All of us want to look ripped. Ripped abs, ripped pecs, ripped glutes... ripped everything. But for most of us, no matter how many pills we swallow, how many powders we mix, or how much we sweat at the gym, we just can't get rid of that spongy layer of surface body fat... the hard to get rid of layer of excess body fat that keeps you looking weak and ordinary. That is until now!



FACT CUTTING GEL™ Gets Rid of Surface Body Fat!

Finally, there's Cutting Gel™, a unique, patented, transdermal gel that penetrates deep into the skin and dissolves stubborn body fat on contact. That's right! A clinically proven, transdermal gel that dissolves surface body fat wherever applied! It's called Cutting Gel™, and it's finally available in the United States in full clinical strength, without a prescription, and without annoying doctor's visits.

FACT CUTTING GEL™ Goes to Work Directly on Your Abs, Biceps, Glutes, Pecs, or Anywhere Else You Rub it In!

Cutting Gel's™ patented, transdermal gel formulation has been specifically designed to reduce resistant surface body fat wherever applied. Apply Cutting Gel™ to your abs, and your abs get ripped. Apply Cutting Gel™ to your quads, your quads get ripped. Apply Cutting Gel™ to your glutes, biceps, triceps, or lats, and the fat literally melts away, leaving pure, ripped muscle behind! And let's not forget, if you're a man over 40 and have a problem with "love handles" you can't live without Cutting Gel™! That extra edge and sets you apart from everyone else in the gym. Best of all, Cutting Gel™ gives you the confidence you need to get ahead and stay ahead as you finally experience the attention a great body demands!

So what's the catch?

There are two. First, because Cutting Gel™ helps release stored fat into the bloodstream to be used as energy, you have to help burn that released fat by exercising or reducing caloric intake so that free fat isn't redeposited. Second, you can't rub Cutting Gel™ all over your body at the same time. There is simply no way for your body to deal with that much newly released fat. So start with the one area you think needs the most help, and use Cutting Gel™ until you get the desired results (usually about ten days). Then move on, one target area at a time, until you get that cut, rock-hard, attention-grabbing look you want and deserve!

You will see the difference (and so will everyone else)!



Or Call 1-800-996-3528 Ext. NSWEB

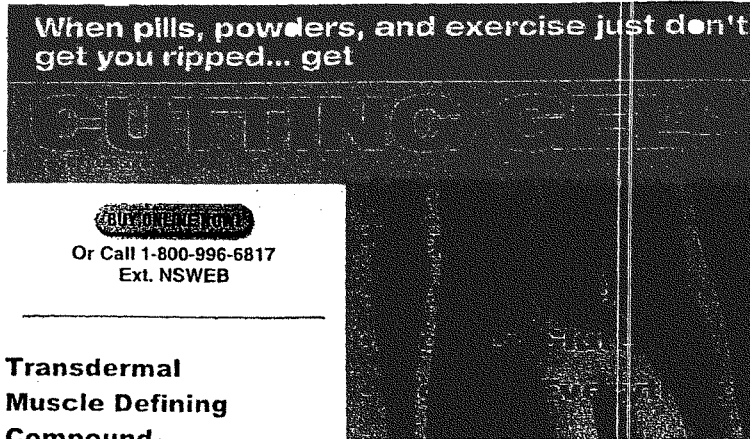
SHARE YOUR SUCCESS STORY



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When pills, powders, and exercise just don't get you ripped... get



**Or Call 1-800-996-6817
Ext. NSWEB**

**Transdermal
Muscle Defining
Compound**

All of us want flat, washboard stomachs, firm buns, and tight, smooth thighs. But no matter how many pills we swallow, or how much we sweat all over our Stairmaster®, we still can't get rid of that extra layer of body fat covering up the results of all our pain and hard work. That is until now!

FACT CUTTING GEL™ Gets Rid of Surface Body Fat!

Finally, there's Cutting Gel™, a patented, transdermal gel that penetrates deep into the skin to mobilize stubborn body fat on contact. That's right! A clinically proven, penetrating gel that reduces surface body fat wherever applied! It's called Cutting Gel™, and it's finally available throughout the United States... in its full undiluted strength.

FACT CUTTING GEL™ Goes to Work Directly on Your Abs, Thighs, Glutes, or Anywhere Else You Rub It In!

Cutting Gel's™ patented, transdermal gel has been specifically formulated to reduce stubborn, excess body fat on contact. Just apply Cutting Gel™ directly to any resistant pocket of surface body fat (the fat around your abs, thighs, hips, or buttocks) and Cutting Gel's™ transdermal formulation penetrates the skin, mobilizing stored fat and leaving only lean, sexy curves behind!

FACT Cutting Gel™ Reduces Surface Fat and Exposes the Toned Muscle Beneath!

You apply Cutting Gel™ topically, directly to the specific area that requires extra definition. Cutting Gel™ penetrates the skin and immediately goes to work, flattening overbloated fat cells by forcing them to release trapped fat into the bloodstream to be burned as energy.

FACT Clinically Proven, Patented Formula!

Cutting Gel's™ clinically proven, patented formula is the only transdermal fat-emulsifying gel directed exclusively to bodybuilders and fitness enthusiasts. NutraSport distributes Cutting Gel™ throughout the United States under exclusive license from Klein-Becker USA. Cutting Gel™ helps give you that extra edge and sets you apart from everyone else in the gym. Best of all, Cutting Gel™ gives you the confidence you need to get ahead and stay ahead as you finally experience the attention a great body demands!

So What's the Catch?

