AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES APPROPRIATIONS FOR 2012

HEARINGS

BEFORE A

SUBCOMMITTEE OF THE

COMMITTEE ON APPROPRIATIONS

HOUSE OF REPRESENTATIVES

ONE HUNDRED TWELFTH CONGRESS

FIRST SESSION

SUBCOMMITTEE ON AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES

JACK KINGSTON, Georgia, *Chairman*

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NOTE: Under Committee Rules, Mr. Rogers, as Chairman of the Full Committee, and Mr. Dicks, as Ranking Minority Member of the Full Committee, are authorized to sit as Members of all Subcommittees.

MARTIN DELGADO, TOM O'BRIEN, BETSY BINA, and ANDREW COOPER,
Staff Assistants

PART 3

Printed for the use of the Committee on Appropriations

PART 3—AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES APPROPRIATIONS FOR 2012

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AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES APPROPRIATIONS FOR 2012

FRIDAY, MARCH 11, 2011.

FOOD AND DRUG ADMINISTRATION

WITNESSES

MARGARET HAMBURG, M.D., COMMISSIONER, FOOD AND DRUGS, FOOD AND DRUG ADMINISTRATION

PATRICK MCGAREY, ASSISTANT COMMISSIONER FOR BUDGET, FOOD AND DRUG ADMINISTRATION

Mr. KINGSTON. The subcommittee will come to order. We are happy today and pleased to have the FDA Commissioner, Dr. Margaret Hamburg and Patrick McGarey, the Assistant Commissioner for Budget for FDA. And you have a whole team behind you. I know that. And we are looking forward to your testimony, although we have read it, you have submitted it. So you are welcome to just summarize it.

I wanted to make a few notes. Of paramount concern right now, of course, are the budget constraints, and I know that you guys were exempted from the President's freeze. But you still have a 16 percent increase and in some of the areas where you do have cuts, they are politically popular programs that will probably be put back in there by our friends in the other body, like the Natural Products Center, which is a $3½ million cut. We certainly would work with you on the House, at least this member would. But I don't know that the Senate is going to go along with that. And I am not sure that you have targeted it that way or not, but that was a concern of mine.

I also wanted to comment on a couple of other things that you have in your budget. You have pointed out that the FDA approves more drugs each year than all the other countries in the world, combined, and that you approve them faster than Europe does, and I think that is great. We are glad to hear it. This committee has heard so many times over the years about slow FDA drug approval. On medical device approval, you are still up there and moving along, which is good and positive. So we are glad to see that.

I am interested in the FDA track that allows the stakeholders and witnesses to work with you and get quarterly progress reports on items of interest. And I think that is something very good.

You have also saved Americans $140 billion a year in generic drugs, which I think is of interest. As you know, I have some real

questions on food safety in terms of what you actually could accomplish in terms of the model that was rushed through in December, even though it was a lot of hearings—there were some hearings, but the last 2 years were marred by the lack of bipartisan inclusion, and I would say that piece of legislation fell in that category as much as anything else; for example, the health care bill. So I think this Congress is going to really keep a very close eye on that. What is your number on that? Yeah, $382 million for that.

Dr. HAMBURG. Some of it from——

Mr. KINGSTON. Two hundred eighteen million in discretionary. And keep in mind, the money we are talking about for your entire budget in many respects is 100 percent borrowed. For every dollar we spend right now in America, 40 cents of it is borrowed. And if you look at the money that we spend, interest on the national debt, over $200 billion a year, and then put in retirement, health care, and national security, that is about all the budget that is paid for, which would be about 60 percent.

And spending is a bipartisan problem. It is something that both parties have their fingerprints all over, and we need to come to reckon about it. I was glad the President appointed a commission on it. We want to work with the President throughout this process. So much of the context right now as we look at various programs and the way you or any other agency spends its money is going to be in that prism of what is the best bang for the buck; what is our want; what is our need; what is a duplication? The GAO report was pretty significant and it came out and underscored a lot of duplication. So those are some of the things that are on my mind. And I want to yield to the ranking member, Mr. Farr.

Mr. FARR. Thank you very much, Mr. Chairman. And thank you very much, Dr. Hamburg, for being here.

I also want to thank you for meeting with the Leafy Green Marketing folks from my district. They were very impressed with the opportunity to talk to you. You have in your testimony one phrase that really struck me.

What you say is the FDA must do its job well, because there is simply no other agency to fall back on, no one to backstop us. Our role is unique and FDA must fulfill this unique role completely and responsibly. And I hope as we go through your budget that we can really help you do that role responsibly. There is too much at risk by doing it in a mediocre way.

So I don't have a lot of comments to make other than we are at a new turning point in American food safety history with the enactment of the bill and the implementation of the bill. A lot of agriculture out there has their eyes on you because they don't know whether the people in your Department know anything about agriculture. They know you know a lot about safeguarding drugs, prescription drugs, and other kinds of programs at FDA, but I think FDA is more known now on the medical side than on the food safety side. So it is a new era, but it is one that is critically important.

For example, Mr. Chairman, that I saw it firsthand. There was an E. Coli contamination of spinach that came from my district. The recall effort was voluntary, so anyone who had anything to do with spinach, whether driving in the trucks, planting in fields, on shelves, or in refrigerators at home, to get rid of it, no matter

where it was grown, because nobody knew where the contamination started. Today Americans don't consume as much spinach as they did before that recall. The contamination episode had a devastating effect. Growers lost hundreds of millions of dollars, and they didn't get covered by any kind of insurance.

So it is extremely important that we and your agency be the good cop. But it also has to be a smart one so that we don't wipe out industries. I appreciate you coming today and I look forward to talking further with you.

Mr. KINGSTON. Thank you, Mr. Farr. We have been joined by Chairwoman Emerson. And I am going to recognize her after Dr. Hamburg summarizes her testimony, if that is okay with you, Mr. Farr. She has got another subcommittee she is chairing. So the floor is yours.

OPENING STATEMENT

Dr. HAMBURG. Well, thank you, Chairman Kingston, Ranking Member Farr, and Congresswoman Emerson. I appreciate this opportunity to present the President's fiscal year 2012 budget for the Food and Drug Administration and to discuss our priorities for the coming year.

This hearing does come at a critical moment for our country and for our agency. We must be prepared to meet and capture the scientific challenges and global realities of our modern world. And the stakes for patients, consumers, our economy, and global economic competitiveness have never been higher.

Our agency is charged with an extremely significant task, to promote and protect the health of the American people. This includes ensuring the safety, effectiveness, and wholesomeness of products that the American people rely on in fundamental, sometimes lifesaving ways—drugs, vaccines, medical devices, our Nation's food supply and more. But it also includes working proactively to foster the scientific innovation that will lead to tomorrow's new breakthrough products.

Both roles are essential to delivering progress to the American people and both roles impact our economy by encouraging consumer confidence, growing key industries and creating jobs. And thanks to the support of the subcommittee, we have been able to see tangible evidence of that impact over the past year.

This year, we approved dozens of new drugs, vaccines for seasonal and pandemic flu and medical devices for hearing and vision loss, severe asthma, and to perform 3–D mammography screening. We applied cutting-edge genome sequencing to trace food-borne illness outbreaks. We launched a new system that identified 100 food safety problems in its first 7 months of operation. We collaborated with the National Oceanic and Atmospheric Administration to develop and perform screening tests to assure seafood safety and to reopen the Gulf Coast fisheries after the Deepwater Horizon oil spill. And that is just a snapshot of what the agency has done in the past year.

As you can see, FDA is charged with an enormous and unique set of tasks and, as was just mentioned, if we do not do our job and do it completely, there is no other agency or entity out there

to backstop us. That is why I am here to ask for your support of the fiscal year 2012 budget for the FDA.

The proposed budget includes $4.4 billion and identifies four priority initiative areas: Transforming Food Safety and Nutrition; Advancing Medical Countermeasures; Protecting Patients; and fostering FDA Regulatory Science and innovations and regulatory science facilities.

Compared to fiscal year 2010, the fiscal year 2012 budget represents an increase of almost $1.1 billion, $382 million in budget authority, and $694 million in user fees. And that amount for user fees includes $60 million for three new user fees that FDA is proposing.

In addition, in an effort to contribute to deficit reduction, we will undertake nearly $30 million in contract and administrative savings across the agency. These four initiatives are critical to our mission of protecting the public health and they also represent important opportunities for our food and medical product industries to grow and strengthen our economy. In other words, they will provide great return on investment for products, for people, and most importantly, for the public health.

And let me explain how. First, Transforming Food Safety and Nutrition Initiative, contains an increase of $326 million to build a stronger, more reliable food safety system that will protect American consumers. We will use these resources to aggressively implement the Food Safety Modernization Act that Congress passed in December. This landmark legislation provides FDA with the tools to establish a prevention-focused food safety system, placing the primary responsibility for prevention on the food producers and processors and leveraging the valuable work of FDA's State and local partners. FDA will also make sure that American families have the information they need to make more healthful food choices through menu and vending machine labeling.

For the Advancing Medical Countermeasures Initiative, FDA proposes $70 million. Medical countermeasures include drugs, vaccines, diagnostic tests and medical equipment that are needed to detect and respond to deliberate, biological, chemical, radiological or nuclear threats, as well as emerging infectious disease threats. All of these threaten the lives and safety of the American people. This investment will help accelerate the development of countermeasures that we truly need to meet critical national security and public health needs.

Third, Protecting Patients. This Initiative, for which we are proposing an increase of $123.6 million, will allow FDA to establish a pathway for approving life-saving biosimilar products. This could offer substantial savings to the Federal Government and private health care. This initiative also includes investments in scientific tools and partnerships to enhance the safety of increasingly complex drugs, medical devices, and biologics.

Fourth, the FDA Regulatory Science and Facilities Initiative contains an increase of $48.7 million to strengthen the core regulatory scientific capacity that supports all elements of FDA's mission, and will enable us to truly streamline and modernize our regulatory work by applying the best possible science, especially as we address more advanced therapies, complex devices and emerging tech-

nologies. It will also allow FDA to outfit and occupy the Center for Biologics and the Center for Drugs Life Sciences Biodefense Laboratory complex, which will play a critical role in shaping our strategies in response to pandemics, emerging infectious diseases, and deliberate biological threats. Even in these difficult times, the FDA's 2012 budget is essential to our ability to take meaningful science-based action on behalf of the American people.

With these investments and your support, I am confident that we can build on our past successes and better ensure our Nation's health. So thank you for the opportunity to testify, and I am happy to answer any questions that you may have.

[The information follows:]

STATEMENT OF MARGARET A. HAMBURG, M.D.
COMMISSIONER OF FOOD AND DRUGS
FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE SUBCOMMITTEE ON AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES
UNITED STATES SENATE

March 17, 2011

FOR RELEASE ONLY UPON DELIVERY

Introduction

Chairman Kohl, Ranking Member Blunt and members of the Subcommittee, I am Dr. Margaret Hamburg, Commissioner of the U.S. Food and Drug Administration. I am pleased to present the President's fiscal year 2012 budget request for the Food and Drug Administration (FDA).

For today's hearing, I am joined by Patrick McGarey, FDA's Assistant Commissioner for Budget and Norris Cochran, Deputy Assistant Secretary for Budget at the Department of Health and Human Services.

In my testimony today, I will outline the important initiatives in FDA's FY 2012 budget request to Congress. My testimony also highlights FDA's unique role in protecting public health and the value that FDA delivers for American taxpayers.

Unique Role of FDA

FDA is charged with ensuring the safety, effectiveness, and wholesomeness of products that Americans rely on in fundamental, sometimes lifesaving, ways – drugs, vaccines, medical devices, our nation's food supply, and more. These are products that people need; products they care about; and products that are critical to their health, safety, and well-being. Our role is unique and if we don't do our job completely and responsibly, there is simply no other agency or entity to backstop us.

Fulfilling our mission – to promote and protect the public health – is a difficult task under any circumstances. But these are especially challenging times. Today, the powerful forces of globalization are reshaping our world. We face complex threats – both accidental and deliberate – that pose new risks to FDA-regulated products and the Americans who rely on them. And we have been forced to rethink the way we do our job.

But we also live in a time of great advances in science and technology. Breakthroughs in the life sciences have provided industry with new opportunities to invest, innovate, create new markets, strengthen our economy and – most important – deliver new products and benefits for the American people.

FDA Innovation, Accountability and Results

My dedicated colleagues at the FDA are deeply committed to the health of American patients and consumers – and they recognize that innovation is essential to progress in public health.

Innovation is the foundation of the successful industries we regulate, and innovation is responsible for remarkable advances across all of the product areas within FDA's jurisdiction – which is why we must work proactively to foster the scientific innovation that will lead to tomorrow's breakthrough products.

Innovation is also critical to maintaining U.S. global leadership in many areas, including medical product development. Currently, most new drugs are approved in the U.S. before they are approved in Europe. And according to a recent industry study, we either are ahead of or tied with Europe for approval of medical devices that fall into the lower-risk category, which represents 90 percent of medical devices.

In my testimony, I highlight some recent FDA actions that allow the food, drug, biologic and device industries – all engines of innovation – to bring new products and technologies to market.

We also recognize that just as FDA supports the ability of industry to innovate, FDA itself must innovate and become more efficient. In FDA's FY 2012 budget, we highlight more than 100 examples in which FDA centers and offices are improving the efficiency of our programs, and, in many of these examples, we are also supporting industry efforts to develop new products. Examples of FDA innovation include the recent launch of the Innovation Pathway, a program to stimulate new, breakthrough technology and advances for medical device manufacturers as well as a scientific collaboration with industry to develop novel technologies to detect new and traditional foodborne contaminants and to develop safe food packaging. These efforts reduce the risk and expense of recalling products that fail to meet safety standards.

FDA is also committed to accountability. During the past year, we developed and implemented FDA-TRACK, an agency-wide system to monitor key performance measures for more than 90 FDA programs. Through FDA-TRACK, we are systematically monitoring FDA's progress as we work to achieve our performance measures and allowing stakeholders and the public to witness our progress through quarterly reports that we post on FDA.gov.

But the best measure of the value that FDA delivers is the opportunity to reduce costs and achieve measurable savings in areas that are important to America's health. One example is FDA support for the generic drug industry, which markets drugs that save American patients and taxpayers $140 billion per year.

A second example is FDA's food safety program, which is making significant progress to reduce foodborne illness that costs the U.S. health care system $88 billion annually. A third example is the FY 2012 Generic Biologics Initiative, which will generate significant savings for the federal government and for private sector health plans.

FDA Accomplishments

Thanks to the support of this Subcommittee, FDA continues to achieve important public health milestones. Since early 2010, FDA has supported industry efforts to bring new products and technologies to market – and to think creatively about how to promote and protect the health of the American people in meaningful and sustainable ways.

During the past year, FDA:

- approved new drugs to treat diabetes, hypertension, osteoporosis, bacterial infections, chronic pain, rheumatoid arthritis, preterm birth, gout, immune deficiencies, schizophrenia, major depressive disorder and pulmonary disease
- approved five new therapies to treat rare diseases
- conducted four workshops to stimulate new orphan drug development
- tentatively approved the 126th anti-retroviral drug under the President's Emergency Plan for AIDS Relief (PEPFAR)
- approved vaccines for seasonal and pandemic influenza
- approved new donor screening tests for HIV and Chagas disease
- cleared a new test to support kidney transplant patients
- approved new medical devices to treat hearing loss, severe asthma and vision loss, and to perform 3-D mammography screening
- cleared technology for physicians to view diagnostic images on iPhones and iPads
- identified measures to prevent radiation overdoses during CT scanning
- permitted the marketing of the first test to identify norovirus, a common foodborne illness
- applied genome sequencing to trace foodborne illness outbreaks
- collaborated with the National Oceanic and Atmospheric Administration (NOAA) to develop tests to re-open Gulf Coast fisheries
- formed public-private partnerships to improve produce safety
- launched a new system that identified 100 food safety problems in first seven months of operation.

FY 2012 Budget Summary

Although the President emphasized in his FY 2012 budget message that the fiscal realities we face require "hard choices," the five-year freeze on federal spending announced in the FY 2012 budget is not an across-the-board cut. Although the overall budget represents a freeze in the aggregate, it also contains investments in areas critical to sustain and grow the American economy.

FDA is one such area of critical investment. As you can see from FDA's FY 2012 priorities – food safety and nutrition, medical countermeasures, patient safety and FDA regulatory science – an investment in FDA is an investment in the economic health of two of the largest segments of America's economy: our food and medical products industries.

Our FY 2012 budget is also an investment in health – in the health of individuals and the public health of our nation. As a result, the budget includes $4.4 billion in budget authority and user fees to protect and promote the health of the American public every day, and through every stage of life.

Contract and Administrative Savings

Although FDA's FY 2012 budget is an overall increase for FDA, it also contains savings that contribute to the Administration's deficit reduction goals. FDA is proposing $29.7 million in contract and administrative savings designed to achieve reductions and cut costs across all FDA program areas.

To achieve these savings, FDA will reduce administrative staff by 46 FTE, lower contract costs by increasing competition, and expand the use of blanket purchase agreements and other agency-wide approaches to reduce contract costs. Where possible, we will also save by using technology to improve how we manage our contracts and the contracting process. Finally, in some program areas, FDA will reduce the cost of employee training by replacing the traditional classroom model with online training.

Transforming Food Safety and Nutrition

For FY 2012, FDA proposes an increase of $326.0 million for the Transforming Food Safety and Nutrition Initiative to build a stronger, more reliable food safety system that will protect American consumers. This increase includes $225.8 million in budget authority and $100.2 million for user fees, including the four new user fees enacted in the FDA Food Safety Modernization Act.

With this increase, FDA will begin to implement the landmark food safety legislation, which Congress enacted last December. Under this initiative, FDA will also ensure – through menu and vending machine labeling – that American families have the information they need to make more healthful food choices.

FDA Food Safety Investment: The passage of the FDA Food Safety Modernization Act (FFSMA), the first major overhaul of our food safety law in more than 70 years, will transform FDA's food safety program. Through FFSMA, Congress enacted new safeguards and enhanced tools to protect America's food supply by preventing food safety problems rather than reacting to problems after they occur.

Regrettably, foodborne illness is pervasive across America. Each year, nearly one of every six Americans gets sick due to foodborne illness. Some cases are severe. One hundred twenty-eight thousand require hospitalization, and 3,000 Americans die from foodborne illness.

FFSMA closes significant and longstanding gaps in FDA's food safety authority. For example, FFSMA gives FDA important new tools to ensure that imported foods are as safe as domestic foods and directs FDA to build an integrated national food safety system in partnership with state, local, and tribal authorities.

FDA will use these resources to establish a prevention-focused food safety system that leverages the valuable work of FDA's state and local food safety partners. In addition to yielding profound public health benefits, the FFSMA focus on prevention offers the opportunity for a dramatic return on the resources that this subcommittee invests in food safety. According to recent studies and the latest estimates of foodborne illness, the health care cost of foodborne illness – not including costs to the food industry – exceeds $88 billion each year.

The combined result of these actions will be a stronger, more reliable food safety system that protects the American people.

In its FY 2012 budget, FDA is organizing its food and animal feed safety programs and investments to implement FFSMA. Our detailed budget documents display the specific dollar amounts that FDA will allocate to implement the 22 separate sections of the law.

Nutrition: As part of the Transforming Food Safety and Nutrition Initiative, FDA will also begin an $8.8 million program to improve nutrition labeling on restaurant menus and vending machines so that consumers can adopt healthier diets. This small but significant initiative offers powerful return on investment. A 2009 analysis estimated the medical costs of obesity at $147 billion per year [Finkelstein, et al., Health Affairs], which means that controlling obesity goes hand-in-hand with controlling health care costs and reducing a significant burden on our economy.

The investments in this initiative will empower consumers to make better nutritional choices and will motivate food producers to develop healthier foods.

Advancing Medical Countermeasures

For FY 2012, FDA proposes $70 million for the Advancing Medical Countermeasures (MCM) Initiative. Medical countermeasures include drugs, vaccines, diagnostic tests, and medical equipment and supplies to respond to deliberate biological, chemical, radiological and nuclear (CBRN) threats and emerging infectious diseases, such as pandemic influenza.

The Advancing MCM Initiative will strengthen FDA's ability to respond to these national security threats by supporting the development of MCMs as well as enhancing review by allowing FDA to work interactively with product developers and government partners from early in the development process. With this investment, FDA will be better able to anticipate and resolve bottlenecks in MCM development and accelerate development of MCM products for pressing public health and national security needs.

MCM Gap: Today, our nation lacks the range of MCMs required for emergency response. For example, there are no countermeasures to treat acute radiation syndrome, which would afflict millions in the aftermath of a nuclear event.

Moreover, no FDA-cleared, rapid, point-of-care diagnostics exist for any of the biothreat agents of greatest concern. Such diagnostic tests are essential to guiding the public health response; ensuring that patients receive the most appropriate treatment; and promoting appropriate use of the limited supplies of MCMs available during a public health emergency.

Analysis of the Need for MCMs: In December 2009, on the heels of the influenza pandemic, HHS Secretary Sebelius called for a comprehensive review of the nation's readiness to defend against CBRN threats. The HHS review was prompted by recognition that influenza vaccine became available only *after* pandemic influenza was already widespread across the United States. The HHS review called on the expertise of the scientific leadership of all federal agencies that work with medical countermeasures, as well as state and local health departments, the National Biodefense Science Board, and the Institute of Medicine.

The review, released on August 19, 2010, identified the barriers to MCM development as well as significant opportunities to improve the path for successful MCM development. The review identified FDA as critical to the success of the MCM Enterprise, primarily because FDA evaluation of product safety and efficacy can significantly affect the course of product development.

The report further recognized that robust FDA engagement from the earliest stages of product development can substantially increase the odds of successful approval. In other words, increased support for FDA's MCM activities is one of the most critical steps the federal government could take to transform the larger MCM Enterprise.

Threat Assessment: Dozens of reports since September 2001 and the October 2001 anthrax attack have affirmed the risk of terrorist groups wielding biological weapons and the suffering, death, and social and economic disruption that would result in the case of an attack. Therefore, the FY 2012 investment in FDA medical countermeasure development and review offers the potential for a strong return on investment.

The analysis of the National Security Strategy warns that the effective dissemination of a lethal biological agent within a U.S. population center would endanger the lives of hundreds of thousands of people and have unprecedented economic, social, and political consequences. The National Security Council warned in 2009 that the economic cost of a well-executed bioterrorist attack on American soil could exceed $1 trillion.

Clearly, such an attack would have profound consequences on our social and political order, and, more broadly, our way of life. Without this investment, America's public health and national security will continue to be at risk.

Protecting Patients

For FY 2012, FDA proposes an increase of $123.6 million for the Protecting Patients Initiative. This increase includes $64.8 million in budget authority and $58.8 million from three new user fees. FDA is proposing new fees for reviewing generic drug applications, paying the cost of medical product reinspections, and inspecting imports that arrive by international courier.

Generic Biologics: With the FY 2012 increase in budget authority, FDA will establish a pathway for approving generic biologics. Generic biologics are biological drugs shown to be highly similar to an FDA-approved biological product. In some cases, generic biologics may also be interchangeable with the FDA-approved biological product.

Biological products include therapies to treat certain cancers, rheumatoid arthritis, age-related macular degeneration, and HIV. These therapies cost $15,000 to $150,000 or more per patient per year – and represent a significant share of Federal government and private sector pharmaceutical costs.

Approving biosimilar versions of these products offers the potential for substantial savings for the federal government and private sector health plans. However, these savings will not materialize unless FDA has the resources to implement a

clear regulatory pathway for approving generic biologics. FDA is requesting these funds for FY 2012 because the sooner we make this investment the sooner we will see savings from generic biologics.

Other Medical Products: In addition to investing in generic biologics, the Protecting Patients Initiative also invests in new scientific tools and partnerships to enhance the safety of increasingly complex drugs, medical devices, vaccines and other biological products. For example, the Protecting Patients Initiative will strengthen FDA efforts to modernize and improve safety throughout the supply chain of medical products at a time when the number of medical products manufactured abroad is increasing dramatically, which presents real challenges for medical product and manufacturing safety.

Safer medical products not only benefit patients, but also benefit the manufacturers of drugs, biologics and medical devices. Safer products reduce health care costs and allow manufacturers to avoid the expense of product recalls.

With the resources in this initiative, FDA will modernize its approach to ensure safety across the supply chain for medical products. The initiative will also expand FDA's capacity to conduct medical product safety assessments and strengthen the safety of vaccines and the blood supply.

The proposals in this initiative offer a high rate of return for the investment of federal dollars. They can reduce the cost of care and promote safe, high quality and accessible health care that Americans deserve. In addition, the Administration is proposing additional measures for FY 2012 designed to reduce costs and increase the availability of generic drugs and biologics.

FDA Regulatory Science and Facilities

For FY 2012, FDA proposes an increase of $48.7 million for the FDA Regulatory Science and Facilities Initiative.

The FDA Regulatory Science and Facilities Initiative will strengthen the core regulatory scientific capacity that supports all elements of the FDA mission. Regulatory science focuses on developing the knowledge and tools to properly assess the safety, effectiveness and quality of products that are being developed or are already on the market. Specifically, this initiative will help modernize and streamline the regulatory pathways that industry relies on to bring new, innovative products to market.

It will also modernize the FDA review and approval process for products that rely on new and emerging technologies. The result will be promising new opportunities to diagnose, treat, cure and prevent disease.

Finally, the resources in this initiative will also allow FDA to outfit the CBER-CDER Life Sciences-Biodefense Laboratory complex. On August 18, 2010, the General Services Administration (GSA) awarded the construction contract for the new laboratory complex at White Oak, and construction work is currently underway. Without this investment, FDA must pay double the rent: the first for a new lab we cannot occupy and second for the old lab we cannot vacate.

The new laboratory complex will help FDA fulfill our scientific responsibilities to promote drug and biologic safety and MCM development and prevent threats, including annual influenza. FDA must make this investment in FY 2012 to ensure that the laboratory is operational and ready for occupancy in FY 2014.

FDA Current Law User Fees

For FY 2012, FDA proposes an increase of $634.5 million for 12 current law user fee programs.

FDA user fee programs support safety and effectiveness reviews of human and animal drugs, biological products, medical devices, and other FDA-regulated products. Fees also allow FDA programs to achieve timely and enhanced premarket review performance. Finally, fees support the programs and operations of the FDA Center for Tobacco Products.

Existing user fee laws authorize fee increases for many FDA user fee programs. The increases expand the available options for treating and curing diseases and addressing other important public health needs.

Conclusion

The FDA budget for FY 2012 contains important investments for critical public health priorities. With these resources, FDA will transform food safety; support the development of urgently needed medical countermeasures; protect patients by assuring that the drugs and other medical products they rely on are safe; and advance regulatory science, which serves as the foundation for all science-based decisions at FDA.

Thank you for the opportunity to testify. I am happy to answer your questions.

Mr. KINGSTON. Thank you very much, Dr. Hamburg.

I also wanted to reiterate what Mr. Farr said about your accessibility. We on both sides of the aisle truly appreciate the time you have given us to answer lots of questions and we will have more today. But we do appreciate the ongoing dialogue. With that, I want to recognize the chairman of the full committee, Hal Rogers of Kentucky.

Mr. ROGERS. Thank you, Mr. Chairman. And by the way, congratulations on your elevation to this chair. We think you will do a wonderful job.

Mr. KINGSTON. Thank you for your role in that, sir.

Mr. ROGERS. We think you will do a great job, and you already have.

I would like to focus, Mr. Chairman, my comments and questions on FDA's role in regulating prescription drugs, particularly opioid narcotics. Undoubtedly these drugs can make a world of difference for patients suffering from cancer or other terminally ill diseases which cause chronic pain. But the abuse and diversion of these drugs is now our country's leading drug problem. In the last decade, there has been a 400 percent increase in those reporting abuse of pain pills.

And in Kentucky, we are losing almost three people a day to prescription drug overdosing. My people and communities around the country are doing their part in recognizing that we will need a multifaceted approach to knock out abuse. Law enforcement, treatment programs, and education will all be crucial, but regulatory agencies need to do their part.

FDA, of course, has an altogether important role in this. In 1995, FDA approved what you thought was the next miracle drug for cancer patients, a controlled-release pain reliever, Purdue Pharma's OxyContin. The active ingredient in Oxy is twice as potent as morphine. Purdue immediately undertook an aggressive marketing campaign to sell as much of their drug as possible. They chased primary care doctors and doctors in rural areas who may not have been as adequately trained in pain management as perhaps others. They underplayed the drug's addictive tendencies. And within 5 years, Oxy had become the most prescribed brand-name narcotic medication for treating moderate to severe pain. Purdue was raking in the dough, and that is about the time the people in my district started showing up in emergency rooms or in the morgue.

In 2001, Frank Wolf and I testified—Chairman Wolf and I testified before the FDA asking that this powerful drug, twice as potent as morphine, only be made available for the treatment of severe pain where it can have the most positive impact on patient comfort and care. Our pleas fell on deaf ears. And the rule continued to be that OxyContin could be prescribed for moderate to severe pain. You got a sore toe? Here, have some OxyContin. Highly addictive. Terribly difficult to shake.

Purdue was ultimately fined in criminal court $600 million for its unscrupulous marketing practices, and several executives even faced criminal charges. They had to reformulate OxyContin, and

you have recently approved the new version. They still sold $3 billion worth of the drug last year and its generic spinoffs aren't far behind. I will let you decide if justice has been truly served.

So what can be done? There is a thing called the "Flamingo Road" where there are more pill-mill crooks operating clinics in Broward County, Florida, than McDonald's drive-through. People from other parts of the country, especially in my district, my State, are hired by drug pushers to get on the bus, go to Florida with them. They all go through the pain clinics, come back with a barrel full of OxyContin and other prescription medicines where they are sold for 10, 15, 20 times what they pay for them. And people are dying because they are too easily obtained. FDA has to be a partner in this fight.

Despite some positive FDA efforts in recent years through additional labeling requirements, collaboration with partner Federal agencies and increased communication with physicians, prescribers, dispensers and patients still are woefully underinformed about the risks associated with these products. FDA has to be fully aware of the implications of these drugs before they go to market, which is why Congress instituted the REMS requirement for extended release pain drugs in 2007, and these potent drugs were carefully classified.

We simply can't keep handing these responsibilities over to profit-driven drug companies. It is reckless, it is irresponsible, and it is why prescription drug overdoses are killing more Americans now than car wrecks. Think of that.

And that is why Mary Bono Mack, the Congresswoman from California, and I have filed a bill called the Stop Oxy Abuse Act which would moderate and change the moderate to severe qualifications to be prescribed for OxyContin to just severe, severe pain only. I would like your reaction to that.

[The information follows:]

OXYCONTIN PRESCRIPTIONS

Potent opioid analgesics have traditionally been indicated for moderate to severe pain. Some advocacy groups have called for the removal of moderate pain in the indications as a means to reduce the number of prescriptions for these products and thereby reduce the opportunities for their abuse. FDA has denied this request for a number of reasons. Pain is a subjective phenomenon and its intensity level is primarily determined by patient report. What one patient might consider "moderate" pain, another patient may consider "severe". Health care practitioners have traditionally used the terms mild, moderate and severe to categorize a patient's pain intensity and to communicate with patients and other health care practitioners. The use of these terms in the indication section of the label along with the limitations of use statement are intended to guide prescribers to understand that OxyContin is not for mild, acute, or intermittent pain where other pain management products would be more appropriate. The label also instructs that it is not intended for use on an as-needed basis, nor is it indicated for pain management after the first 12–24 hours following surgery unless the patient had already been receiving the drug prior to surgery and the postoperative pain was expected to be moderate to severe and to persist for an extended period of time. The labeling is directed toward legitimate use of these medications. Chronic pain described by some as 'moderate' can be very disruptive and extended release opioids can be an appropriate choice for these patients. Removing the term moderate from the indications for these drugs could result in considerable confusion, and would not likely impact the availability of the drugs or the amount of abuse and diversion associated with them.

I am going to leave several questions for the record, Mr. Chairman, if that would be okay.

Mr. KINGSTON. Without objection.

Mr. ROGERS. Vern Buchanan from Florida, a Congressman, has a bill that would reclassify all hydrocodone combination drugs—Vicodin, Lortab and others—as Schedule 2 drugs, which are more difficult to prescribe and obtain. Would this cut back on abuse? I wanted to leave that for the record.

[The information follows:]

RECLASSIFICATION OF HYDROCODONE COMBINATION DRUGS

Hydrocodone, when dispensed as a single drug—not in a combination product—and not exceeding 15 mg per dose, is currently a Schedule II drug. Today, all marketed hydrocodone drugs that are combination products—for example, hydrocodone combined with another pain reliever such as acetaminophen—are Schedule III drugs. Schedule II drugs require a new prescription each time they are dispensed, whereas Schedule III drugs can be refilled without a new prescription. Rescheduling all hydrocodone combination products from Schedule III to Schedule II would affect automatic refills for a prescription. Although this change might make it more difficult to obtain these medications frequently for non-medical use, this change would also create an impediment to legitimate use by patients being treated for acute pain.

While it is true that drug usage data for hydrocodone products documents extensive use, there is a legitimate medical need for these drug products. To date, data on abuse potential of hydrocodone combination products support their continued placement in Schedule III. FDA has not seen rates increasing for visits to hospital emergency departments related to hydrocodone product use, when compared to oxycodone, a Schedule II product, according to data taken from the Drug Abuse Warning Network of the Substance Abuse Mental Health Services Administration, also known as SAMHSA. Nor does FDA see increased rates of addiction, as evidenced by the need for opioid treatment, for hydrocodone compared to oxycodone, according to data from the SAMHSA Treatment Episode Data Set. This type of data, however, is not sufficient for drawing conclusions about how to impact specific criminal activity such as cutting back on pill-mill operations.

Mr. ROGERS. Number two, Congress required REMS to ensure that the benefits of a drug outweigh the potential risk. I have heard some real concerns that FDA is allowing the drug companies producing extended release pain medication to develop a one-size-fits-all REMS. Considering that each medication is different and poses unique risks to patients and the public, how will this one-size-fits-all approach encourage innovation in risk management?

[The information follows:]

REMS

Dr. Hamburg: FDA's Center for Drug Evaluation and Research, also known as CDER, is in the process of developing a Risk Evaluation and Mitigation Strategies, commonly known as a REMS for high potency long acting and extended release opioid products. This REMS, which will include measures intended to increase physician and patient knowledge about the appropriate use of opioid drugs in the treatment of pain.

On July 22 and 23, 2010, FDA presented its proposal for a class REMS for long-acting and extended-release opioid drugs at a joint meeting of the Anesthetic and Life Support Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee. The objective of the meeting was to gather additional feedback and comments from the Committees and the public on its proposal to require a REMS for the class of long-acting and extended-release opioid products.

FDA is currently analyzing the advice received from the Committees and from public comments. Once these have been thoroughly analyzed, FDA may issue a REMS request letter to the sponsors of these drugs. The letter would describe the proposed REMS and provide a timetable for the submission of the REMS and its implementation. Affected sponsors would be required to implement the REMS, once it is approved.