There are two. First, because Cutting Gel™ releases stored fat into the bloodstream to be used as energy, you have to help burn that released fat by exercising or reducing caloric intake so that free fat isn't redeposited. Second, you can't rub Cutting Gel™ all over your body at the same time. There is simply no way for your body to deal with that much newly released fat. So start with the one area you think needs the most help, and use Cutting Gel™ until you get the desired results (usually about ten days). Then move on, one target area at a time, until you get that toned, tight, sexy look you want and deserve!

Get CUTTING GEL™ Today! You Will See the Difference (and So Will Everyone Else)!



Or Call 1-800-996-6817 Ext. NSWEB

SHARE YOUR SUCCESS STORY



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Exhibit F

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New Product Update from Savage Dermologic Laboratories™

PATENTED TOPICAL GEL REDUCES TUMMY FAT!

"This new, highly concentrated formula allows for precise, targeted delivery... making it the first true spot-reducing gel capable of effective reduction of dense abdominal fat."

Dr. Nathalie Chaveau, PhD, RD, Director of Women's Health, Savage Dermologic Laboratories™

No part of the female figure is sexier or more attractive than a flat, sculpted stomach. But maintaining a sleek, shapely midsection is easier said than done — particularly if you're over 25.

Don't blame yourself if your tummy has gotten suddenly out of proportion — blame the natural makeup of a woman's body. Beginning in your early 20's, or after pregnancy, nature conspires to redistribute adipose (fat) tissue... even if you exercise, diet, and maintain an ideal weight, your body shape changes.

Unfortunately, the first sign of the natural aging process happens in your midsection — that infuriating "tummy pooch" that utterly ruins your look, your wardrobe, and your confidence. But there's a beautiful solution — Savage® Tummy Flattening Gel™, the topically applied, deep-penetrating concentrate specifically designed to mobilize the persistent, stubborn fat that makes your tummy bulge.



the breakdown of regional fat cells. Savage Tummy Flattening Gel is a quick-penetrating gel so thick, concentrated, and smooth some people call it a "fat burning paste"... everyone who's used it simply calls it a "miracle."

The "Fine Print"

As with all Epidril formulations, there are two caveats. First, because Savage Tummy Flattening Gel works by forcing stored fat out of abdominal fat cells and into the bloodstream to be burned as energy, you have to help burn off the released fat by exercising or decreasing caloric intake so circulating fat is not redeposited. Second, you might be tempted to use more than the recommended dosage of Savage Tummy Flattening Gel. Don't... there is simply no way for your body to deal with that much released fat.

See Visible Results in Approximately 19 Days. Guaranteed!

Use Savage Tummy Flattening Gel as directed, and you will begin to see dramatic, visible results in approximately 19 days. Remember, nothing builds more confidence than a youthful, flat, firm, trim tummy. Nothing. And the quickest way to capture a perfectly sculpted midsection is with the new, area-specific, clinically proven, super-concentrated Savage Tummy Flattening Gel. Guaranteed to work for you or your money back... no questions asked!

Savage Tummy Flattening Gel is available at select day spas and specialized cosmeceutical retailers, or call 1-800-917-8096 ext. TG165. Order today! Supplies are extremely limited.

Savage Tummy Flattening Gel... a formula you can trust, backed by an unconditional, money-back guarantee you can count on.

ORDER NOW!
24 HOURS/TOLL-FREE:
1-800-917-8096
EXT. TG165
\$119 USD
(four to six-week supply)

WWW.SOAVGE.COM

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CLINICALLY PROVEN*

How It Works — The Science

It is well documented that when beta adrenergic stimulants such as Epidril™ are added to a culture dish with adipose (fat) cells, the cells deflate as they release their stored fat — very similar to the way a balloon deflates when stuck with a pin. The evidence is conclusive. Epidril has been verified by two published clinical trials and has been awarded a United States Patent (No. 4,525,359).

Although many Epidril formulations have successfully targeted fat cells in the thighs and buttocks, researchers have just discovered something most women have known for years: abdominal fat ("Tummy Pooch") isn't "ordinary" fat... it's extremely difficult to target — in part because of its inherent structural density. So, although Epidril-containing gels have been proven to emulsify fat on contact, ordinary transdermal products are simply not powerful enough to precisely target resistant abdominal fat.

The Power of Savage Tummy Flattening Gel

The ultimate power of Savage Tummy Flattening Gel results from a patent-pending process that allows precise delivery of its ultra-concentrated Epidril base formulation to resistant areas of dense abdominal fat — selectively accelerating

*Clin. Ther. Vol 9 No 4 1987: 443-449; Other Res. Vol 3 Suppl 4 Nov 1995: 3615-6885
*All references to the term Savage refer to the full trade name of Savage Dermologic Laboratories™.

NOTE: Many of our clients who have experienced dramatic results with Savage Tummy Flattening Gel™ in an individual "before" picture, credit a possibly dermocosmetic ingredient. If you are seriously considering treatment, we strongly recommend that you consult a physician specializing and experienced in this topical technique.

SOVAGE
Dermologic Laboratories
A Division of Meiss Becker Corp.

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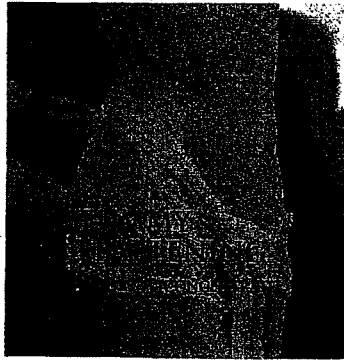
Exhibit G

ORDER NOW! | Lip Plumper | Breast Augmentation Serum



"This new, highly concentrated formula allows for precise, targeted delivery... making it the first true spot-reducing gel capable of effective reduction of dense abdominal fat."