The REMS proposal presented at the July 2010 meeting focused on prescriber and patient education. Under this proposal, sponsors would be required to provide patients with Medication Guides conveying information on the safe use of all opioid

medications as well as product specific information. Sponsors would also be required to develop prescriber education programs covering appropriate patient selection, dosing, and monitoring, and training for patient counseling in the safe use, storage, and disposal of opioids. The proposed REMS would foster innovation in patient and prescriber education, which are essential for improving prescribing practices and ensuring the safe use of of long-acting and extended-release opioid drugs.

Mr. ROGERS. And then finally, what is FDA doing to incentivize and speed up the development of more tamper-resistant or abuse-resistant formulations of these drugs?

[The information follows:]

TAMPER- OR ABUSE-RESISTANT DRUGS

FDA classifies Investigational New Drug applications for purportedly tamper-resistant or abuse-resistant formulations of opioid analgesics as Fast Track drugs for review purposes. FDA reviews New Drug Applications for these products on a Priority Review schedule of six months. In certain circumstances, the labeling for these products could include data supporting the tamper-resistant or abuse-deterrent features—albeit with a disclaimer that the impact on actual abuse is unknown—which would allow the manufacturer or distributor to describe these features in their advertising and detailing.

Mr. ROGERS. Dr. Hamburg, I appreciate your being here today and answering these questions and presenting your budget request. And I am very focused on—in my own way, on the drug abuse problem that is afflicting the country and killing young people even as we speak.

Today in Kentucky, three people will die from drug overdoses that could have been prevented. And I think the FDA needs to join the fight. Thank you, Mr. Chairman.

Mr. KINGSTON. Thank you. Dr. Hamburg.

Dr. HAMBURG. Well, thank you very much, Congressman Rogers, for your very powerful statement about the serious problem our Nation faces with respect to the abuse of prescription drugs. And as you point out, it is one that takes a devastating toll on individuals, on families, on communities and our Nation, and its impact is very, very severe and far-reaching. And successful, meaningful, and enduring solutions to it, as you also point out, require true partnerships because there are many players that need to play a role.

FDA has a critical role and we care deeply about it and I am personally very committed to helping lead the agency to engage more deeply on these issues with our counterparts in government and in other sectors and to look very carefully at where we have responsibilities and where our activities and policies can make a difference. We are, as you said, looking very carefully at how we can more effectively use the authorities and tools that we have in terms of warnings and indications for use.

We also have mounted a major initiative around the safe use of prescription drugs, and it is critically important, and the area that you focused on in your comments is a key component of what we want to accomplish there. There also is an administration-wide effort focused on this. And that is very key, to engage law enforcement, to engage educators, to engage the DEA who would be involved in making decisions in terms of the reclassification.

Mr. ROGERS. Can I help you spell Broward County, Florida? Nine out of ten prescriptions for oxycodone in the country are coming from Broward County, Florida; 9 out of 10. It is an absolute pill-

mill heaven. There are thousands of them there. And I have asked the Attorney General to send enforcement to Broward County to help us stamp out the problem. We have asked the Governor of the State for a drug prescription monitoring program, which he has refused, although some 40 States already have the system in place.

Where do I turn? Can you change the rules by which these medicines are prescribed for just severe pain? Why not do that?

Dr. HAMBURG. Well, I think these are important issues and as you pointed out, they do involve many different agencies coming together. We approve—we review and approve medical products for a certain indicated use, and that can certainly be a part of our considerations. There are also very important activities that have to do with the oversight of the providers and how they are doing their prescriptions, the training of providers and enforcement activities. So I think——

Mr. ROGERS. It is very simple. It is really simple. This drug OxyContin was built, designed, constructed for severe pain, right? I mean, it is a 12-hour release pill. It is a wonderful drug for those in severe pain in terminal cancer cases and others, for example. But it is so easily dispensed and it is so easily taken and it is such a wonderful drug to be abused, but young people especially are crushing the 12-hour release into an instant release, and you can imagine the pleasure that gives. And it is irresistible. But it is killing people. Can't you change that formula by which they are prescribed, simply leave out "moderate"?

Dr. HAMBURG. In how we are approaching the warning labels, the indications for use, we are very mindful of those concerns.

You also raised another very important point that I want to underscore, which is how can we bring better science to bear to make products that are safer and less subject to abuse and the opportunities for innovation in this area. We need to go forward today to address the current problem. We also need to be making sure that we are pursuing those avenues as well. I am heartened to hear about your work in this area and the bill that you are proposing. We are eager to work with you. It sounds like maybe I should make a visit down to Broward County and learn more about it.

Mr. ROGERS. Absolutely. I will pay your way.

Dr. HAMBURG. I don't know that that would be allowed.

Mrs. EMERSON. Mr. Chairman, can I ask you to yield just for a second and make a comment? I agree with you. I am just getting off a broken arm. And the first drugs that they threw at me were an OxyContin-type drug. And while I was in pain, and probably a lot of pain, I wasn't in severe pain. And so I was afraid to take the drug because I didn't know—I know the effects are really pretty dramatic. But every single time I would go for a follow-up, Do you need some more OxyContin, do you need some more of this drug, do you need some more of this drug? And I took four Advil, which did the trick for me.

But I understand. I mean, they were just throwing the stuff at me. And I am thinking it is just ridiculous. So I just flush it down the toilet, which I am not sure you are supposed to do that. I can't remember how you are supposed to get rid of it.

Dr. HAMBURG. You are.

Mr. KINGSTON. We don't have to remove that from the record. We have unanimous consent.

Mrs. EMERSON. But anyway, it is troubling. It is very troubling to me who just recently, 6 weeks ago, dealt with this same problem.

Dr. HAMBURG. It is an incredibly important issue with huge ramifications. We are eager to work with you. We are involved in activities in this domain. There is more that we can do. I think the partnership in terms of this administration-wide effort is going to make a real contribution as well. But I would be eager, you know, to sit down with you, to visit the Flamingo Road—did you call it—and also really lay out in more detail where we as the FDA can make a targeted difference.

Mr. ROGERS. That is the reason I asked you today. That is why we are here. That is why I am here, is to have you answer the question. If you strike out the word "moderate" and they can only prescribe it for severe pain, we can then prosecute people who are unscrupulously making zillions of dollars under the guise they can prescribe it for moderate pain. This is done every second of the day. But if you only allow them to prescribe for severe pain, we could then prosecute and go after the unscrupulous doctors and pain clinics that are killing our people. It is pretty simple.

Dr. HAMBURG. I think as you point out, targeting for appropriate use is absolutely key, and we are trying to achieve that through what we are doing in the REMS arena and strengthening those. I think it is hard to—I don't think that you would be satisfied with the results by simply addressing that change in indication, because it is the broader abuse that is happening that is—you know, I think causing this serious national problem and it is—how you define "moderate" and "severe", I think we need to have a concerted effort that is targeted at many levels to address a problem that is cross-cutting, that involves both what are the kinds of drugs that are available, how are they prescribed, what are the oversight and restrictions on the use and abuse of those drugs and how that is enforced.

Mr. ROGERS. Mr. Chairman, I appreciate your indulgence with me for the time. That is exactly what we had to do in my district. The State newspaper came out with a story that ran for 6 weeks, front-page screaming headlines that my area was the pain prescription capital of America, which prompted me to start an organization we called UNITE, Unlawful Narcotics, Investigations, Treatment, and Education. It is an amazing organization. We have got 26 undercover agents now that do nothing but arrest people selling drugs. They have put in jail 3,700 pushers selling these drugs from the Flamingo Road source.

We have kids in hospitals every day. We have got kids dying every day in the emergency rooms. We have got drug courts in every county. We have built treatment centers. I go to drug court graduations for people who finally kicked the thing and hear these wonderful tales. It is a pervasive, deep, widespread problem, killing more people than the automobile wrecks in the country, and yet you sit there and say we will not really talk about changing the prescription rules for this killer drug. And I won't rest until we see an answer, ma'am.

Dr. HAMBURG. Well, I am happy to continue to examine these questions and go back with our expert team. My point, though, is that I think if we really want to make a meaningful and enduring difference, it is a different problem than simply changing the indication, because it is—whether it is an indication for severe or moderate, the prescriber ultimately is making the decision of whether it should be given to that patient for their pain. And I am not confident that a label with an indication only for severe pain is going to change the behavior of those on Flamingo Road.

Mr. ROGERS. It will give us a chance to prosecute those people that are prescribing that medicine for other than severe pain, and we can stop—make a big point in stopping the problem at the source. You are in charge of the steering wheel here. And I expect some movement on this issue. And if you don't do it, we will do it for you. I cannot be much plainer than that.

I hate to be blunt, but this is beyond a minor issue. This is a killer in my district. It is killing my constituents and all around the country. And you could make a difference.

Dr. HAMBURG. Well, I am eager to make a difference. I appreciate the severity of this problem and its huge ramifications on the lives of people and the dislocations in communities that occur and the terrible pain that so many have experienced. I do feel that we have a critical role to play and we will engage fully. I think that to be successful, it needs to be a broader partnership, and I am also committed to engaging in those partnerships so that we can make real measurable progress in this domain.

Mr. ROGERS. We will be listening. Thank you, Mr. Chairman.

Mr. KINGSTON. Thank you, Mr. Chairman. Mr. Farr.

Mr. FARR. I share your concern, Mr. Chairman. And also I think you have to go upstream and also look at the manufacturers and the salespersons and the people that sell that to the end users.

I know my cousin is a doctor and he says that most of the information they get about drugs comes from the drug salesperson who tells them you ought to use this for this and that. If there is that much supply out there going to doctors' office, then there has also got to be something with the way the message is being given to doctors. And I hope we can look into that as well.

MEDICAL COUNTERMEASURES

I think this conversation really goes to the point of how important your agency is, the Food and Drug Administration, and how difficult it is going to be to manage these critical issues in the United States if Congress indeed cuts and slashes your budget.

So a couple of things that I would like to see is if we could get a better bang for the buck. One is in the area of countermeasures, medical countermeasures. As you know, the Medical Countermeasures Initiative was framed in the course of 2000, it was based on the fact that we put a lot of money into preparing for the flu pandemic. I think Mr. Rogers played a major role in pointing out that that was real serious. And what happened last year is that the HHS shifted 170 million dollars from their accounts to FDA accounts, to cover the new Medical Countermeasures Initiative. But you need some, as I understand it, you need some language to expand the other types of countermeasures you can work on besides

the flu. Essentially the idea is if we want to have an infrastructure to do that. We could look at countermeasures that would be made for other kinds of emergencies that might come from biological weapons or other things that could break out, contamination could break out, beyond influenza. We have kind of isolated this work to one countermeasure.

I wonder if you could speak for just a second how important that is, how important it is to keep the money, how important it is to get the language you need to be able to have those other countermeasures.

Dr. HAMBURG. Thank you, Congressman Farr. This is a very important area for the health and security of our Nation. We do face a set of serious biological threats from the naturally occurring, such as pandemic flu or something like SARS, if you remember a few years ago, or as yet an emerging infectious disease threat. We also know that we are highly vulnerable, perhaps increasingly vulnerable to deliberately caused biological threats and biological terrorism, chemical terrorism, radiological and nuclear terrorism, and the impact in terms of the health of individuals would be enormous; also the huge dislocations to our society, the disruptions in life as we know it, the impact on the economy, the public's trust and confidence in government and critical institutions and our national security at its core.

So we want to be able to provide the kinds of medical countermeasures necessary to fully prepare us both to rapidly detect and respond to an emerging threat and to treat and contain a threat should it occur. In a way, it is a form of deterrence to be better prepared and to limit the damage that can occur.

Mr. FARR. As I understand it, you have the money to do the work. You just don't have the authority to look at these other countermeasures?

Dr. HAMBURG. Well, exactly right. The Secretary of Health and Human Services, Kathleen Sebelius, began a new initiative last summer in the medical countermeasures arena and FDA was given resources to begin important work from the monies that had originally been appropriated for pandemic response.

Mr. FARR. And we put that language giving you that authority in our legislation, but it didn't get into the latest version.

Dr. HAMBURG. Right. In order for us to be able to expand these activities to address not just pandemic threat, but the continuum of biological threats before us, we do need additional language. It is a no-cost proposal. But that would allow for the use against this broader set of very important, potentially devastating biological threats.

So we would be very appreciative if you could take a serious look at that. I think it would make a huge difference to our ability to move forward in critical ways. There are important gaps in key areas. We don't have a treatment for acute radiation sickness, such as would occur after a terrorist attack using a radiological device. We don't have antiviral drugs to treat a number of critical, potential microbial threats. We don't have the diagnostics that we need to rapidly detect an emerging problem so we can treat it appropriately.

Mr. FARR. Yes or no? Can we assume that if these funds are not provided through the mechanism proposed in the budget amendment, that there is very little or no chance you can fund those activities within the appropriation in H.R. 1?

Dr. HAMBURG. That is the case. This is a program where we are building a new capacity. These targeted additional dollars are essential to fulfilling the mission of assuring that we have the medical countermeasures that we need. We also in the President's fiscal year 2012 budget are asking for monies to continue those programs that we are beginning to put in place now.

So it is going to make a difference. And, interestingly, as this broader initiative around medical countermeasures was being developed, one of the things that emerged was that the role of FDA was absolutely crucial to success; that it involve other components of government, but that the FDA's role in actually being able to review and approve for safety and effectiveness these medical countermeasures was the linchpin of success.

So we very much appreciate your taking a serious look at this and helping to support efforts that will make such a difference to our Nation and our security.

Mr. FARR. Thank you.

Mr. KINGSTON. The gentleman's time has expired. Mrs. Emerson.

DRUG SUPPLY CHAIN

Mrs. EMERSON. Thank you, Mr. Chairman. Thank you so much for being here, Dr. Hamburg, and for the good job that you do. I know you share my concern about the possibility for counterfeit drugs to enter the United States supply chain, whether it is from within the United States or from abroad. Yet the potential for this corruption of the system and the potential rewards for doing so is growing. And it is really interesting and frightening to see how sophisticated some of the methods the counterfeiters are using.

And I am thinking about one in Enfield, Connecticut, last year where $76 million worth of drugs were stolen; and in another year before, in Chesterfield, Virginia, in which about $5 million of drugs were stolen. But this illustrates the fact that this is a problem bigger than mere counterfeiting, and it extends to stolen drugs which are removed from the supply chain and simply lost before reappearing, and that can possibly be here and it can possibly appear as treatments for us.

So last year, the committee included language asking FDA to examine methods and technologies by which these drugs can be tracked within the supply chain from the manufacturer to the patient with a minimum of cost to either party or anyone in between. And I wanted to follow up with you on that request for new standards just to gauge your opinion of the possible role for the FDA, as well as to ask you if you see a need for this kind of a national system to ensure the drugs that we Americans are taking are safe as well as affordable.

Dr. HAMBURG. You raise a critically important issue. And increasingly in our globalized world, we need to be thinking about drugs coming from many parts of the world and complex supply chains that drugs go through with webs of producers, manufacturers, suppliers, repackagers, exporters, importers. And all along the

way, there are opportunities for the potential introduction of problems, sometimes unintentional, and, sadly, we know often deliberate. And we know that counterfeiting is increasingly a very significant criminal enterprise. And in fact because the penalties for trafficking in counterfeit drugs are much less than in illegal drugs, there is real concern that organized crime is increasingly entering this space as well. And we know that the impacts on people are huge.

You mentioned drug diversion. There was a recent case where insulin was stolen, disappeared from the marketplace and then reappeared. But the only way we found out that it reappeared is that we started getting reports that diabetic patients were taking insulin. They were depending on this drug for a very serious medical problem and it was having no impact. And we determined that their lots of insulin in fact were from this stolen—so the ability to track and trace, as you pointed out, is absolutely essential.

We would very much welcome the chance to work with Congress to look at the opportunities for new legislation. I know that there is a bill that Congressman Dingell has introduced that would give additional authorities to FDA to help us to secure the safety of the supply chain and address these global challenges.

Mrs. EMERSON. Let me ask you. California has a standard which it is set to—I think it is set to be implemented in 2015. And even with the best possible State model, do you think a state-by-state approach is more effective; or is it more efficient to have one single national approach to the problem?

Dr. HAMBURG. I think that this is a problem that crosses State borders and crosses international borders, and I think the goal of standards that are harmonized is very, very important. It is important to our ability to really address the problem. I think it is important to industries as they think about how they would implement it, and the cost of implementation as well.

Mrs. EMERSON. Can you estimate the pervasiveness of the counterfeit problem?

Dr. HAMBURG. We need better data. It is actually a worldwide problem that we don't fully know the nature and scope of it. I think, startlingly, we do know that in some parts of the developing world, as much as between 30 and 50 percent of the drugs available in the marketplace for serious diseases are in fact counterfeit.

In the United States, we have a much more closed system and the FDA is working every day to ensure that the drug supply is safe and that when you go to your pharmacy what you get is what it purports to be. But we know that the problem is a real one here as well, and that we need to be proactive and aggressive and we need to be very cognizant, as I said, of the fact that as the world becomes more globalized and more and more of our drugs are coming from being manufactured overseas——

Mr. KINGSTON. The gentlewoman's time has expired.

Mrs. EMERSON. I will look forward to working with you, Doctor.

Dr. HAMBURG. You can tell this is a topic I care about.

Mrs. EMERSON. I look forward to working with you, Dr. Hamburg. And thank you, Mr. Chairman, for allowing me to go early.

AVASTIN

Mr. KINGSTON. Mr. Nunnelee.

Mr. NUNNELEE. Thank you, Mr. Chairman. Thank you, Dr. Hamburg, for being here.

I would like to focus for a little bit on the drug—I believe it is pronounced Avastin. As I understand it, FDA granted accelerated approval for Avastin for the treatment of breast cancer in 2008 and now FDA is looking at withdrawing that approval. Is my understanding correct?