Dr. Nathalie Cheveau, PhD, RD, Director of Women's Health, Savage Dermalogic Laboratories™



body shape changes.



Or Call 1-800-917-8096
Ext. SOVWEB

No part of the female figure is sexier or more attractive than a flat, sculpted stomach. But maintaining a sleek, shapely midsection is easier said than done — particularly if you're over 25.

Don't blame yourself if your tummy has gotten suddenly out of proportion — blame the natural makeup of a woman's body. Beginning in your early 20's, or after pregnancy, nature conspires to redistribute adipose (fat) tissue... even if you exercise, diet, and maintain an ideal weight, your

body shape changes. Unfortunately, the first sign of the natural ageing process happens in your midsection — that infuriating "tummy pooch" that utterly ruins your look, your wardrobe, and your confidence. But there's a beautiful solution — Savage Tummy Flattening Gel™... the topically applied, deep-penetrating concentrate specifically designed to mobilize the persistent, stubborn fat that makes your tummy bulge.

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Although many Epidril™ formulations have successfully targeted fat cells in the thighs and buttocks, researchers have just discovered something most women have known for years: abdominal fat ("Tummy Pooch") isn't "ordinary" fat... it's extremely difficult to target — in part because of its inherent structural density. So, although Epidril™ - containing gels have been proven to emulsify fat on contact, ordinary transdermal products are simply not powerful enough to precisely target resistant abdominal fat.

The Power of Söavage Tummy Flattening Gel

The ultimate power of Söavage Tummy Flattening Gel results from a patent-pending process that allows precise delivery of its ultra-concentrated Epidri™ base formulation to resistant areas of dense abdominal fat — selectively accelerating the breakdown of regional fat cells. Söavage Tummy Flattening Gel is a quick-penetrating gel so thick, concentrated, and smooth some people call it a "fat burning paste"... everyone who's used it simply calls it a "miracle."

The "Fine Print"

As with all Epidri™ formulations, there are two caveats. First, because Söavage Tummy Flattening Gel works by forcing stored fat out of abdominal fat cells and into the bloodstream to be burned as energy, you have to help burn off the released fat by exercising or decreasing caloric intake so circulating fat is not redeposited. Second, you might be tempted to use more than the recommended dosage of Söavage Tummy Flattening Gel. Don't... there is simply no way for your body to deal with that much released fat.

See Visible Results in Approximately 19 days, Guaranteed!

Use Söavage Tummy Flattening Gel as directed, and you will begin to see dramatic, visible results in approximately 19 days. Remember, nothing builds more confidence than a youthful, flat, firm, trim tummy. Nothing. And the quickest way to capture a perfectly sculpted midsection is with the new, area-specific, clinically proven, super-concentrated Söavage Tummy Flattening Gel. Guaranteed to work for you or your money back... no questions asked!



Or Call 1-800-917-8096 Ext. SÖWEB

Share Your Success Story



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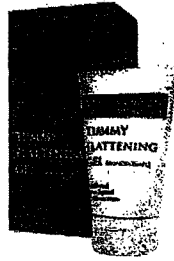
028

Savage

Page 1 of 1

SÖVAGE
Dermologic Laboratories

Tummy Flattening Gel



4 oz. tube
(Approx. 4 - 6 week supply)

\$119.00

**Add To
Basket Now!**

Save \$10.00
(2) 4 oz. tubes
(Approx. 8 - 12 week supply)

\$228.00

**Add To
Basket Now!**

Exhibit H
[videotape]

541

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030

Exhibit H-1

OFFICIAL TRANSCRIPT PROCEEDING

FEDERAL TRADE COMMISSION

MATTER NO. 0023300
TITLE BASIC RESEARCH, L.L.C.
DATE RECORDED: AUGUST 23, 2002
TRANSCRIBED: SEPTEMBER 18, 2003
PAGES 1 THROUGH 8

VIDEOTAPE - LEPTOPRIN

**FOR THE RECORD, INC.
603 POST OFFICE ROAD, SUITE 309
WALDORF, MARYLAND 20602
(301)870-8025**

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FEDERAL TRADE COMMISSION

I N D E X

| <u>VIDEOTAPE:</u> | <u>PAGE:</u> |
|-------------------|--------------|
| Leptoprin | 3 |

For The Record, Inc.
Waldorf, Maryland
(301) 870-8025

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FEDERAL TRADE COMMISSION

In the Matter of:)
Basic Research, LLC) Matter No. 0023300
)
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August 23, 2002

The following transcript was produced from a
live tape provided to For The Record, Inc. on September
15, 2003.

For The Record, Inc.
Waldorf, Maryland
(301)870-8025

4

1 **Period!**
2 **1-800-460-2990**
3 **www.leptoprin.com**
4 **MALE ANNOUNCER: Specifically developed for the**
5 **significantly overweight, backed by two United States**
6 **patents, two published clinical trials and an ironclad**
7 **100 percent money back guarantee. Leptoprin is simply**
8 **the most powerful, clinically proven weight control**
9 **compound available, period.**
10 **ON SCREEN: Before photo**
11 **203 lbs.**
12 **1-800-460-2990**
13 **www.leptoprin.com**
14 **RHONDA WILLIAMS: I've gone from 203 pounds**
15 **down to 153 pounds.**
16 **ON SCREEN: LOST 50 LBS.**
17 **Results May Not Be Typical**
18 **Rhonda Williams**
19 **Titusville, Florida**
20 **1-800-460-2990**
21 **www.leptoprin.com**
22 **RHONDA WILLIAMS: I went from a size 18 down to**
23 **a size 7 dress. If you had told me that I would have**
24 **dropped 50 pounds, I would never have believed it. And**
25 **now look at me.**

For The Record, Inc.
Waldorf, Maryland
(301) 870-8025

1 ON SCREEN: 1-800-460-2990
2 www.leptoprin.com
3 FEMALE ANNOUNCER: If you're one of those
4 people who constantly worry about five or six vanity
5 pounds, Leptoprin is not for you. Leptoprin is much too
6 expensive and much too powerful for the casual dieter.
7 But if you're one of the millions of Americans who are
8 20, 30, 50 pounds or more overweight, you need Leptoprin.
9 ON SCREEN: Before photo
10 404 lbs.
11 1-800-460-2990
12 www.leptoprin.com
13 TONY TRUPIANO: You don't have to be fat.
14 ON SCREEN: LOST 147 LBS.
15 Results May Not Be Typical
16 Tony Trupiano
17 Detroit, Michigan
18 1-800-460-2990
19 www.leptoprin.com
20 TONY TRUPIANO: Eight months ago I wore these
21 pants at 404 pounds. I've lost 147. I'm actually going
22 to frame these pants and put them on my wall. I am.
23 ON SCREEN: Before photo
24 235 lbs.
25 Amy Richardson

For The Record, Inc.
Waldorf, Maryland
(301) 870-8025

1 St. Louis, Missouri
2 1-800-460-2990
3 www.leptoprin.com
4 AMY RICHARDSON: I'm currently down to 175.
5 ON SCREEN: LOST 60 LBS.
6 Results May Not Be Typical
7 Amy Richardson
8 St. Louis, Missouri
9 1-800-460-2990
10 www.leptoprin.com
11 AMY RICHARDSON: My husband was floored. He
12 was amazed.
13 ON SCREEN: \$153 + sh
14 Full 30-Day Supply
15 Satisfaction Guaranteed!
16 OR YOUR MONEY BACK!
17 1-800-460-2990
18 www.leptoprin.com
19 MALE ANNOUNCER: So, if you're significantly
20 overweight, there's only one weight control compound
21 developed specifically for you. It's Leptoprin.
22 ON SCREEN: \$153 + sh
23 Full 30-Day Supply
24 Satisfaction Guaranteed!
25 OR YOUR MONEY BACK!

For The Record, Inc.
Waldorf, Maryland
(301)870-8025

7

1 Call Now! Toll Free!
2 1-800-460-2990
3 www.leptoprin.com
4 Consult your physician before
5 beginning any weight loss program
6 MALE ANNOUNCER: Call toll-free, 1-800-460-2990
7 to order your risk-free supply of Leptoprin. That's 1-
8 800-460-2990 right now. Leptoprin is guaranteed to work
9 for you or it costs you absolutely nothing.
10 So, when is a diet pill worth \$153 a bottle?
11 When it works, really works.
12 ON SCREEN: LOST 60 LBS.
13 1-800-460-2990
14 www.leptoprin.com
15 AMY RICHARDSON: It's like you're a new person.
16 ON SCREEN: LOST 147 LBS.
17 1-800-460-2990
18 www.leptoprin.com
19 TONY TRUPIANO: It's been an amazing journey.
20 ON SCREEN: LOST 50 LBS.
21 1-800-460-2990
22 www.leptoprin.com
23 RHONDA WILLIAMS: It works.
24 (The commercial was concluded.)
25

For The Record, Inc.
Waldorf, Maryland
(301) 870-8025

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CERTIFICATION OF TYPIST

MATTER NUMBER: 0023300
CASE TITLE: BASIC RESEARCH, L.L.C.
TAPING DATE: AUGUST 23, 2002
TRANSCRIPTION DATE: SEPTEMBER 18, 2003

I HEREBY CERTIFY that the transcript contained herein is a full and accurate transcript of the tapes transcribed by me on the above cause before the FEDERAL TRADE COMMISSION to the best of my knowledge and belief.

DATED: SEPTEMBER 18, 2003



ELIZABETH M. FARRELL

CERTIFICATION OF PROOFREADER

I HEREBY CERTIFY that I proofread the transcript for accuracy in spelling, hyphenation, punctuation and format.



KATHY J. DE MENT

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040

Exhibit I

AG WATERHOUSE

LIPTOPRIN

LIPTOPRIN

The... High... For... Pump... Greater...

CO

The advertisement features a dark, textured background. On the left side, there are three vertically stacked images: a box of Liptoprin, another box of Liptoprin, and a mechanical component. The text is arranged in columns, with the brand name 'AG WATERHOUSE' at the top. The product name 'LIPTOPRIN' is repeated twice. A large block of text is partially obscured by the dark background, with some legible words like 'The', 'High', 'For', 'Pump', and 'Greater'. At the bottom left, the letters 'CO' are visible.


WATERHOUSE
[Back To Home](#) | [Leptoprin-SF](#) | [Contact Us](#)

LEPTOPRIN™

Tired Of Diet Failure?

For the millions of Americans who are significantly overweight (more than 20 lbs. excess body weight and/or a BMI [body mass index] greater than 27) there is simply no longer any way to deny the genetic link to obesity. That's why ordinary diet pills and so-called "fat magnets" (if they work at all) so often fail to help the significantly overweight. The genetic link to obesity also means that repeated diet failure and chronic overweight is not your fault. Unless a weight-control compound addresses the genetic factor — and helps you overcome your genetic predisposition to obesity — your attempts at weight loss become no more than an exercise in futility (and a waste of time and money).

But now there's Leptoprin™ — the first weight-control compound designed to mitigate the profound effect that variations in the human genetic code have on the storage, use, and disposition of body fat.