Dr. HAMBURG. There is an expedited approval mechanism that is available that enables, on the basis of fairly early data on drug safety and effectiveness, to grant a modified form of approval, expedited approval, and then require additional studies to be done; and then a decision is made based on that accumulation of a broader set of data, whether the drug should get full formal approval. And in this case after additional studies were done and the advisory committee of experts was also brought in to review the data, a decision was made not to give Avastin full approval.

We are, I should say, in the process of working within the legal framework of this approval regulatory mechanism to—we granted the company that makes Avastin a hearing. They are going to be coming to a public hearing with the FDA, making their case. And because we are in the middle of that process, I actually can't comment any more deeply about this drug.

Mr. NUNNELEE. So you can't tell me what—you approved it then, and you are putting it on hold now, and you can't tell me what is the problem?

Dr. HAMBURG. Well, the additional data that was collected and examined, both by FDA scientists and reviewed by this panel of outside experts, did not support the full approval for the indication. However, as I said, because we are in the middle of a legal process and I ultimately will be reviewing all of the data under this system of a public hearing and a subsequent decision, that I am really not at liberty to have a full discussion of the matter.

Mr. NUNNELEE. Sure. It is my understanding that this drug doesn't cure breast cancer, but it does prolong a woman's life. And the initial indications were it might prolong it as long as 5 to 7 months, and now maybe it is only 3 to 5 months. And because it didn't do what it was originally thought——

Dr. HAMBURG. If I could, because I am in a difficult legal situation here, because there is—there is a legal process with a hearing, and ultimately I need to be the final decision-maker, and so I need to be at a distance from this—if I could ask our center director, Center for Drug Evaluation and Research, to speak to these issues.

Dr. WOODCOCK. Thank you. I am Janet Woodcock. I am the head of the drug center at FDA. Avastin's trials in breast cancer—it is approved for multiple cancers, many of these are full approvals—showed—the original trial showed an effect on what is called progression-free survival, which does not have anything to do with living longer. It has to do with how long before your xrays show that the disease progresses. The subsequent trials did not show the same effect. It was a much smaller effect on how long it took the xrays to worsen, all right?

There is not a claim that Avastin improves survival in this setting in breast cancer life. The dispute is over the length of time that it takes to progress once you have metastatic disease. Does that make sense?

Mr. NUNNELEE. I may have said it wrong. Initially you thought it would do it in 5 to 7 months, and since it is a little bit shorter, you are saying let us just pull it?

Dr. WOODCOCK. The initial was a surrogate. That is why it is called accelerated approval. Progression-free survival is generally—and in this case was that your xrays don't get worse is considered a surrogate for having some actual benefit to the people, say, not developing pain or fractures or actually maybe living longer. The subsequent trial showed a small effect on your xrays not getting worse, which our advisors and our oncologists did not feel would translate into a clinical benefit that somebody would feel, either reduced pain, reduced progression, or longer life.

Mr. KINGSTON. The gentleman's time has expired. Ms. Kaptur.

HEPARIN

Ms. KAPTUR. Thank you very much, Mr. Chairman. I would like to take a little bit of a different tack than some of the other members have and begin with the statement, the obvious assertion that America will experience economic recovery when people get jobs and they go back to work. And thus I follow with interest the continuing outsourcing of U.S. jobs, including by pharmaceutical companies making medicines and devices everyplace else in the world and moving jobs outside our country.

Every day I ask myself, how can we make goods in America again so people can go back to work? There are some who believe that we can fix what is wrong with our economy not by creating jobs in our country, but by simply cutting back on public health and safety, as is evidenced in H.R. 1, the continuing resolution offered by the majority party that cuts FDA inspectors for pharmaceutical safety.

It is a very interesting set of arguments we are getting involved in: how we help our country recover. And thus I want to return to questions I have asked in the past regarding heparin and tracking what is really going on with the manufacturer of heparin, the cost of that to the public sector through Medicare and Medicaid, and go back to March 2008 when the New York Times had an article, Dr. Hamburg, that said the Food and Drug Administration at that point had linked heparin to 19 deaths and hundreds of severe allergic reactions, though the agency was continuing to investigate. And those deaths and allergic reactions were due to components that ended up in heparin that came from China; I believe through Canada, though I am not sure.

So I wanted, first of all, to ask you whether you have completed your investigations and how many people may have died from those imported components. That is question number one. Have you finished your report? Is there additional data?

[The information follows:]

HEPARIN

CDER's Office of Surveillance and Epidemiology, also known as OSE, completed a review of adverse event reports from the Office's Adverse Event Reporting System in June 2009. OSE's analysis considered as much data as possible on the adverse event reports with use of heparin. However, we are not able to definitively attribute deaths to heparin administration due to confounding factors or lack of detail in the reports submitted to FDA. We continue to monitor for adverse events that are reported with the use of heparin. FDA does not have the details of the reports from Germany that you refer to and therefore cannot confirm the number of lives lost in Germany.

Then I want to ask you this. You kindly submitted for the record from previous questioning I had done, questions that I had asked regarding heparin. And for people in the audience who don't know, heparin is actually made from pig intestines. I represent a lot of hog farmers, so obviously they are interested in why we would go to China for the ingredients for heparin. And those intestines are ground up, proteins are extracted, and ultimately we get a liquid that people receive in hospitals when they go in for operations. I don't know whether it is a blood thinner.

Dr. HAMBURG. It is a blood thinner.

Ms. KAPTUR. A substitute for the—not the red blood cells but for the white blood cells.

Dr. HAMBURG. It keeps you from getting blood clots.

Ms. KAPTUR. Now, what is interesting about what you wrote in answer to my questions, you said, "FDA approves applications to market Heparin"—market Heparin—but it doesn't say anything about manufacturing.

So one of my questions to you is, it is unclear where or in which country ingredients are made. And I want to know, for the three or four companies that are listed that are supposedly marketing Heparin, how many of the ingredients actually come from the United States?

I am going to push you a little bit on this, maybe not today but in further questions. We see where China and India may be places where all these ingredients are being made.

I am also going to ask you about damages. And I know that my time is up here. But our government and the American people were not able to recover damages, is that my understanding, civil or criminal, from the Heparin deaths due to contaminated imports?

And where would I get how much money is being made by these pharmaceutical firms in marketing these products versus what it actually costs them to manufacture? Can you get at that, or where do I have to go for those numbers?

[The information follows:]

DRUG MARKETING PROFITS

The information that you are requesting is not information that companies must report to FDA. In addition, FDA does not track this information because it is not meaningful for evaluating the safety and effectiveness of drugs. The financial information would likely be available from the pharmaceutical firms themselves or from other sources of industry financial information.

Dr. HAMBURG. Well, you have asked a string of questions embedded in the one important issue of Heparin. And some of it we may need to get back to you on, in terms of your deep interest in this.

The experience with the contaminated Heparin was a very serious one. I think it was an eye-opener, not just to the FDA, but also

to the pharmaceutical industry and to our Nation more broadly, about the fact that we really needed to be paying attention to the fact that the supply chain for many products in this Nation is complex and global.

As you point out, the precursor for Heparin that is used in the United States and manufactured by United States manufacturers, but much of the precursor does come from China, which I think has more pigs than anyplace in the world. But——

Ms. KAPTUR. We have a lot in Ohio, too, and we would like to compete in this market.

Dr. HAMBURG. But, you know, it caused, you know, as you pointed out, serious allergic reactions and many deaths. In response to that——

Ms. KAPTUR. Do we know yet, ma'am, how many deaths yet?

Dr. HAMBURG. I think it was, in this country—it is impossible to know exactly how many. But in terms of the documented deaths, I think people do——

Ms. KAPTUR. Why is it impossible to know?

Dr. HAMBURG. Well, because sometimes the providers don't make the association between the death of a patient and the contaminated Heparin. Patients that get Heparin, you know, in the hospital often have very complex medical illnesses, and when a person expires, the connection wasn't necessarily made that it was because of the Heparin. As we saw a couple of cases and the investigation was done and we began to understand the link between the Heparin and a set of symptoms and fatalities—but we know that it took a serious toll.

In response, we have put into place a number of important protective measures, new screening tests, and safety systems, also working with the regulatory authorities in China on this and working with the private sector, so that we have safeguards that this kind of event with Heparin will not occur again. But it is a warning call about vulnerabilities in the system that we need to work on.

I think my time is up in responding to you, but we are happy to follow up further with you.

Ms. KAPTUR. Thank you.

And I want to thank the chairman for his generosity.

Trying to get to the bottom of this has been extraordinarily difficult. And we are going to keep digging, we are going to keep drilling down into this one.

And I would just say to the chairman, you know, we are all struggling to try to find the money to balance the budget. And if you look at the amount of money that our government pays through the Medicare and Medicaid accounts for Heparin, for a drug that is off-patent, for material that is off-patent, unbelievable. So this has many legs to it.

And I thank you very much. And we will have many follow-up questions on Heparin. Thank you.

Mr. KINGSTON. Well, I thank the gentlewoman.

And, as you can see, Dr. Hamburg, members of this committee have a lot of passion about our issues and do appreciate your time.

I want to visit the discussions you and I have had about food safety and the Food Modernization Act. Using the CDC numbers which you have—and I agree with you, 3,000 deaths a year is horrible. We need to do something about it—48 million illnesses.

But where I have an issue, taking the emotion out of it—and I know we have talked about this, but that 3,000 people dying a year is down 40 percent from last year. Again, you know, it is too high; we need to keep working. But it is down 40 percent from the CDC numbers. Forty-eight million foodborne illnesses a year, that is down 37 percent, a decrease of 28 million from last year. Still too high, but in a country of 311 million people eating three meals a day, 365 days a year, we are consuming 340 billion meals a year. And if you divide that into the 48 million, you still have a food supply that is 99.99 percent safe.

Where is my math flawed on that?

Dr. HAMBURG. Well, I think that the key numbers are that, you know, we know that about one in six people get sick every year from foodborne illness——

Mr. KINGSTON. Well, let me interrupt you a minute. Key numbers come from the CDC, and those are the numbers I have used, so those are the numbers I want to stay with. Where is that math flawed?

Dr. HAMBURG. Yeah, well, I think that is consistent with their numbers. I mean, I think, as you point out, we are seeing preventable deaths. We are seeing even more preventable illness. That is associated with a set of other preventable costs—costs to the health-care system, costs to economic productivity.

Mr. KINGSTON. But you agree with my math, that it is 99.999 percent safe?

Dr. HAMBURG. I would have to sit down and follow your math. But we have one of the safest food supplies in the world, there is no doubt about it. And we should be proud of that, and we should make sure that it is maintained that way.

Mr. KINGSTON. Well, the concern that I have is, are we targeting the 3,000 smartly and efficiently and effectively? Because if we move that number from 99.999 percent to 100 percent, which you and I and I think everybody on this committee certainly would want to do, are we going to get there? Are we going to get that last percentage? Are we going to get it with this bill?

And I will tell you why I have concerns about that. Sixty percent of the illnesses come from Norovirus. And there is nothing in there that attacks it. In your testimony, you mentioned that you have permitted a test for it last year, but that is the only mention of Norovirus.

And the CDC, on March 4th, said that, "Appropriate hand hygiene is likely the single most important method to prevent Norovirus infection and control transmission. Reducing any Norovirus presence on our hands is best accomplished through handwashing with water and plain antiseptic soap." And yet we are talking eventually 17,000 to 18,000 new FDA employees, and that is not addressed in here. Sixty percent of the illnesses.

The second highest number of illness is from salmonella. Of course, I come from poultry country. Now, before the Food Modernization Act, FDA did finalize the salmonella egg rule, July of last year. And something like 79,000 illnesses or 30 deaths, but that it could be avoided with this new food safety requirement which you put into effect July of last year.

So, you know, I don't want to say that box is checked. I am going to let you respond to it.

The third highest is Clostridium, and you don't mention that in your budget.

And it would appear to me that those are the three things that we need to target in order to close that percentage. And, you know, in this tight budgetary time, I think that would be a lot smarter of an approach.

Dr. HAMBURG. You know, Mr. Chairman, I understand your concerns. And I think that we all recognize that we have a food supply that is generally very safe.

I think no one can argue, though, that we are experiencing a set of preventable outbreaks due to a range of microbes, some which cause more severe disease, some which are more prevalent. But it is a range of concerns, and it is a changing panoply of concerns.

SALMONELLA

Salmonella wasn't thought to be such a major concern in products like peanuts. Today we know that it is a very different situation. So——

Mr. KINGSTON. But actually say today—this was only July that we had the new salmonella rule for eggs. And that wasn't——

Dr. HAMBURG. Well, that is for eggs.

But if I can just—you know, I think what we need and what——

Mr. KINGSTON. And I want to point out that the peanut problem, which occurred in Mr. Bishop's district—and he and I are all on the same page of it—but that was a criminal act and not so much food safety as much as it was a criminal act.

Dr. HAMBURG. But we are increasingly seeing salmonella in those kinds of products, is what I am saying, is that there is a—you know, we can't only have a food safety system that addresses problems that have happened. We need a system, as the Food Safety Modernization Act calls for, that really puts an emphasis on preventing the introduction of contamination of any kind.

And that is what I think is the huge opportunity here, is to move toward a system that is really based on prevention so that we can prevent those unnecessary deaths, we can prevent the unnecessary costs to the health-care system, we can prevent the unnecessary costs to industry and to our economy more broadly.

We also, in a globalized economy, have a whole set of additional threats to the safety of our food supply that we need to be very mindful of and prepare for.

So we are trying to create a food safety system for the 21st century and beyond, and I think that we have a responsibility to take that very seriously. Congress has given us the mandate to do so. And, you know, I am very excited about the opportunities to keep moving the dial so that our food supply is as safe as it possibly can be.

Mr. KINGSTON. My time has expired.

Mr. Farr.

Mr. FARR. Thank you, Mr. Chairman.

I wish we had a whole week of this panel. By the way, I don't think we have ever had a head of the agency that has such a tremendous academic and medical background as you have had. I am just truly appreciative that you took this job.

You are the first responder to any problem that happens in illness in America, no matter where it comes from. And your agency is the one that has to stop it, find cures for it. I think that we sometimes, in this big budget slashing that we have to do here in Congress—and I wish it wasn't so much slashing as, to use a medical term, since you are a doctor, is that we could do, you know, just microscopic surgery, is what we really need. Just as surgery is done that way, it has to be very smart and very effective. But we don't do it that way.

I am thinking that we ought to have a week up here discussing what would be a day without the FDA. If you didn't have the FDA, everything would come to a grinding halt in this country. Because, indeed, you are responsible for articles used in food or drink, for not only mankind but for animals, things that we don't think about that are regulated, like chewing gum—you put a lot of that in your mouth—dietary supplements and dietary ingredients, infant formula, beverages, even including alcoholic beverages, fruits and vegetables, fish and seafood, dairy products and shell eggs, raw agriculture commodities such as what we grow in our area, you know, like lettuce and carrots and things like that, the canned and frozen foods, live food animals, bakery goods, snack food, candy, chewing gum, animal feeds—I mean, just a whole list of things.

FOOD SAFETY MODERNIZATION ACT

In our new law that we passed in Congress, the Food Safety Modernization Act, which did pass with broad bipartisan support, and for that—and the chairman has already pointed out the number of deaths that occur in this country due to foodborne illness—the President has requested $183 million for implementation of the new food safety law.

My question that goes to you is, what would happen if that money was not appropriated, if Congress did not give you the President's request of $183 million to take these new responsibilities and tougher responsibilities that we have mandated upon you?

Dr. HAMBURG. Well, we are very committed to moving forward with the implementation of the Food Safety Modernization Act. And we are beginning to implement some of the very many new mandates and requirements contained in that bill. We will be able to make significant progress in key areas. We will continue to be able to put forward the——

Mr. FARR. If you don't get the money is the question, though.

Dr. HAMBURG. Yeah. If we don't get the money, we will not be able to fulfill all of the requirements of the act, without a doubt. We will, importantly, not be able to fulfill the very ambitious inspection mandate, domestically and internationally, which will mean that we won't be able to get that hands-on look at——

Mr. FARR. Let me follow up just on the inspections. A lot of the products that we eat, particularly if you think about the fresh vegetables we eat in the wintertime, a lot of those do come from Mexico, and have to be inspected coming across the border.

We also send and sell around the world a lot of food grown in the United States. California grows 80 percent of all the almonds eaten in the entire world. And that is more almonds than all the people in the United States eat, so we have to export those. Those require inspections in order to be purchased by foreign countries.

If our side of the inspection falls down, we don't live up to our regulations, what does that do to the movement of food supply, particularly with fresh fruits and vegetables that don't have any resale?

Dr. HAMBURG. Yeah, that is a very important question. About 40 percent of the fresh fruit and produce that we do eat in this country comes from outside our borders. So FDA has a very serious responsibility to be able to assure the safety of those products. And it means not just inspections at the border, which are hard to do and very costly and time-intensive, but actually going out to where the products are coming from and trying to assure the safety of that supply chain.

FOOD SAFETY SYSTEM

As you point out, you know, we also need to have confidence in a robust food safety system in order to support our exports of foods to other parts of the world. And when there is an outbreak, a preventable foodborne outbreak, it can have a very devastating impact on the health of that sector of the food industry, in terms of sales domestically, as you well know, and also the ability to do exports.

And if we can't do the inspections that we need to do, we will not be able to assure the American people that the food that they are putting on their plates and serving their families is safe and wholesome.

Mr. FARR. If you don't do the inspections, food doesn't move.

Dr. HAMBURG. Food doesn't move.

Mr. KINGSTON. Thank you, Mr. Farr.

Mr. Farr and members of the committee, we are expecting a vote maybe in the next 5 to 10 minutes. And it is going to be 2 votes followed by a 10-minute recommit. And what I would like to do, if it is okay with the committee, is when the first bell goes, I would like to vote, come back, give the gavel to Mr. Nunnelee, then he can vote, and we can sort of rotate in and out. That way, we can maximize our time with Dr. Hamburg, if that is okay.