Leptoprin™ is an extremely powerful anorectic agent and is not intended for use by the casual dieter who is merely attempting to shed five or ten "vanity" pounds. However, if substantial, excess body fat is adversely affecting your health and self-esteem, then it's time for you to discover Leptoprin™ — the first comprehensive weight-loss compound designed specifically to overcome your genetic predisposition.

Leptoprin™: The Result of an Extraordinary Collaboration

Leptoprin™ (or more correctly, its patent-protected core compound, Leptoprin™) is the result of an extraordinary collaborative effort between Dr. Daniel B. Mowrey, Director of Scientific Affairs, APRIL (American Phytotherapy Research Laboratory), Salt Lake City, Utah, and Dr. Edward G. Fey, University of Massachusetts Medical Center, Worcester, Massachusetts.

Though working independently, both doctors were keenly aware of the growing body of evidence linking obesity to certain genetic "markers." In September of 1998, Drs. Mowrey and Fey discovered each had access to compatible patents for variant methods of regulating obesity. As they familiarized themselves with each others' work, it became clear that combining the patented formulations could overcome genetic anomalies responsible for significant overweight. In fact, a recent report ("The Human Obesity Gene Map: The 1999 Update") published in *Obesity Research*, the official journal for the North American Association for the Study of Obesity, disclosed, "The number of genes and other markers associated or linked with human obesity phenotypes continues to expand and now reaches well over 200" (Vol. 8 No. 1 Jan. 2000, p.105). For example, gene FABP2, located at 4q28-q31, impacts abdominal fat, body mass index, and fat percentage — while others are more specific, such as gene INS, located at 11p15.5, which influences waist-to-hip ratios in obese women (pp.99-100).

Leptoprin™ Helps Overcome Genetic Link to Obesity

Leptoprin™ is the first product designed specifically for the significantly overweight by helping to overcome the genetic link to obesity. First, significantly overweight people have a genetically-based tendency to store excess dietary calories as body fat. Leptoprin™ helps overcome this tendency by effectively increasing the body's ability to destroy calories in



Or Call 1-800-569-5319
Ext. AGWWEB

**Powerful
Anorectic
Agent Helps
Overcome
Genetic
Link To
Obesity**

specialized "wasting cycles" within fat, muscle, liver and other body cells. Second, Leptoprin™ dramatically interferes with the process of converting calories to fat. Third, Leptoprin™ exerts a profound "lipolytic" action — it "mobilizes" stored fat, moving it out of the fat cell and thereby reducing the size of the fat cell mass. Fourth, Leptoprin™ inhibits the creation of new fat cells (yes, scientists now know that we create new fat cells throughout life). Fifth, Leptoprin™ increases the special process (called apoptosis) in the body that results in the destruction of immature fat cells before they become bloated with fat. Sixth, Leptoprin™ is especially effective in prolonging all of these actions in the body for the longest possible time. In short, Leptoprin™ is such a breakthrough discovery for the significantly overweight because Leptoprin™ aids in the defeat of destructive genetic influences on the cellular regulation and coordination of dietary calories; their intake, their conversion to body fat, and their removal from body fat stores. In other words, Leptoprin takes away "pre-programmed genetic failure" and gives the significantly overweight control over their lives once again.

Leptoprin™: Now Available in The United States Without A Prescription

In a report dated February 19, 2000, Dr. Mowrey stated "Although Leptoprin™ is much too powerful for the 'casual dieter,' the ability of Leptoprin™ to help people overcome the genetic implications of obesity leads me to believe Leptoprin™, and its base formulation Leptoprin™, is the most effective means of providing considerable benefit to that vast population of American men and women who are significantly overweight. That is, until science develops a reliable means of altering the genetic code." **If You're Significantly Overweight, You Need Leptoprin™** If you're significantly overweight (more than 30 lbs. of excess body weight and/or a BMI greater than 30), there is only one weight-control compound specifically designed for you... it's Leptoprin™. Patent-protected, clinically established, and guaranteed to help you become the thinner, healthier, and more active person you've always wanted to be.



Or Call 1-800-589-5319 Ext.

AGWEB

WARNINGS: Do not take this product if you are taking MAO inhibitors or a prescription drug for anticoagulation (thinning of the blood), diabetes, gout or arthritis or any other prescription drug unless directed by a physician. Do not take this product if you have any of the following conditions: high blood pressure, cardiovascular disease, thyroid disease, prostate problems or diabetes. Improper use may be hazardous to your health. Keep out of the reach of children. Consult a physician or licensed health care professional before using this product if you have, or have a family history of, heart disease, thyroid disease, diabetes, high blood pressure, recurrent headaches, depression or other psychiatric condition, glaucoma, difficulty in urinating, prostate enlargement, or seizure disorder, or if you are using any other dietary supplement or over-the-counter drug containing ephedrine, pseudoephedrine, or phenylpropanolamine (ingredients found in certain allergy, asthma, cough/cold and weight control products). Exceeding recommended serving may cause serious adverse health effects including heart attacks and stroke. Do not take if sensitive to or allergic to aspirin. Do not use if pregnant (it is especially important not to use aspirin during the last 3 months of pregnancy unless specifically directed to do so by a physician because it may cause problems in the unborn child or complications during pregnancy), nursing, have asthma, or have stomach problems (such as heartburn, upset stomach or stomach pain) that persist or recur, or if you have ulcers or bleeding problems, unless directed by a physician. If ringing in the ears or temporary loss of hearing occurs, consult a physician before taking again. Discontinue use and call physician or licensed health care professional immediately if you experience rapid heartbeat, dizziness, severe headache, shortness of breath or similar symptoms.

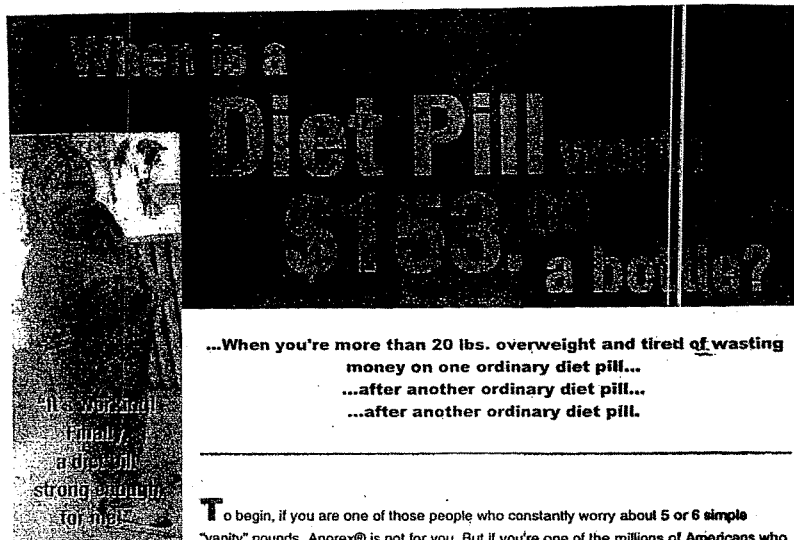
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Exhibit J



When is a
Diet Pill
...a diet pill?

...When you're more than 20 lbs. overweight and tired of wasting money on one ordinary diet pill...
...after another ordinary diet pill...
...after another ordinary diet pill.

It's not just
finally
a diet pill
strong enough
for me!

**HUMAN GENES
NOW!**

Or Call
1-800-996-6775
Ext. KBWEB

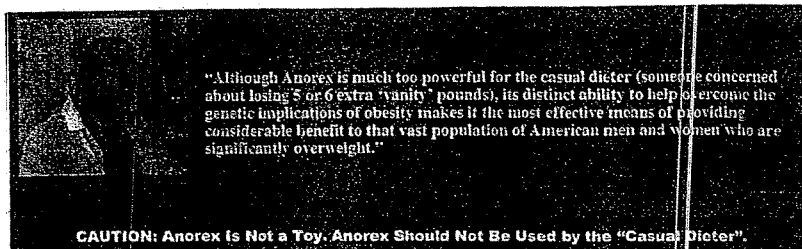
To begin, if you are one of those people who constantly worry about 5 or 6 simple "vanity" pounds, Anorex® is not for you. But if you're one of the millions of Americans who are significantly overweight (more than 20 lbs. of excess body weight and/or a BMI [body mass index] greater than 30) there is no longer any way to deny that ordinary diet pills and so-called "fat-burners" (if they work at all) so often fail to help the significantly overweight.

Why? Because ordinary diet pills fail to overcome the genetic link to obesity (a genetic link that can no longer be denied). Unless a weight-control compound addresses the genetic factor — and helps you overcome your genetic predisposition to obesity — your attempts at weight loss become no more than an exercise in futility (and a waste of time and money).

But now there's Anorex — the first weight-control compound designed to mitigate the profound effect that variations in the human genetic code have on the storage, use, and disposition of body fat. Anorex is an extremely powerful anorectic agent and is not intended for use by the casual dieter who is merely attempting to shed five or ten "vanity" pounds. However, if substantial, excess body fat is adversely affecting your health and self-esteem, then it's time for you to discover Anorex — the first comprehensive weight-loss compound designed specifically to overcome your genetic predisposition.

Anorex®: The Result of an Extraordinary Collaboration

Anorex (or more correctly, its patent-protected core compound, Leptoprin™) is the result of an extraordinary collaborative effort between Dr. Daniel B. Mowrey, Director of Scientific Affairs, Klein-Becker USA, Provo, Utah, and Dr. Edward G. Fey. Though working independently, both doctors were keenly aware of the growing body of evidence linking obesity to certain genetic "markers." In September of 1998, Drs. Mowrey and Fey discovered each had access to compatible patents for variant methods of regulating obesity. As they familiarized themselves with each others' work, it became clear that combining the patented formulations could overcome genetic anomalies responsible for significant overweight. In fact, a recent report ("The Human Obesity Gene Map: The 1999 Update") published in *Obesity Research*, the official journal for the North American Association for the Study of Obesity, disclosed, "The number of genes and other markers associated or linked with human obesity phenotypes continues to expand and now reaches well over 200" (Vol. 8 No. 1 Jan. 2000, p.105). For example, gene FABP2, located at 4q28-q31, impacts abdominal fat, body mass index, and fat percentage — while others are more specific, such as gene INS, located at 11p15.5, which influences waist-to-hip ratios in obese women (pp.99-100).



Anorex® Helps Overcome Genetic Link to Obesity

Anorex is the only weight-control compound designed to help you overcome your genetic link to obesity. **First:** If you are significantly overweight, you have a genetically based tendency to store excess dietary calories as body fat. Anorex helps overcome this tendency by effectively increasing your body's ability to destroy calories in specialized "wasting cycles" within fat, muscle, liver, and other body cells. **Second:** Anorex dramatically interferes with the process of converting calories to fat by upsetting genetically programmed reduction in the normal lipolytic cycle. **Third:** Anorex exerts a profound "lipolytic" action — it "mobilizes" stored fat, moving it out of the fat cell and thereby reducing the size of the fat cell mass. **Fourth:** Anorex reduces body fat mass in the significantly overweight by inhibiting the creation of new fat cells (yes, scientists now know that we create new fat cells throughout life) through the genetically programmed process called "adipose tissue cell differentiation." **Fifth:** Anorex destroys immature fat cells before they can become bloated by increasing the genetic factor recently identified as "apoptosis," or the genetically pre-programmed degeneration of fat cells. **Sixth:** Unlike ordinary diet pills that lose their effectiveness in a short period of time, the uniquely processed, patented compounds that make up the Anorex formula provide sustained reinforcement required to successfully overcome the genetic factors responsible for your chronic condition. **In short,** Anorex is a breakthrough for the significantly overweight because Anorex aids in the defeat of destructive genetic influences on the cellular regulation and coordination of dietary calories: their intake, their conversion to body fat, and their removal from body fat stores. In other words, Anorex takes away "pre-programmed genetic failure" and gives you control over your life once again.