Oh, okay, just one vote. And so, yeah, there will be plenty of time. We will be able to get this done. Aren't you glad?

Mr. Nunnelee.

Mr. NUNNELEE. Thank you, Mr. Chairman.

I want to continue the questions about the Food Safety Modernization Act. You may have already stated it, but let's look at it specifically. How much is requested in your 2012 budget for implementation of the Food Safety Modernization Act?

Dr. HAMBURG. How much is requested?

Mr. NUNNELEE. Yes.

Dr. HAMBURG. It is $183 million.

Mr. NUNNELEE. $183 million. How will we know this time next year if that $183 million has achieved the results that were intended by the bill's passage? What specific methods of monitoring and tracking will we have this time next year?

Dr. HAMBURG. Well, we do intend, of course, to track very carefully our performance as we move toward implementation of the Food Safety Modernization Act. And I think we recognize that there are a number of key areas that we have to make significant progress on moving forward.

We need to begin to put in place the preventive risk-based approach, working with the industry and with farmers and producers to make sure that we have identified and agreed on where the points of vulnerability are and what can be done to shore them up.

We need to continue to expand our inspections. Of course, it takes a number of years before an inspector is trained and able to go out in the field and really perform at full capacity. So some of the impacts of dollars today won't be seen for a few years down the road.

We will be strengthening our import safety activities to make sure that we both expand our inspections overseas but also work more closely with sister regulatory authorities and with industry to assure that foods are being produced, manufactured according to our standards.

We will be working closely with State and local partners, and that is a very important additional component of the Food Safety Modernization Act that we haven't had a chance to talk about yet. Very much it is a partnership. We will be working with States and localities in terms of helping them to strengthen their capacities and the contribution that they make to monitoring the safety of the food supply and responding to outbreaks when they occur.

So there will be very clear activities under way. We will be promulgating produce safety rules. We will be putting in place other guidances and taking other actions concretely in terms of what is required for implementation.

But I do want to caution that much of the transformation that needs to happen and the building up of program will take time. It is not a 1-year activity. And it needs to be a sustained activity, as well.

Mr. KINGSTON. Will the gentleman yield?

Mr. NUNNELEE. Sure. I always yield to the chairman.

NEW HIRES

Mr. KINGSTON. You are talking about 17,000 new employees and about $1.4 billion in a 10-year period, correct? That is what the findings were. That is correct?

Dr. HAMBURG. Is it—that number of new employees seems awfully high.

Mr. KINGSTON. In a 10-year period of time, that is what everyone was saying last year in Congress in the debate.

Dr. HAMBURG. That was—I don't know how many FTEs they were. Did they speak in FTEs?

Mr. KINGSTON. All right. It was a CBO estimate. You are talking a massive bureaucracy in a time that, for every dollar we spend,

40 cents is borrowed, in the background of a 99.99 percent safety rate in food.

I yield back.

Mr. NUNNELEE. Your response was on activities. And I am new here, but my observation is that when government measures and monitors, it measures activities, not results. And so I guess the follow-up question is not how are we going to measure your activities, but how are we going to know in 2012 has this $183 million achieved any results?

Dr. HAMBURG. Well, as we put in place this program, we are asking for this money in fiscal year 2012, and, as I said, you won't see the results that same fiscal year in all cases. But in terms of impacts on people—and that, of course, is what really matters—you know, we will see, if we do this right, fewer outbreaks of foodborne disease. We will see fewer people sickened by the foods they eat. We will see a system that can better assure that not just food produced in this country but food produced overseas coming into this country will—that that imported food will be produced according to our same standards and will, again, be as safe and wholesome as we can assure.

Mr. NUNNELEE. All right. I think my time has expired. I will get back and follow up on the next round.

Mr. KINGSTON. The gentleman's time has expired.

Ms. Kaptur.

Ms. KAPTUR. Thank you, Mr. Chairman.

MENTAL HEALTH

I would just ask you to submit for the record, Dr. Hamburg, if you could, in the past year how many drugs have been approved in the arena of serious mental illness. Every year I ask for that. I am always interested. It is very slow in coming. I am wondering if you have been able to expedite the platform for these very, very debilitating illnesses that affect millions of people across our country.

[The information follows:]

MENTAL ILLNESS DRUGS

From February 28, 2008 to November 10, 2010, FDA has approved 11 new drug applications, or NDAs, to treat mental illness. Four of these NDAs were new molecular entities. Additionally, 41 supplements for a new indication with labeling changes were approved for drugs to treat mental illness. During the same period, FDA approved 108 generic drug applications for products to treat mental disease.

HEPARIN

But I want to go back to the Heparin issue. First, I want to ask your opinion as a doctor. How complex a medical product do you believe Heparin is versus other products that you regulate? Is it at the top level of complexity? Is it medium? Is it simple? How do you——

Dr. HAMBURG. It is a very complex molecule, there is no doubt about it.

Ms. KAPTUR. All right. Do you know, as FDA, at which sites all of the ingredients of Heparin are produced?

Dr. HAMBURG. Heparin is produced with one of these supply chains I was describing that has multiple inputs. And there is pre-

cursor materials that come from many different sites, and then it is consolidated——

Ms. KAPTUR. And are you at those sites? Is FDA at those sites?

Dr. HAMBURG. We don't have the resources to be at every site where every component of a product that is in an FDA-approved drug is made. We try very hard to use our resources wisely, and we are at manufacturing sites to inspect them before we approve a new drug. But that is where the drug itself is manufactured.

Ms. KAPTUR. Made, not where the ingredients come from.

Dr. HAMBURG. You know, we work with companies to try to assure the safety——

Ms. KAPTUR. Ma'am, I will tell you, I am a little uncomfortable with what you are saying to me. If I bake a cake at home and I look at where the ingredients are from, for example, I know where they are from, or at least I think I do, by reading the label. But for these drugs and medical products like Heparin, it seems like there is a lot more that is being offshored and we don't really know—how do under what conditions those pigs actually live?

Dr. HAMBURG. Well, one of the reasons why we have really developed a much broader international program is so that we can get a better handle on these kinds of issues. We now have offices in China, for example, to enable us to be on the ground, working with manufacturers, working with regulatory authorities there.

Ms. KAPTUR. I really wish I could get you on the ground in Ohio so we could provide them with real competition. As I look at some of the answers that were provided to past questioning, it looks like Illinois has really got this thing wrapped up, and maybe there is not as much competition as we think. Because we are looking at three companies here, all in Illinois—Schaumburg, Illinois; Deerfield, Illinois; Lake Forest, Illinois—three companies. I wonder if they have connecting doors. I don't know. I will have to take a ride over to Illinois and take a look.

But according to information that you provide—you know, I am really asking—I am going to become an expert in Heparin. If Americans died, we ought to know why. And we ought to really go back and understand that production chain intimately, because it will instruct us on what is happening with other medical products as well.

According to your answers to us in the record, one of my questions was, what percent of Heparin's ingredients are domestically produced versus foreign-produced? FDA could not give an exact answer on that. Here is what they said: "The percent of Heparin components produced domestically versus abroad is determined by each manufacturer according to their specifications." And then it says, "Manufacturers of the finished product, Heparin, to be marketed in the United States do disclose the source of the active pharmaceutical ingredient," but you are not necessarily on the ground where that source is being produced. And you say, "FDA would need to review each application to determine the percentage of foreign-made components in each finished Heparin product available on the U.S. market." So, basically, FDA doesn't know.

And it also says, there is a note, "Please note that the drug applications contain information that is a trade secret." Now, as I understand it, Heparin is off-patent. Am I correct? This has been

around for a long time. It is a trade secret, commercially confidential or otherwise protected from disclosure to the public under the Freedom of Information Act, the Trade Secrets Act, the Privacy Act.

If something is off-patent, I mean, tell me here, why don't the American people have a right to know where the ingredients of Heparin come from specifically? What is missing in the law?

Dr. HAMBURG. I think, you know, the problem is that Heparin and many other products are made in complex ways that have ingredients that come from many places. The companies take responsibility for making sure, to the degree that they can, that the supply chain is safe and intact. And we have a responsibility to oversee that process.

But in terms of our resources to be in every place where a precursor material is made, it is not——

Ms. KAPTUR. Is it within your purview to impose user fees on those companies to ensure that that product that comes back here is safe? Or do you need more legislative authority to do that?

Dr. HAMBURG. You know, with respect to Heparin, after the problem arose, there were some fundamental things that needed to be done to shore up the safety of that product and, also, that could be applied more broadly, things that involve more intensive screening of the precursor products, more intensive screening of the manufacturing procedures, more intensive screening of the final product——

Ms. KAPTUR. And who is paying for that, ma'am?

Dr. HAMBURG. It is a—you know, we are working with industry. They do provide user fees for components of the work that we do. Budget authority pays for many aspects of this program. And industry directly, through their work, takes responsibility for components of it, as well.

Ms. KAPTUR. Thank you. There will be more questions.

Mr. KINGSTON. Thank you.

Mr. Latham.

Mr. LATHAM. Thank you, Mr. Chairman.

And welcome. I apologize for not being here earlier. As you may be aware, there are a few other things going on this morning also. And I want to thank you for coming by and visiting. I appreciate that very, very much.

LIVESTOCK ANTIBIOTICS

Last summer, the FDA released its final draft guidance 209 on antibiotics used in livestock production to keep animals healthy and products safe. In the guidance, you laid out plans to phase out the use of growth promotion or production antibiotics, as the FDA refers to them, and increase veterinary oversight on the farms.

The production antibiotics FDA proposes to eliminate serve two roles: to improve the overall health of growing the animal, and, thus, leads to improvement in feed efficiency and growth as a result of improved health and gut integrity.

Given this final draft guidance will directly impact the health of animals and livelihood of a lot of pork producers—and you may be aware, in Iowa, we have, like, six pigs for every human in the State

of Iowa—I am really curious as to what sort of outreach has the FDA done with the producers themselves to get their input.

These are farmers who, you know, care for these animals. They produce a bountiful and safe food supply. And I really think that that type of outreach is extremely important to really understand modern production agriculture.

And if you could just talk about that, what kind of outreach, or is there communications going on at all.

Dr. HAMBURG. Well, very much so. And our Center for Veterinary Medicine has been deeply engaged in this issue and in those conversations.

It is a very important concern. As you know, antibiotics are vital for treating illness and disease in humans and animals. It is a vital resource, but it is a limited resource in terms of the number of antibiotics available. And there are not many new antibiotics in the pipeline. We don't want to be in a position where antibiotic resistance develops and we no longer have tools to treat serious disease in people or animals.

And that is why we are moving to try to define a framework for their use that is really as judicious and thoughtful as possible, never denying antibiotics for appropriate treatment when there is an indicated medical need, but reducing use that can contribute to antibiotic resistance and is not medically indicated, not for therapeutic purposes.

We have been working closely with producers and with the industry, have had, you know, a lot of ongoing conversations and a lot of, you know, back and forth. We are trying to move in a voluntary way to accommodate many of these concerns, and working with the veterinary community so that we can make sure that antibiotics are administered as appropriate and with appropriate oversight.

Mr. LATHAM. Just to clarify, are you saying it is better to wait until the animals get sick or to have healthy animals all the way along?

Dr. HAMBURG. Well, we want to have healthy animals, but we don't want to use our antibiotics in ways that can cause additional serious problems. And antibiotic resistance is a very real problem.

When there is a therapeutic indication, antibiotics should be used. When it is for growth-promotion purposes, that can contribute to antibiotic resistance; it doesn't serve a therapeutic purpose. And in terms of the overall health and wellbeing of animal and human populations and our ability to have this vital resource of working, effective antibiotics, we need to move in some new directions.

Mr. LATHAM. I still question whether you are saying, you are not—in my mind, it is better to have a healthy animal to begin with, just like healthy human beings, rather than to wait until you have—I would think it was more of a food risk with diseased animals, if you wait until after the fact.

And the idea of growth promotion or whatever it is, is just because they are healthy; it is not because they have hormones or something being fed to them.

Dr. HAMBURG. But we know that you can reduce the use of antibiotics in those settings without compromising health of animals.

And we need to be judicious in how we use these very vital resources.

ANIMAL ANTIBIOTICS

Mr. LATHAM. But I think you should give some credit, and, certainly, I would hope that there is input from producers. I mean, they are facing record-high input costs. They are not going to be overusing anything, because their bottom line is very much affected. And also, it is to their economic advantage to have the healthiest animals possible out there to go into the food system.

So, in my mind, it is a concern that you don't give the appreciation maybe of the producers and their position that should be, I think, well-deserved.

So, anyway, thank you.

Mr. NUNNELEE [presiding]. The chair will recognize Ms. DeLauro.

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

Good morning, Commissioner.

Dr. HAMBURG. Morning.

H.R. 1

Ms. DELAURO. To all, my apologies. Secretary Sebelius was testifying in HHS, but I wanted to make it to the hearing this morning. And thank you for the good work that you all do at the FDA.

Three years ago, Commissioner, the Science Board reported that the FDA was so underfunded that it could not perform its public health mission. Congress responded by increasing funding in 2009 and 2010. That progress stalled with this year's continuing resolution. And the House passed H.R. 1, which would cut FDA funding by $241 million.

I have a series of questions that I would like answers to, and specific. My view, as somebody who runs for office every 2 years, that if you can't quantify what you have, if somebody can't tell you where it is all coming from and where your votes are coming from, you don't have any idea whether or not you are going to win. So it is about the numbers.

How would FDA accommodate that kind of a cut? And what would it do to efforts to address problems identified by the Science Board in 2008?

Specifically, if the cuts in H.R. 1 were implemented, would it lead to fewer food safety and medical product inspections? How many?

Would the cuts impact the amount of imported foods and medical products that get inspected? How many?

Given that cuts would have to be enacted in a short amount of time, would furloughs or reductions in the FDA inspection force be necessary?

The President's budget closes some of the gap on needs identified by the Science Board. Where does it leave us if we lose ground in 2011 and then fail to fund adequately in fiscal year 2012?

What would that do to the agency's ability to perform its mission? What are the risks to public health if FDA isn't able to perform its mission?

Dr. HAMBURG. Well, we do face, you know, a very worrisome situation in terms of the facts that, as you recognize, FDA's mandates and responsibilities far outstrip our resources. For many, many years, many decades, truly, we have been underfunded, underresourced, as that Science Board report pointed out. And they called for very significant increases to our budget over a 5–year period.

We have been very grateful for the resources that we have gotten over the last 3 years to help build our budget. And it has enabled us, I think, to put in place important programs in key areas to protect the health of the public.

If we had to face cuts of the magnitude you are describing, you know, it would be devastating. The size of the cut is equal to the budget of, you know, one of our centers. Of course, we would absorb it across the agency——

Ms. DELAURO. I am looking for some specific numbers, Madam Commissioner, because I think that the impact is lost if we do not have the numbers.

And, again, you know, I was concerned about funding last year at this time when we spoke about what the Senate was going to do with the bill on food safety, et cetera, and in order to move on a piece of legislation which is so good and which is so much needed. But without the resources to do it, what are the consequences?

Now, it is not a question of even the—it is a question of the resources for 2012. But we have looming here H.R. 1. I want to know very specifically, as I said, how many food and medical product inspections? What impact on imported food and imported medical products?

[The information follows:]

H.R. 1 FOOD AND MEDICAL PRODUCT INSPECTIONS

FDA estimates that the reductions to the FDA budget in the House-passed version of H.R. 1 will result in approximately 1,250 fewer FDA inspections of firms that provide or manufacture food and medical products. In addition, House-passed version of H.R. 1 will result in a significant decline in funding that we could provide to our state counterparts to support development of an integrated national food safety system as well as a decline in funding to provide employee training that would negatively affect the level of expertise within our workforce.

And, you know, if you can't answer them today, I really want it laid out very specifically so that it is well-known what we are playing with here at our risk. And we need you to talk about the agency's ability to perform its mission and what the risks are to public health—above all, what the risks are to public health.

[The information follows:]

H.R. 1 PUBLIC HEALTH RISKS

FDA estimates that the reductions to the FDA budget in the House-passed version of H.R. 1 will diminish the ability of FDA to perform its mission and protect the public health. FDA's ability to assure the safety of America's food supply and medical products will be substantially reduced. For example, the magnitude of the cuts may result in approximately 1,250 fewer FDA inspections of firms that provide or manufacture food and medical products. The reduced number of inspections can result in an increase in the number of manufacturing and safety incidents that threaten the health of patients and consumers.

In addition, FDA also estimates that the reductions for FDA in the House-passed version of H.R. 1 would result in 7,500 fewer FDA import inspections to assure that imported foods and medical products meet safety standards. A lower inspection rate

makes it difficult for FDA to monitor the safety of a growing volume of food and medical product imports. The result is that Americans could suffer increased foodborne illness and experience greater medical product safety problems resulting in more sickness and deaths.

In addition, FDA also estimates that it must conduct analysis of 3,300 fewer food and medical product samples to identify safety problems. This reduction in laboratory sample analysis may result in increased incidents where foodborne contamination and drug, device, and biologic safety problems would go undetected.

Furthermore, FDA's ability to implement the new food safety legislation will be severely limited. The H.R. 1 reduction will likely increase the risk of recurring outbreaks of foodborne illness and lead to greater industry losses of revenue and market share.

Overall, cuts of this magnitude may limit FDA's ability to stimulate and support industry innovation that offers promising new opportunities to diagnose, treat, cure, and prevent disease. These lost opportunities would diminish industry innovation and compromise the development of new products that would improve the lives of patients.

I don't know if you have any of those numbers today——

Dr. HAMBURG. I can't give you exact numbers in terms of how many fewer inspections. I can tell you that it will be significant. We will be unable to do inspections, domestically and internationally, at the level that we need to be doing. We are already not at the level that we want to be and that we know really matters.