Anorex®: Now Available in The United States Without Prescription

In a report dated February 19, 2000, Dr. Mowrey stated "Although Anorex is much too powerful for the 'casual dieter,' the ability of Anorex to help people overcome the genetic implications of obesity leads me to believe Anorex, and its base formulation Leptoprin, is the most effective means of providing considerable benefit to that vast population of American men and women who are significantly overweight. That is, until science develops a reliable means of altering the genetic code."

If You're Significantly Overweight, You Need Anorex®

If you're significantly overweight (more than 20 lbs. of excess body weight and/or a BMI greater than 30), there is only one weight-control compound specifically designed for you... it's Anorex. Patent-protected, clinically established, and guaranteed to help you become the thinner, healthier, and more active person you've always wanted to be... or it costs you absolutely nothing!

Or Call 1-800-996-6775 Ext. KBWEB

WARNINGS: Do not take this product if you are taking MAO inhibitors or a prescription drug for anticoagulation (thinning of the blood), diabetes, gout or arthritis or any other prescription drug unless directed by a physician. Do not take this product if you have any of the following conditions: high blood pressure, cardiovascular disease, thyroid disease, prostate problems or diabetes. Improper use may be hazardous to your health. Keep out of the reach of children. Consult a physician or licensed health care professional before using this product if you have, or have a family history of, heart disease, thyroid disease, diabetes, high blood pressure, recurrent headaches, depression or other psychiatric condition, glaucoma, difficulty in urinating, prostate enlargement, or seizure disorder, or if you are using any other dietary supplement or over-the-counter drug containing ephedrine, pseudoephedrine, or phenylpropanolamine (ingredients found in certain allergy, asthma, cough/cold and weight control products). If you are sensitive to ephedra or other stimulants, we recommend Anorex® SF Stimulant-Free. Exceeding recommended serving may cause serious adverse health effects including heart attacks and stroke. Do not take if sensitive to or if allergic to aspirin. Do not use if pregnant (it is especially important not to use aspirin during the last 3 months of pregnancy unless specifically directed to do so by a physician because it may cause problems in the unborn child or complications during pregnancy), nursing, have asthma, or have stomach problems (such as heartburn, upset stomach or stomach pain) that persist or recur, or if you have ulcers or bleeding problems, unless directed by a physician. If ringing in the ears or temporary loss of hearing occurs, consult a physician before taking again. Discontinue use and call physician or licensed health care professional immediately if you experience rapid heartbeat, dizziness, severe headache, shortness of breath or

similar symptoms.

"Share Your Success Story"



[Home](#) | [Andrex-SE](#) | [Dermalin](#) | [Oxystone](#) | [TessioGel](#) | [Mazrafin](#) | [Thyrozarin](#) | [EpidiLean](#) | [StriVectin](#)





Anorex®

"Weight Control Compound for the Significantly Overweight"



180 Capsules
(Approx. 30-Day Supply)

\$153.00

**Add To
Basket Now!**

360 Capsules
(Approx. 60-Day Supply)
SAVE \$15.00

\$291.00

**Add To
Basket Now!**

560

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Exhibit K

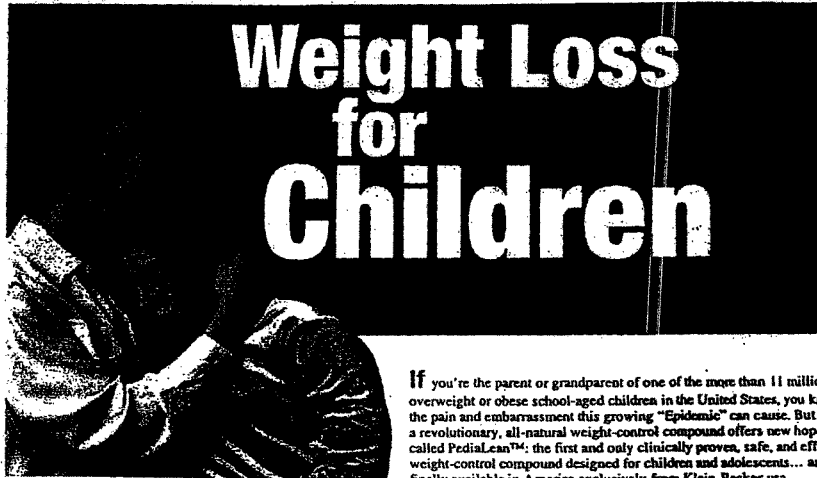
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Exhibit L

New Product Update by Klein-Becker usa™



If you're the parent or grandparent of one of the more than 11 million overweight or obese school-aged children in the United States, you know the pain and embarrassment this growing "Epidemic" can cause. But a revolutionary, all-natural weight-control compound offers new hope: called **PediaLean™**; the first and only clinically proven, safe, and effective weight-control compound designed for children and adolescents... and finally available in America exclusively from Klein-Becker usa.