We will be delayed in our ability to review and approve new medical products that come before us. That will have impacts on people who need and are counting on those products. It will have broader impacts on the economy and the health of the companies making those products, the jobs associated with that, our ability to maintain exports in key areas and our global economic competitiveness.

Ms. DELAURO. Uh-huh.

Dr. HAMBURG. We will not be able to do the work that needs to be done to assure the safety of the blood supply—fundamental things that matter to people every day.

So we need to be, obviously, very thoughtful. We all recognize that we have to tighten budgets. And, you know, we will work with Congress going forward to examine how we can achieve important cost savings. And the President's proposed budget does contain some significant administrative and contract savings across the agency. But we have critical programs, unique programs that are vital to the health and safety of people.

Ms. DELAURO. It is going to be important to this committee. And I just outlined some in the food safety area that I think we need to have a catalog of—and you mentioned the blood supply—of what that would that mean. I think it is critically important for this committee to know that, in terms of what its actions are going to be. And I also believe it is critically important for the public to know what is about to befall them if this piece of legislation sees the light of day.

Thank you.

Dr. HAMBURG. Thank you.

FOOD SAFETY MODERNIZATION ACT

Mr. NUNNELEE. I will recognize myself for a follow-up on where I was at the last line of questioning, back on the Food Safety Modernization Act.

We talked about how the budget request for this year is $183 million. I will acknowledge that I am new here and I am still learning. The approach that I have to take is the exact same approach that I took in my business before I got here, probably the same approach that American consumers have. It is, What are we asked to spend, and what are we going to get for what we spend?

So, $183 million for this year. Do you have a 10-year estimate as to what the enforcement of the Food Safety Modernization Act would cost?

Dr. HAMBURG. We believe that, in order to fully implement the Food Safety Modernization Act and all of its many important mandates and requirements, that we would need the money that is outlined in the President's fiscal year 2012 budget and we would need likely comparable increases over the next couple of years to get us to the overall working budget for this program.

As a businessman, though, I think you can appreciate that there are some investments that have a greater return on investment. And I think it is really important to underscore that this opportunity that we have to really transform the food safety system in our Nation is going to have much more profound impact than what you are paying up front in terms of those dollars.

It is going to reduce costs to the health care system, preventable costs. It is going to reduce unnecessary lost work productivity, which is going to be important to our economy. It is going to support the health and growth of critical sectors of our economy, the food industry, enabling them to have broader markets here at home, more trust and confidence of consumers, as well as stronger export markets.

So there is huge return on investment. And the costs of these outbreaks of foodborne disease that we know can be prevented are enormous, in the billions, you know, well over $100 billion.

Mr. NUNNELEE. All right. I want to continue to pursue it, but I think the chairman is back.

TRANSFORMING FOOD SAFETY AND NUTRITION

Mr. KINGSTON [presiding]. I am only worried about your voting right now.

See, Dr. Hamburg, we are trying to run this in a manner that is fastest on everybody.

I want to talk to you about the dietary guidelines. And I know that you have been involved in this in New York City and so forth. And I know that salt is always on everybody's drop list. But there are so many articles that take the other side of salt. And I will submit these for the record, but there are five or six of them right here that kind of, on a fact-based discussion level, talk about the sodium intake and, you know, give a counter side to it.

And I think, as somebody with FDA, while it is okay for an advocacy group to take a position, I don't think that FDA should take a position on that until they have looked at all the facts. And I am going to submit these to you. And I would like you to get back to me and let me know what your comments on that are for the record.

ENFORCEMENT OF TITLE XXI

Mr. KINGSTON. I also want to switch gears right now and talk to you about a GAO report that came out about a year ago, and it was on the Office of Criminal Investigations. And the gist of it was that the FDA Office of Criminal Investigations operates almost autonomously, with the director deciding which cases he or she would report to FDA's senior management.

Are you familiar with that report?

Dr. HAMBURG. I am.

Mr. KINGSTON. Have you taken steps to rein that in? Because what the GAO said is that investigations really should come through you and be part of the FDA core mission and consistent with it and prioritize, rather than have an autonomous group over there doing it their own way.

And the GAO report also pointed out that their budget had risen by 73 percent since 1999 and the number of employees has gone up 40 percent.

So would you care to comment on that?

Dr. HAMBURG. Well, that component of FDA does serve a very important role, but——

Mr. KINGSTON. Well, no, that is not my question. My question is, have you implemented the GAO recommendations? Or do you disagree with them?

Dr. HAMBURG. Well, we reviewed it very carefully, took it extremely seriously, and a group of individuals followed up in terms of developing a set of actions that should be taken based on that GAO report. We are moving forward with that. In addition, we have——

Mr. KINGSTON. Well, where are you right now? I mean, can you give me a list of what they are investigating and why they are investigating it?

Dr. HAMBURG. You know, I am not sure that I would be allowed to give you a list of what they are investigating and why, since they are ongoing investigations. I would have to, you know—I would be happy to, if I could. But in terms of the kinds of work that they do, it relates to some of the important questions that Congresswoman Emerson was asking about, the control of counterfeit drugs——

Mr. KINGSTON. So you feel like what they are doing is consistent with the core mission, even though FDA's senior management did not know what they were doing?

Dr. HAMBURG. You know, I think that the GAO raised a number of very important concerns that we are taking seriously. And, as I said, you know, we looked at it and have developed a set of action steps. We are also working closely with the department's IG because it is all part of a coordinated effort to address a set of enforcement and investigation activities.

So we are currently in a period both of trying to examine systems and how it works; we have new leadership that is overseeing that component of FDA broadly. And we are recruiting for a new head of that office.

Mr. KINGSTON. What is their budget?

Dr. HAMBURG. I don't know off the top of my head.

Do you know?

We would have to get that for you.

[The information follows:]

OCI BUDGET

For FY 2010, the Office of Criminal Investigation's budget was $47,095,762, which includes payroll and operating expenses. The Office of Criminal Investigations has 244 FTE.

Mr. KINGSTON. Okay.

Mr. McGarey, you are aware they have increased 73 percent? That was the GAO number.

Mr. MCGAREY. Yes.

OFFICE OF CRIMINAL INVESTIGATIONS

Mr. KINGSTON. All right. Here is one of my questions. And I am going to confess, it may be partly personal. There are two Members of Congress who ride bikes to work, and I am one of them. If I Google "Novitzky"—do you know Jeff Novitzky? You do know him?

Dr. HAMBURG. I don't know him personally, but——

Mr. KINGSTON. Does he answer to you? Who does he answer to?

Dr. HAMBURG. Well, he is an employee of that office.

Mr. KINGSTON. And so, who would be his boss?

Dr. HAMBURG. Well, his boss would be the head of that office, reporting through our——

Mr. KINGSTON. And that is the vacancy right now, the head of that?

Dr. HAMBURG. There is a vacancy, and we have an acting head, of course, in that office. And then——

Mr. KINGSTON. So he would answer to the acting head?

Dr. HAMBURG. And to the ACRA, the Assistant Commissioner that oversees our inspectorate.

Mr. KINGSTON. So he is four away from you, so to speak? Is that——

Dr. HAMBURG. I suppose that——

Mr. KINGSTON. Here is my question. And, you know, all the very important issues in food safety and drug safety and everything. If I Google "Novitzky"—and I invite you to do it, because I did it this morning; I just wanted to confirm. "Novitsky and Lance Armstrong," do you know how many hits come up?

Dr. HAMBURG. No, I don't.

LANCE ARMSTRONG

Mr. KINGSTON. 116,000. And including going to France to investigate Lance Armstrong. Now, if he has broken the law, then that is a very serious matter. But it almost appears to me that there is a little adventurism going on here, that Mr. Novitzky is operating on his own.

I would like to know how much has been spent on this investigation and why so much money has been spent. And is there anybody here who could give me the answers to that?

Dr. HAMBURG. I don't think we could give it to you now, but we would be happy to follow up with you. And this is also, you know, in conjunction with the Department of Justice.

[The information follows:]

LANCE ARMSTRONG INVESTIGATION COST

The FDA Office of Criminal Investigations, known as OCI, estimates that it has expended $17,450 to cover investigative travel costs covering a timeframe from mid-2009 through February 2011. These are the only expenditures allocated to this case from OCI's operating budget thus far. This does not include estimates of agent salaries. OCI has one primary case agent assigned to this investigation.

Mr. KINGSTON. But you are aware of this investigation?

Dr. HAMBURG. I am.

Mr. KINGSTON. And you are aware that, I believe, millions have been spent, lots of time?

Dr. HAMBURG. I don't know——

Mr. KINGSTON. And I would like to know what priority that is in the food chain, because what I am very concerned about—and I hope that I am proven wrong—but that, because it is a celebrity, and one great way to make a name for yourself in this town and in politics is to bring down a celebrity—and, certainly, all people, whatever their status is, need to follow the law. But it appears that millions of dollars are being spent, lots of employees are involved in this. And I am not sure why so many resources would be put in front of the issues with Heparin that Ms. Kaptur raised or the issue with OxyContin that Mr. Rogers raised or the issues that Mrs. Emerson raised.

So what I want to see from you on this priority list—and I understand you have to keep some of this quiet—but I would like to know where this is in the priority list and see how many dollars have been spent. Because I really believe this is one man's tear, maybe a personal issue, after somebody else. And I am not sure where the balance is.

But, again, I want to know where it is on the priority list, why it is where it is on the priority list, how many people are in this investigation, and how much it has cost the taxpayers.

Dr. HAMBURG. Okay. I appreciate your concern and have raised some similar questions, myself, within the agency. And we will get back to you.

[The information follows:]

LANCE ARMSTRONG INVESTIGATION PRIORITY

Under a long-standing policy established by the Department of Justice, FDA does not comment on open investigations.

Mr. KINGSTON. And do you know the irony of it?

And, Mr. Farr, I am going to shut up in a minute.

But I just want say to you as a bike rider, it is one of the healthiest things Americans can do right now. And I know of your personal interest in health. But this is an icon who revolutionized bike riding and brought it home to so many Americans. And, again, if he is guilty, you know, that is a different matter. But I just sense that, you know, this is blown out of proportion, in terms of resources put into it. But in terms of public health, this is a huge icon that your agency is trying to take down. And maybe it should; I am not saying you are wrong on this. But what I am saying is you are really going after somebody whose name is synonymous with "health."

Dr. HAMBURG. I understand what you are saying. You know, it is an ongoing investigation in coordination with the Department of

Justice. You know, I can't speak to the details, but we would be happy to provide you with some of the information that you asked for.

I also hope you wear a helmet when you ride your bicycle.

Mr. KINGSTON. I do. And I occasionally stop at red lights, as well.

Mr. Farr.

Mr. FARR. Well, Mr. Chairman, with this disclosure of how much you ride a bike, I want to invite to you the greatest bike-riding event in the entire world. It is called the Sea Otter Classic, out in Monterey. It features bike events of every single type, international. So I hope someday——

Mr. KINGSTON. As long as they have a slow lane, I might be able to make it.

Dr. HAMBURG. Well, and I have to confess, I tried to do a bike ride of the 17 Mile Drive but turned around before we completed the whole circuit. I can sort of blame my kids for not wanting to go further, but——

Mr. FARR. Well, we are a bike-friendly community. Thank you.

A lot of this discussion has been around cuts and essentially new appropriations.

FSMA USER FEES

Mr. FARR. I would like to focus for a minute on user fees. When we passed the Food Safety Act, we had some user fees in there in the House version. It got knocked out in the Senate version. There was a user fee and an annual registration fee, the Food Safety Enhancement Act annual registration fee of $500 a year for food facilities. And I understand that the food facility or the industry supported it and consumer groups supported it and it was to provide FDA with needed additional funding. Where is that user fee proposal now?

Dr. HAMBURG. I think that at the present time, there is an interest in continuing discussions around fees that could help to support the Food Safety Modernization Act. As you know, industry had been supportive, or components of industry at least, of some kind of a registration fee. Clearly, when you think about food safety, it is an issue where both the public and industry have huge investments and concerns in terms of the outcomes, the benefits. So it makes sense for it to be a shared responsibility in terms of supporting the programs.

We hope that there will be continuing discussions with industry and with Congress about user fees, and I think as the President indicated in his budget, we are hoping that in 2013 there will be proposals that deal with that. But action before then would be most welcome as well.

Mr. FARR. We need the authority to do that. Perhaps we ought to revisit that, Mr. Chairman. My district, when I was on the county board of supervisors—and I think in every county in California, the county environmental health offices have a restaurant inspection fee. Every kitchen is required to be inspected. Of course, nobody likes that. You know what? It has an incredible effect on making sure that the food preparation in all our restaurants and food for-profit institutions are done according to health standards, and I think there doesn't seem to be anybody wanting us to repeal that

fee. I think you get—if people find a benefit for the fee, they will use.

There is another fee that the President's budget anticipates is going to raise $61 million. It is a volunteer fee. It is called the Voluntary Qualified Importer Program. I wondered if you could just tell me how that is working. As we talked about earlier, I am very concerned about safe imports, because a lot of fresh product grown in Mexico comes into the United States and fresh product grown in the United States goes to Mexico and because Mexico is the number one trade partner with the State of California, and California is the largest ag State in the union, a lot of that trade with Mexico is agriculture.

IMPORTED FOODS

If that agriculture trade is delayed because of inspection issues, either on the Mexican side or the U.S. side, it is just lost. Everyone is concerned about this. You want to do thorough—but quick—inspections. So you created this sort of fast-track program, to move food product expeditiously.

I wondered if you think this qualified importer program is going to work and work so that those who are paying to be in the program will get fast tracked.

Dr. HAMBURG. I think as we have talked about already, the challenge of dealing with all of the imported foods is a huge one, and we need to find ways to extend our reach and we need to find ways to have a risk-based approach. And this is one way to help in that regard where we can reward people with good track records in terms of being able to recognize that they have demonstrated adherence to standards and quality. They don't need the level of inspection, et cetera that other purveyors may require. We need a risk-based strategy overall so that we can really target limited resources. But we are developing a set of new tools and strategies, some that came with the Food Safety Modernization Act, in order to extend our reach internationally and to utilize third parties.

Mr. FARR. Do you expect to meet that goal of $61 million in fee revenues this year?

Dr. HAMBURG. I think we don't yet have the foundation of a program in place and it will take a while to build up a program. But I think that we would anticipate that it will be a program that will be subscribed and successful. And I would hope we would be able to recover that amount of money. But again, this is a request for 2012. So we won't be seeing it immediately.

LEAFY GREENS

Mr. FARR. Well, would you pass on my sincere thank you and appreciation for the work that Mike Taylor is doing in meeting with growers. I know. I know where you are. You are hiding back there; but, Mike, sincerely, the effort you have made to sit down and listen and show the concern and understanding for a very complex process of trying to ensure leafy green food safety. Mr. Chairman, almost everything we produce in the United States has some kind of process where you can sterilize it and sanitize it, except leafy greens like lettuce. You can't cook it. There is no heat process. So

you really have to develop all of that food safety into the growing practices and to be able to have traceability in that.

And the industry is—the California industry is way ahead of the world, and we are excited about it. And remember, they were the ones that came before this committee when Rosa was chair, and I think shocked us all by saying we need to be regulated. Well, they went out and set up a bunch of tough regulations and now they are asking the Nation to be regulated like they are. And I think it is a good program.

Mr. KINGSTON. I agree with the gentleman, and I had an opportunity to be briefed on what the California program was, which is voluntary, and I thought it was a very positive step. Incidentally, for what it is worth, one of my first jobs was a cook, and the way we sanitized the lettuce was—I hate to say this in front of Dr. Hamburg—but we soaked it in salt in order to kill the bugs. And I am not sure if that would meet her standards or not. But it was so much better. Dr. Hamburg, I might have to give you some some time.

Ms. DELAURO. Sounds good to me, Jack.

Mr. KINGSTON. I knew I could count on you. The Italians would appreciate.

Ms. DELAURO. Lots of salt, pepper, oil and garlic and parsley. That is all you need to make it happen. That is right.

Mr. KINGSTON. The Southerners and the Italians merge on that.

Ms. DELAURO. Thank you.

GENERIC DRUG FUNDING

Commissioner, H.R. 1 dropped the language specifying the level of generic drug funding in the 2010 bill. There is no report accompanying that bill. So there is no idea of what level the bill would provide. Since H.R. 1 also cut funding for the drug-centered FDA by 10 percent below 2010, 14 percent below the 2011 request for the drug center, we can assume that a cut in generic drug would use at least these amounts and probably much more, given the lateness in the fiscal year.

Let me ask you about your concern about the impact of the cuts to CDER on generic drug review work. And do you, of course, see a slowing of application reviews and a loss of savings to patients in the health care system as a result? And again, what I am trying to get some idea of so that we know what the consequences are, is a sense of how many fewer generic drugs would be approved under H.R. 1. What can you tell us?

Dr. HAMBURG. Well, we have been making progress in the generic drug area in terms of addressing the backlog and moving product review forward, and it is really quite impressive. We review about—we approve about two drugs per business day at the present time. And we know that generic drugs are making a huge difference in terms of access to critical medicines. And this cut would set us back. It would mean that our backlogs would increase, and we would have fewer drugs being reviewed and approved in a timely way.

Ms. DELAURO. Do you have any idea how many?

Dr. HAMBURG. Again, I would prefer to get back to you with exact numbers. Again, it is one of those issues where we have to

not be penny-wise and pound-foolish. A small cut to that program is going to have repercussions in terms of costs to the health care system. I think about 75 percent of prescriptions in this country today are generic drugs, and they are resulting in huge savings.