What is PediaLean?

The active ingredient in **PediaLean™** is **Pediaropin™**, an all-natural micronized fiber concentrate derived from a plant (tuber) called *P. rivi*. This tuber has been used as a food source for thousands of years, but recently have scientists discovered an effective method for micro-processing the plant into a high-molecular-weight powder which make ultimately effective as a children's weight-control tool.

Klein-Becker's proprietary micronization process guarantees that **PediaLean™** is not only safe, but is the one and only weight-control compound designed, manufactured, and clinically proven safe and effective for use by overweight children and adolescents.

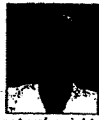
Does **PediaLean™** work? You bet it does! In a well-controlled double-blind clinical trial, each and every child who used **PediaLean™** as directed lost a significant amount of excess body weight... a success rate of 100%.

Professional Support and a Shoulder to Lean On

But **PediaLean™** is more than a great weight-loss formula for your child. It's a complete program of online support accessible from home, office, or anywhere you may be. Simply log on to www.WeightLossForChildren.com – the exclusive, easy-to-use, online service developed just for **PediaLean™** parents – and you'll find a place where all your questions will be answered by our panel of Doctors, Registered Dietitians, and Exercise Specialists... each dedicated to help you and your child succeed.

You'll also get full access to a personalized, easy-to-follow eating and exercise plan for your child based on gender, height, weight, and age. In addition, you will find information on all aspects of children's health, as well as practical solutions to difficult problems – like how to maintain good nutrition using today's "fast foods." But that's not all. The most

Or Call 1-800-617-6080 Ext. KBWEB



"It's just baby fat," "She'll grow out of it," and "Oh, he's just a growing boy"... these are the traditional excuses parents use to justify their child's overweight condition. The old excuses can no longer stand... especially now that there is a safe, natural weight-loss compound designed and developed specifically for children. Combined with a proactive program specifically created to support both parent and child – this natural weight-control compound resulted in significant weight loss in virtually every child studied. For your child's sake, for your sake, you must take advantage of this clinically proven solution."

Dr. Nathalie Chevreau, Ph.D., R.D., Director of Women's Health, Klein-Becker usa

**Published Medical Studies Don't Lie...
Clinically Proven Safe and Effective**

Study Design - To evaluate the efficacy of PediaLean's™ active compound, 23 children who completed the study, 12 males and 11 females of average age 10 years and 2 months (range 5.2-15.8), with average excess weight of 51±16%, were given PediaLean™ (in conjunction with a suggested normocaloric diet for the age and size of each child [about 15% protein, 30% lipids, 55% carbohydrates], and modest physical exercise), were then compared to 30 controls (average excess weight of 50.3±11.5%, average age of 11.8 years) for whom only diet and physical exercise were advised.

Results - After eight weeks, the 23 PediaLean™ children showed a drop of excess body weight from 51±16% to 41.3±15% (p<0.0005). Specifically, the obese girls went from an excess weight of 46.5±15.6% to 38.7±15.8% (p<0.0005) and the boys from

55.2±15.8% to 43.8±14.7% (p<0.005). In the Control Group, no meaningful decrease occurred (51±10.6% vs 49.3±12.4, p n.s.).

More importantly, the weight loss persisted. After a 4 - 6 month follow-up, the excess body weight of the children who used PediaLean™ continued to decrease significantly (PediaLean™ 40.1±14.9 Vs Control 49.2±13.3, p<0.005).

What does this mean in plain English?

Children who used PediaLean™ along with a healthy, but not calorie-restricted, diet and modest exercise lost an incredible 20% of their excess body weight. Those who followed the same diet and exercise program, but did not take PediaLean™, failed to lose any significant excess weight at all. In other words, the only difference between success and failure was PediaLean™. (Individual results may vary.)

popular feature of WeightLossForChildren.com is our wonderful "Pan Only" Message Board... a place of compassion and practical advice from a community of parents who have walked in your shoes and are there to help. They understand how you feel because they've been there themselves. There's even a free personalized weight-control plan for you at www.MyFreeDiet.com. You will love both sites!

Order PediaLean™ Today!

So order today, then log on to www.WeightLossForChildren.com to begin a new life for you and your child. By the way, as with all Klein-Becker formulations, PediaLean™ comes with our no-nonsense, 100% money-back guarantee: simply stated, if you're not completely satisfied with your PediaLean™ purchase, return the unused portion within 30 days for a full, prompt, and complete refund... no questions asked! Call now

Ingredients!

Directions For Use!

Go To WeightLossForChildren.com

Or Call 1-800-617-6080 Ext. KBWEB

Home | Laminol | Anorex | Anorex-SE | DermoBio | Qzytens | TestoGel | Mamratin | Thyrovarin | Stirovecin



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Q: What are the ingredients in PediaLean™, and are they safe?

A: Peditropin, the trade name for the active ingredient* in Klein-Becker's PediaLean™, is a proprietary, high molecular weight, micronized natural fiber concentrate and contains no ephedra or stimulants of any kind. The all-natural fiber concentrate is derived from a tuber (plant) called *P. rivi*ri. People have been using this tuber as a food source for thousands of years, but only recently have scientists discovered an effective method for micro-processing the plant in a way which makes it ultimately effective as a children's weight-control tool. The proprietary micronization process is exclusive to Klein-Becker USA, and guarantees that you and your child obtain the finest, highest-quality product available. Thus, PediaLean™ is not only safe, but is the one and only weight-control compound designed, manufactured, and clinically proven safe and effective for use by overweight children and adolescents.

*PediaLean™ also contains negligible amounts of an all-natural binding agent (rice flour) which aids in the encapsulation process.



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