Ms. DELAURO. Savings. That is the point I want to try to make, because we are taking a look at how we are trying to save money and cut back the cost in health care. Now, there is also something that—you don't have to comment on this—something that I wanted to go after, and that is this opportunity that the pharmaceutical companies have where they pay to delay, pay to delay a generic drug from coming to the market, so that they are in essence paying their competitors to do that. They have agreements in order to do it. If that were not allowed and if we could move generic drugs to the market sooner, on that one specific item I mentioned on the pay to delay, if the Federal Government is purchasing drugs for TriCare, for Medicare, for Medicaid, it is about a $3 billion savings. And when you think about the savings that can be made if we have generic drugs going to the market, that in fact we can begin to look at how health care costs get reduced, which is what we are trying to do.

The other piece is what I mentioned in terms of the pay to delay, immediately—and that follows on the generic drug piece, because $3 billion we could apply to some other effort, including reducing the deficit rather than taking the money from food safety modernization or from inspectors or for dealing with some of the other areas that we do. And those are the places that we ought to start, rather than putting at risk the health and safety of people in this country.

If I can quickly do a food modernization piece, because it is hard for me to stay away from this area, the legislation calls for the inspection of high-risk food facilities once every 5 years initially, and dropping to a frequency of once every 3 years. Low-risk plants would initially be inspected every 7 years and then dropped to one, once every 5 years.

Based on the information you currently have, how many food facilities would fall into the high-risk category and how many would fall into the low-risk category? And in order to meet the mandate, how much more funding would FDA need to reach those inspection frequencies and how many more inspectors would you need to hire?

Dr. HAMBURG. Well, first I should have thanked you for your leadership on food safety over the years. It has been most appreciated. In terms of your question, let us see if Michael Taylor—he says 8,000 in the high-risk category in 2012.

HIGH- AND LOW-RISK ASSESSMENTS

Mr. TAYLOR. Yes, the ongoing assessment of the bill. That is the current——

Ms. DELAURO. Eight thousand in the high——

Mr. TAYLOR. In 2012 we are shooting for about 8,800 high-risk assessments. And that will play out as the bill is implemented.

Ms. DELAURO. Low-risk category?

Mr. TAYLOR. We do a total of 15,000 inspections, if you include the State inspections. And we mostly divide up—we do most of the

high-risk, and States share in that, but also do some low-risk inspections.

Ms. DELAURO. Which is why my prior comments about knowing what we are able to do or not able to do when you are looking at high risk, 8,000; not a small number for us to have—not the tools that you need in order to be able to get the job done.

STATE AND LOCAL PARTNERS

Dr. HAMBURG. And the mention of the inspections done by States gives me the chance to underscore a point that I did make earlier, but I think you were out of the room. But another casualty of cuts in H.R. 1 would potentially be our opportunity to help support the State and local partners and the ability to help strengthen those on-the-ground programs that are so important to an integrated food safety program.

Ms. DELAURO. Thank you, Mr. Chairman.

Mr. KINGSTON. Thank you, Ms. DeLauro.

FOOD MARKETED TO CHILDREN

Dr. Hamburg, I wanted to talk to you about the Interagency Working Group on Food Marketed to Children, the tentative proposals that came out in December 2009; and we are having a comment period, and I know it is the Federal Trade Commission and the Center for Disease Control, USDA and you, and it really is something that concerns me, the potential overreach based on these guidelines that are sitting on the table right now, and I know we are having a comment period. But under these guidelines that are out there, the food that would not be allowed to be advertised on television shows in which 50 percent of the audience is children, could include peanut butter sandwiches, eggs, granola bars, noodles, chocolate milk, pretzels, Cheerios, bread, Graham crackers and cheese.

Mr. Taylor, I can see you squirming. I will go on. Raisin bread, vegetable soup, yogurt, some salad dressing and, again, natural cheese. And what bothers me is that—oh, and the television shows that teenagers watch, basically college football, Fresh Prince of Bel-Air, Full House, Jane Goodall's Heroes, NASCAR—it is the only thing I can keep up with—Nick News, Comedy Central, Sports Center, USA soccer. So these items would not be allowed to advertise on there. Doesn't that strike you as an overreach, particularly since these items are allowed on WIC to be sold?

Dr. HAMBURG. I think that the effort is really geared at trying to make sure that there is an opportunity for information about health products to be as accurate and informative as possible, and that certain products that are targeted to youth audiences in particular often are targeted in ways that are misleading in terms of their nutritional value, and it is the appeal of the sugary—sweetened sugar, sugary cereal.

Mr. KINGSTON. Let me ask you this. It seems the nanny state has a solution for everything. Good old Momma Government is here to tell you how to raise your kids. I might want to serve my kids baloney sandwiches. In fact, these peanuts, which this committee routinely enjoys eating, two packages would exceed your

guidelines and they would not be allowed to advertise because of the salt.

Mr. Taylor, I am going to invite you to come speak next time because—he is kind of like a referee in the background. You can't see him from here. But what does the nanny state want?

HEALTHY KIDS

Mr. FARR. Healthy kids.

Mr. KINGSTON. Let us talk about healthy kids. Are you familiar with the family-friendly MTV show called Skins?

Dr. HAMBURG. I am not.

Mr. KINGSTON. Well, it is not exactly something you want your 14-year-old necessarily watching. And yet you could watch Skins, which is basically kind of a titillating-type show. I haven't watched it. I have channel-surfed through it. But you could watch that show, but you could not buy Cheerios—Cheerios would not be allowed to advertise on it. Doesn't that strike you as—even for momma government—a little bit inconsistent?

Dr. HAMBURG. Well, from the FDA perspective, our role is to try and provide accurate information to consumers so that they can make informed choices, hopefully informed choices that——

Mr. KINGSTON. But isn't the labeling law going to do that?

Dr. HAMBURG. I think it is very, very important to provide that kind of information so that people can begin to see what is in their foods.

Mr. KINGSTON. I know you want it so that when I take my wife out for a romantic Valentine's dinner, we have to read through the content of the food before we can order our fish and steak. And I am not going to let you steal my romantic evening from it, but I have got to say I don't know where the nanny state is planning to stop. It is just one thing after the other that you want to control.

But think about it. I want to invite you to look at a review of the show Skins and think, We are saying, fine, you can watch it, freedom of speech, parental control, I am not here knocking Skins, but I am saying it is ironic that you can watch Skins but Cheerios can't be advertised on it because that might really hurt our teenagers, not the fact that they are all running around in skimpy little clothes.

Ms. DELAURO. I have got to watch the show, Jack.

Mr. KINGSTON. If I haven't drummed up a little advertising and interest in the show. Mr. Farr.

Mr. FARR. Thank you, Mr. Chairman. I have to run because we got called for votes. But I think if we are going to go into what is advertised on television, let us go after all these prescription drugs that are just drowning the airwaves. By the time they give you the disclaimers, they tell you you are going to die. I don't know why anybody wants to buy it. But they seem to be very effective and I think it is abusive.

BORDER PRODUCTS

Getting back to border issues, I wondered if you could get me some information to give to this committee on the number of tests conducted on microbials and pesticides for fresh produce at the border. You don't have to give me that right now, but if you could get

it to the committee, and the time it has taken the agency to return the results of those tests. I am really looking for the number and the time.

[The information follows:]

MICROBIAL AND PESTICIDE INSPECTION TESTS

In FY 2010, ORA performed more than 2,200 microbiological analyses and more than 1,700 pesticide analyses on imported fresh produce samples. These numbers reflect multiple microbiological analyses performed on samples. For example, an imported produce commodity may be analyzed for the presence of Salmonella, E. Coli and Shigella. This would constitute a single product sample with three distinct analyses.

MICROBIAL AND PESTICIDE TEST RESULTS

The time for reporting microbiological findings of products sampled during import exams will vary based on the product being analyzed, the type of analysis, such as foodborne pathogen, and the analytical finding. The minimum timeframe in which a negative analytical finding may be obtained from a rapid screening method for microbe testing typically ranges between three to five days. However, when analyzing more complex products and foodborne pathogens, this timeframe will range between 10 to14 days. In addition, when the initial screening results are not negative, an additional four to eight days is required to perform confirmatory testing. FDA continues to do research and collaborate with others to develop both more rapid and sensitive screening and confirmatory tests.

MICROBIAL AND PESTICIDE INSPECTION RESOURCES

ORA continues to prioritize its available resources to maximize our public health protection impact. We continue to identify and implement new rapid screening methods in our field laboratories, providing FDA with the ability to rapidly screen imported commodities for the presence of microbiological contaminants. In addition, we continue to use our mobile laboratories at the borders to provide on-site microbiological screening of imported products. These laboratories allow ORA to screen a high volume of imported product in an expedited manner, providing FDA with greater assurance products do not contain microbiological contaminants.

Mr. FARR. And then I want to know whether you have—and you can do that in writing to the committee—enough resources to carry out and analyze and quickly report the results for those tests. This is where speed is essential, and if there are any gaps in being able to provide that speed, I would like to know about it.

COCOA BEANS

And lastly, I just want to read something and get that also on the record in writing, because I am not looking for the answer today. But I would like for you to be aware of an issue regarding import procedures for issuing release notices for cocoa beans. It has come to my attention that several of the cocoa processing industry are facing time delays and additional financial burden at U.S. ports because of the need to clean the product at the port, not at the processing facility. I don't even know all the facts, but I will submit it to you and you can get back to us.

[The information follows:]

COCOA BEAN IMPORTS

Imported cocoa beans from Brazil, Indonesia, and Malaysia are subject to, detention without physical examination—or DWPE—due to a historical presence of live insect infestation. The product can be released into U.S. commerce if the importer shows the product complies with import standards or if the importer reconditions the product to successfully address the insect infestation problem. The surest way

to accomplish the latter is to have the cocoa beans fumigated and then cleaned of any insect detritus.

FDA does not require cocoa beans to be fumigated or cleaned at the Port of Entry. According to Chapter 9 of FDA's Regulatory Procedures Manual, the importer should provide to FDA details of the process the importer will follow for fumigating and cleaning the cocoa beans. Chapter 9 describes two acceptable methods of reconditioning shipments of cocoa beans. Either one of the options, if correctly implemented, will result in a release of the shipment into U.S. commerce. There is no requirement stating these activities be carried out in any particular location or at the Port of Entry, though certain activities should occur before the cocoa beans are delivered to the roasting plant.

In 2010, FDA met with the National Confectioners Association—or NCA—regarding concerns over the fumigation and cleaning process. Some FDA Districts were requiring processors to hold 'tailings', such as sticks, rocks, and dead insects, for FDA to examine after the fumigation and cleaning process. NCA explained it was not feasible for industry to comply with this requirement because of current industry practice. After reviewing the information provided, FDA determined that it generally would not need processors to hold tailings to obtain release. FDA provided this information to the affected District offices and is in the process of reviewing the entire guidance regarding reconditioning of imported cocoa beans subject to DWPE.

Dr. HAMBURG. Thank you. I have to confess I am not up to speed on cocoa bean imports, but we will get back to you with information on that. And on the other, it is very, very important.

ONSITE DIAGNOSTICS

I would just add to what you said about time being essential with the testing of fresh produce coming into the country, it is an area where we have huge opportunities to apply better science so that we can have onsite diagnostics to give us answers quickly and to be able to move products more swiftly, which matters to companies, and it matters to the quality of the produce, and it matters to people who want those foods on their plates.

Mr. FARR. When you think about it, as we move from a fast-food society to this so-called slow food, fresh food, we are going to have to be extra fast at making sure the slow food is what we claim it to be. Thank you.

Dr. HAMBURG. Thank you.

Mr. KINGSTON. Mr. Farr, I was just complaining to the very distinguished Democrat clerk that I think you guys took out our timekeeper back here on the television. So you might have another 2 minutes if you want.

Mr. FARR. I am finished, Mr. Chairman. We have got to go.

Mr. KINGSTON. Dr. Hamburg, we appreciate it. We are going to have to run on you. We will have a lot of questions for the record. But I do want to say you are an extremely important agency to every single household in America, And we all take a lot of pride in your work and we all have opinions of what you are doing right and what you are doing wrong. But we want to work through this process with you, and we appreciate what you are doing. And while the hearing is ending, our discussions won't.

So thank you, and this committee stands adjourned.

FDA QUESTIONS FOR THE RECORD

U.S. HOUSE OF REPRESENTATIVES

APPROPRIATIONS FOR FY 2012

MARCH 11, 2011

QUESTIONS SUBMITTED BY REPRESENTATIVE KINGSTON

FDA BUDGET INCREASES

The FDA proposes $382 million in new discretionary spending, including:

- new food safety law implementation and nutrition programs – +$218 million
- countermeasures to chemical and biological threats – +$70 million
- development of a pathway to approve biosimilars – +$56 million
- improve science capacities and facilities – +$49 million

You have four major components that you are requesting increases for: food safety; countermeasures to chemical and biological threats; biosimilars; and improving science capacities and facilities.

Mr. Kingston: What is the priority here?

Response: All of the FDA priorities that you cited – food safety and nutrition, medical countermeasures, patient safety and FDA regulatory science – are important investments for FDA that are critically important to two of the largest segments of America's economy: our food and medical products industries. These priorities are also an investment in the health of individuals and the public health of our nation. The Administration has chosen to advance these priorities during this challenging budget environment in recognition of the fundamental nature of the FDA mission and how indispensible these investments are to protecting America's health.

Mr. Kingston: For each of the requested increases, by component, please provide the number of additional FTE's that FDA is proposing to fund, where they will be located, what the estimated costs are to train and equip each new FTE, how much of the increase is for external grants and contracts, and what grade level at which they will be hired.

Response: I would be happy to provide an estimate of the cost to train and equip new full-time equivalent positions hired with FY 2012 budget increases and how much of the FY 2012 increase is budgeted for external grants and contracts:

FDA FY 2012 Initiatives Total Budget Authority Request by Initiative Required to Train and Equip FTE and to Execute External Grants and Contracts (Dollars in millions)				
	Transforming Food Safety	Advancing Medical Countermeasures	Protecting Patients	Regulatory Science and Facilities
Total Request	$218.4	$70.0	$56.3	$48.6
Total amount of request used for external grants and contracts during FY 2012	$57.5	$3.9	$9.7	$9.9
Total amount of request used to train and equip FTE during FY 2012	$4.9	$2.0	$1.3	$0.4

In addition, I would be happy to provide the hiring grade level for the FTE requested in FY 2012 budget increase:

Total Budget Authority FTE requested by GS Level				
	Transforming Food Safety	Advancing Medical Countermeasures	Protecting Patients	Regulatory Science and Facilities
GS Level				
6	0	1	0	0
7	83	8	30	0
9	0	3	0	0
11	6	9	5	2
12	227	32	9	7
13	97	73	51	27
14	19	31	15	8
15	3	8	8	5
AD	0	0	0	1
Additional FTE requested	435	165	118	50

In response to your question about the location and grade level for each position, all of the positions will be located at the FDA Maryland offices in Rockville, White Oak and College Park or the FDA Laboratories in Laurel, Maryland. In addition, positions hired for activities at the National Center for Toxicological Research will be located as the toxicology research laboratories in Jefferson, Arkansas. FDA must locate its staff at these sites so that they can receive proper training and supervision for their new responsibilities and so that they can effectively interact with their colleagues to resolve

scientific and policy issues that support the FDA public health mission, or provide essential support for such activities.

The Regulatory Affairs positions will be stationed through out the 20 district offices, 13 laboratories, and 177 resident posts and border stations that FDA field staff operates from to conduct inspection, field exams, field laboratory analysis and other public health responsibilities that the FDA Office of Regulatory Affairs performs.

FIREWALLS AT FDA

We have talked on this subcommittee in the past about the firewalls that are established at FDA to ensure that the FDA employees are free from industry pressure on product approvals.

Mr. Kingston: Tell the Committee specifically what firewalls are in place in terms of user fee programs?

Response: In the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research, reviewers are generally insulated from direct contact with companies submitting marketing applications. Any contact between FDA and a sponsor is generally conducted through the regulatory program manager, who does not make decisions on whether drug products are approved or not. Furthermore, drug review staff does not generally know which sponsors have paid a user fee and which have received a waiver. This situation allows science-based decisions without regard to payment of user fees. Finally, the Prescription Drug User Fee Act (PDUFA) performance goals are designed to measure the time it takes to complete a review, not approval time.

The Center for Veterinary Medicine has a team that handles the user fee program management, and the team is separate from the review process. This team determines who is billed for fees, grants or denies fee waivers, and ensures that sponsors are not in arrears before releasing applications for review. These functions are maintained separately from scientific review functions to safeguard the process and keep the review staff impartial to any industry pressures.

The Medical Device User Fee payment process is administered by FDA's Office of Financial Management and not by the product submission review divisions. This safeguard keeps the collection of user fees function separate from the product review function. The review of science information regarding safety and effectiveness begins only when the document control center is notified that the appropriate user fee has been received.

Mr. Kingston: Tell the Committee specifically what firewalls are in place related to post-market drug safety and advertising?

Response: Safeguards have been developed to ensure the integrity of both the post-market drug safety and advertising programs. When staff are conducting post-market safety work, they have no knowledge of the user fee status of the companies whose drugs are being reviewed for safety issues. When post-market promotional materials are reviewed, there are several levels of review involving experienced staff in the Center for Drug Evaluation and Research, also known as CDER. Team leaders, at a minimum, review and concur with reviews drafted by staff members before those reviews are issued. If companies contact staff members directly about items under review, the staff members are not allowed to discuss substantive issues in that venue. Substantive issues are only discussed in formal meetings or teleconferences where the staff person's team leader, at a minimum, is also present. These meetings frequently include other Division of Drug Marketing, Advertising and Communication staff and potentially including regulatory counsel, an associate director or director.

Mr. Kingston: Are you confident that these firewalls protect consumers and taxpayers?

Response: FDA believes that these protections against influence protect consumers and taxpayers. However, FDA recognizes the need to periodically assess these protections to continue to assure that they provide adequate protection.

REAGAN-UDALL

The Reagan-Udall Foundation was established by Public Law 110-85, the Food and Drug Administration Amendments Act of 2007. The law calls for a 14- member board, and the foundation was established to identify and address unmet scientific needs in the development, manufacture and evaluation of the safety and effectiveness of FDA-regulated products, including postmarket evaluation.

The Foundation is a nonprofit organization designed to bring together experts, consumer advocates and researchers to help FDA improve its drug, manufacturing, product, and food safety processes to accelerate innovation. The law allows FDA to provide between $500,000 and $1.25 million each fiscal year to manage the Foundation. The Foundation is authorized to accept funds from private entities to develop its recommendations for FDA. By law, federal and private funds must be kept separate. Congress has prohibited FDA from transferring any funds for the operation of the Foundation since fiscal year 2008.

There has been a prohibition on FDA funds being transferred to the Reagan-Udall Foundation since fiscal year 2008.

Mr. Kingston: Please provide the Committee with an update on what FDA is doing in partnership with the Reagan-Udall Foundation.

Response: As part of FDA's innovation strategy, FDA has identified several high priority scientific areas that FDA would like to engage in with the Reagan-Udall

Foundation, also known as RUF. FDA will explore opportunities to collaborate with RUF in the areas of food safety, novel approaches for developing therapies to fight TB, and methods to enhance FDA's ability to use clinical data sets for active post-market product surveillance. In addition, FDA has asked RUF to consider developing a visiting scholars program to bring outside expertise to FDA on topics targeted to support our Innovation Initiative, which may include bioinformatics. As we finalize FDA's new Strategic Plan for Science, other opportunities may emerge.

Although RUF has been able to hire only one person, it has been able to finalize a partnership with the Bill & Melinda Gates Foundation to improve the development of novel multi-drug TB regimens. The Gates Foundation asked RUF to bring together domestic and international TB stakeholders to prioritize the work needed to resolve scientific hurdles in the development of such therapies. FDA's role is to ensure that the scientific parameters of this work are sound and targeted to the high-priority unresolved questions. The scientific work will be done by private parties, academia, industry, and advocacy groups. FDA will benefit from improved scientific methods for reviewing novel therapies. The public health benefit from improved TB treatment is enormous.

Mr. Kingston: If the prohibition language was removed from the bill, what would the impact be to FDA's budget if you did transfer $500,000 but not more than $1.25 million to the foundation?

Response: The impact of RUF will be scientific, not budgetary. FDA would need to maintain its proposed budget level for FY 2012 so that FDA can achieve the full scope of its mission to protect American patients and consumers. A major benefit of the work that the RUF would accomplish is the potential to accelerate the development of improved science to evaluate the safety and effectiveness of the products that FDA regulates and to accelerate the development of new products. This is work that FDA could not otherwise undertake, either because we do not have the necessary expertise or because FDA should not be in the leadership role. With funds to support personnel and related infrastructure costs such as computers and office space, RUF could undertake a more robust set of programs in areas of scientific importance to FDA.

Mr. Kingston: What in your view are the potential benefits to having the foundation, and having the FDA being an active partner? What downside, if any, do you see?

Response: Congress created RUF as a private entity, distinct from FDA, because of the important work RUF can do that FDA cannot easily, or should not, undertake. FDA, in its role as regulator, should not lead a collaboration when the scientific information produced may come to FDA for evaluation.

RUF can organize complex scientific collaborations that need a neutral third party to convene the participants, negotiate complex working arrangements and data sharing agreements, and help resolve disputes among participants.

The difficult work to develop and manage such consortia can divert significant FDA resources away from FDA's core product approval and surveillance activities.

Patient advocacy groups are now looking to RUF as a mechanism for addressing their scientific issues. Science that is too complex and expensive for one group can be accomplished through partnerships of multiple patient groups, with academia, and industry. One important benefit of RUF is its ability to incorporate these stakeholders in its scientific work.

FDA will not be an active partner in all RUF projects. While in some cases, active FDA involvement to ensure appropriate scientific approaches will be warranted, in other cases FDA must have a more arms length role. For example, FDA may identify the priorities and define scientific standards, but not engage in execution of the science.

FDA'S NEEDS TO ALIGN RESOURCES TO KNOWN PROBLEMS FIRST

We keep hearing this figure of 48 million Americans with foodborne illnesses, but what you won't hear is that -- only 20 percent of these illnesses are from known or specified pathogens. Drill down even further, and you then have to look at the make-up of the illnesses from known pathogens. Nearly 60 percent of the illnesses from known pathogens come from Norovirus.

How do we address this number one issue? CDC's March 4 update of Norovirus states .... "Appropriate hand hygiene is likely the single most important method to prevent norovirus infection and control transmission. Reducing any norovirus present on hands is best accomplished by thorough handwashing with running water and plain or antiseptic soap." In FDA's 630 page FY 2012 budget request, I cannot find one mention of norovirus.

Now the second highest cause of illness is Salmonella. Under its authority before the Food Safety Modernization Act, FDA finalized the Salmonella egg rule in July 2010. According to FDA's own press release, FDA said that as many as 79,000 illnesses and 30 deaths due to consumption of eggs contaminated with the bacterium Salmonella Enteritidis may be avoided each year with new food safety requirements for large-scale egg producers.

The third highest cause of known foodborne illness is Clostridium – where there in one mention in FDA's 2012 budget and that was related to food defense.

I can go on and on, but it is going to be challenging to provide additional resources for the Food Safety Modernization Act until I am convinced that the Agency has a comprehensive plan that first seeks to understand what they are looking for (80 percent of illnesses are unknown), and secondly, makes some attempt to tie increased levels of activities to the known, illness causing pathogens. If we are going to make any new progress in fighting foodborne illnesses, we need a clear strategy.

Mr. Kingston: Would you agree with me that we have an extremely safe food supply?

Response: It is true that the United States has one of the safest food supplies. The food industry does a good job of providing abundant, safe food to U.S. consumers. However, there has been a continuing series of food safety problems – major recalls, outbreaks, and illnesses – most of which are preventable. The Food Safety Modernization Act, which gives FDA new tools to prevent foodborne illness, received the support of industry and consumer groups and represents a consensus that improvements in the current system are necessary.

Mr. Kingston: The new law aside, can you please explain to me FDA's strategy to reduce the foodborne illnesses so that we can make headway on the 48 million illnesses?

Response: FDA agrees that there is a need for a comprehensive plan for food safety. It is critical that we put in place a framework for a risk-based decision-making system for food and feed safety. FDA has implemented risk-based strategies in the past – for selecting facilities for inspection and targeting imports for border sampling – but Food Safety Modernization Act has the advantage of providing a comprehensive risk-based decision-making statutory framework. Investments in this framework will allow FDA to build a system that puts resources to their optimum use to combat foodborne illness.

Mr. Kingston: After spending hundreds of millions of dollars making sure that food is safe along the farm to table continuum, how many foods are free from pathogens and were safe before the food was rendered unsafe by improper storage or handling?

Response: Food can be contaminated at any point along the farm-to-table continuum. Therefore, all participants from growers to consumers have a role to play to help ensure food safety. Improper storage and handling does contribute to food safety problems.

It is not possible to estimate how many foods are free from pathogens and were safe before food handling. However, to address this aspect of food safety, in October 2010, FDA announced a Retail Food Safety Initiative, which focuses on strengthening controls at the retail level and widespread, uniform and complete adoption of the FDA Food Code which contains model requirements for proper storage and holding of foods. We are also investing in the Partnership for Food Safety Education to improve food safety through science-based strategies to change consumer behavior.

Mr. Kingston: How many meals were perfectly safe until contaminated by ill food handlers?

Response: As we emphasized previously, food can be contaminated at any point along the farm-to-table continuum. This includes contamination by ill food handlers. In

October 2010, FDA announced a Retail Food Safety Initiative, focusing on strengthening controls at the retail level and widespread, uniform and complete adoption of the FDA Food Code. One of the action steps included in this initiative is to make the presence of certified food protection managers a common practice. Recent data point to a correlation between the presence of a certified food protection manager and better food safety practices and behaviors. FDA will work with its partners to encourage and facilitate the development of effective training and certification for food handlers, addressing the challenges of providing training for a workforce with a high turnover rate and with various educational and cultural backgrounds. FDA, working with the Conference for Food Protection, will consider modifications to the Food Code to expand the presence of certified food protection managers.

FDA TRANSPARENCY

Last year you testified that the FDA was undergoing a transparency initiative that was going to allow more transparency into what FDA is doing, how you are doing things, what decisions have been made, and how those decisions were arrived at.

Mr. Kingston: What is the current status of this initiative?

Response: In April 2010, FDA successfully launched FDA-TRACK, our agency-wide performance management and transparency program. FDA-TRACK analyzes and reports monthly performance of FDA program offices and key agency initiatives such as our egg farm inspection and our accelerated recruiting efforts. Each quarter, the FDA-TRACK team updates the measures and performance results and those results are provided to FDA leadership. Each of the FDA program offices and key initiative results are then posted to the FDA-TRACK website at www.fda.gov/fdatrack allowing the public to assess FDA's performance on the indicated measures and key projects. To date, the website has attracted over 250,000 visitors and 7,500 monthly subscribers. Visitors are able to send feedback and requests for information. Many visitors have suggested performance measures that they would like to see, some of which FDA has adopted.

Mr. Kingston: How much did the FDA spend in FY 10 on this initiative? What are the estimates for FY 11 and FY 12?

Response: FDA spent approximately $900,000 in salaries and benefits in FY 2010 to implement the FDA TRACK performance management system that serves all FDA programs. We estimate that the salaries and benefits amounts for FY 2011 and FY 2012 will decrease to approximately $700,000 since less staff time will be required. . FDA-TRACK is supported by staff who dedicate varying percentages of their time on the initiative.

Mr. Kingston: What kind of performance measurement is in place to tell you if this is achieving the transparency that you believe FDA should have?

Response: Prior to the launch of FDA-TRACK, we performed an analysis that found that many of FDA program offices had existing performance measures in place, but reported performance information only on an annual basis. FDA-TRACK enables data-driven decisions by analyzing and reporting the monthly performance of FDA program offices and key FDA initiatives such as our egg farm inspection and accelerated recruiting efforts. The results are analyzed, discussed with FDA leadership and posted on a quarterly basis, together with annual performance targets to give the transparency that FDA should have and the American public deserves. Currently, there are performance measures in place to monitor and track the development of FDA-TRACK such as feedback from the public and the number of quarterly briefings held. The positive feedback that our stakeholders provide is also a good indicator of FDA-TRACK performance.

TRANSFORMING FOOD SAFETY & NUTRITION

The budget request includes funding for a Transforming Food Safety and Nutrition Initiative. Many of the elements are in response to the Food Safety Modernization Act, but there are also elements included that speak to HHS and Presidential public health priorities.

Mr. Kingston: Can you tell the Committee of the funding that you are requesting for the Transforming Food Safety and Nutrition Initiative how much of the initiative is to carry out the Food Safety Modernization Act and how much of the initiative is to fund HHS and Presidential health priorities?

Response: The 2012 request for Transforming Food Safety and Nutrition includes a request for an additional $226 million in budget authority. Of the $226 million, the investment in implementing the FDA Food Safety Modernization Act is $183 million. The $226 million also includes an investment of $8.8 million to support new standards for restaurant menu and vending machine nutrition labeling. The remaining amounts in the Transforming Food Safety and Nutrition Initiative include funding for GSA Rent, Other Rent and Rent Related costs, program support and pay costs. All of the funding in this initiative for food safety, nutrition, rent and other costs support HHS and Presidential health priorities.

Mr. Kingston: How many new rules, regulations, changes to policy guidance, etc. are required by the Food Safety Modernization Act?

Response: The Food Safety Modernization Act represents a unique opportunity to improve food safety, but it also represents a challenging workload for FDA. The new law that Congress enacted three months ago requires FDA to issue approximately 50 new regulations, guidance documents, and reports during the next three years.

Mr. Kingston: What is the current status, including cost-benefit analysis, of each proposed rule, regulation, policy guidance, etc. related to Food Safety Modernization Act?

Response: FDA is establishing a process to implement the many provisions of the Food Safety Modernization Act. Many of the regulations are due in 12 to 14 months and work is progressing on all of them. As required by law, FDA will include a cost-benefit analysis in the proposed and final rules issued under the Food Safety Modernization Act. However, we cannot begin the cost-benefit analysis until we have preliminary drafts of these regulations.

Mr. Kingston: According to your budget materials, funding for the food safety elements of the Food Safety and Nutrition Transformation will reduce the number of foodborne illnesses. How many fewer foodborne illnesses will we have in 2012 if this initiative is funded?

Response: The Food Safety Modernization Act, also known as FSMA, is a comprehensive new law with many important new provisions. The food safety results and the reductions in foodborne illnesses will not be immediate and will come in phases as FDA builds a new food safety system envisioned by Congress in the FSMA. However, as we survey the text of the Food Safety Modernization Act we can foresee that these standards can contribute to a meaningful reduction in deaths from foodborne disease over time, and a corresponding decrease in illnesses and hospitalization. In addition, farmers and food processors will experience billions of dollars in savings as outbreaks and recalls diminish.

The FY 2012 funding for Transforming Food Safety is a down payment on the implementation of the Food Safety Modernization Act and will serve as a foundation to ensure that we can achieve the modern food safety system envisioned in the Act, and maintain our current food safety activities.

The provisions of the Food Safety Modernization Act will be implemented in accordance with their statutory deadlines over the next several years and it may be premature to expect a drop in foodborne illness in 2012 due to the implementation of the new law. However, we do expect to see a reduction in salmonellosis from Salmonella Enteritidis in 2012 as a result of FDA's egg safety rule which went into effect for the largest producers in July 2010 and will become effective for additional producers in July 2011.

Mr. Kingston: How does additional funding allow FDA to enhance integration between Federal, State, local and foreign health partners? What is not being done currently in this regard? Why is not being done?

Response: Additional funding allows FDA to enhance integration by providing state and local partners incentives to enroll in and implement program standards such as the Manufactured Food Regulatory Program Standards and Retail Food Regulatory Program Standards. In addition, these resources will support additional states adopting implementation of standards, increase the number of program standards, and increase the number of food inspections that a state agency can conduct in support of FDA's inspection mandates established in the Food Safety Modernization Act. The additional

funding in the FY 2012 budget will also provide for continued development and implementation of enhanced IT systems that will integrate with other government agencies such as Customs and Border Protection and enhance the sharing of information with state and local regulatory partners.

Similarly, additional funding would also allow for an increase in FDA collaboration with foreign regulatory partners. It would also allow FDA to directly work with foreign regulatory partners to fully understand their regulatory system and their oversight of food and feed. Conducting audits of their systems will assist the agency in determining where to target our foreign inspection and import resources. This may include additional time on FDA-performed foreign inspections for regulatory counterparts to participate in our inspections.

Mr. Kingston: How much less time will be required to detect and respond to food outbreaks if this funding was approved?

Response: FDA is working closely with the Centers for Disease Control and Prevention, also referred to as CDC, and state and local health and environmental health agencies to detect and respond to outbreaks as fast as possible. FDA will dedicate some of the funding in the FY 2012 request to improve surveillance and response through the development of a national integrated food safety system. Surveillance and detection of outbreaks and foodborne illnesses is primarily a function of local and state health agencies. At the federal level, CDC works with the local and state health agencies to review reports of outbreaks, assess clinical laboratory tests, and coordinate epidemiologic studies to determine if an outbreak or cluster of illnesses is linked to a specific food. To improve response to foodborne outbreaks, we have to ensure that we view this effort in an integrated approach that ensures consistency and timeliness of interviews of ill individuals, testing of clinical samples, and reporting of results in addition to tracing of products, removal of products from the market and investigation of the problem.

In addition, implementing the preventive controls framework envisioned in the Food Safety Modernization Act should contribute to fewer foodborne outbreaks and illnesses in the future. FDA will put in place preventive standards and ensure high rates of compliance with those standards, resulting in fewer foodborne outbreaks and illnesses. These are all important developments related to improving food safety and detecting and responding to outbreaks of foodborne illness. At this time, however, we cannot provide a precise estimate of the time required to detect and respond to outbreaks, in part because that is not the only outcome that FDA seeks to achieve with its FY 2012 Transforming Food Safety Initiative.

ON FARM REGULATION

The budget justification indicates that FDA is going to spend some of the funds for the food safety initiative for Preventive Controls on Farms. I would also note that the money would be used to provide extensive outreach, education, and technical assistance, especially for small growers.

Mr. Kingston: What regulations is the FDA proposing for on-farm handling and processing of fresh fruits and vegetables?

Response: The Food Safety Modernization Act (FSMA) was signed into law on January 4, 2011, and this new legislation is aimed at transforming FDA's food safety efforts. FDA is currently developing a proposed produce safety rule and a proposed preventive controls rule. After notice and comments on the proposals, FDA, will issue final rules to fulfill FSMA mandates. The produce safety rule will set minimum standards for safe production and harvesting of fresh fruits and vegetables and will cover farms and on-farm packing houses. The preventive controls rule will cover food facilities that are required to register, including facilities that process fresh fruits and vegetables such as facilities that manufacture/process fresh-cut produce. As FDA works to develop the preventive controls rule it is revising its current good manufacturing practices regulation to incorporate new knowledge about the food industry and safe manufacturing, processing, and holding practices.

Mr. Kingston: Will an economic analysis be conducted prior to any regulations being drafted for on-farm handling and processing of fresh fruits and vegetables?

Response: FDA will examine the economic impacts of the Produce Safety and Preventive Control rules that will cover fresh fruits and vegetables as well as other foods. FDA will examine these impacts under Executive Order 12866 and the Regulatory Flexibility Act, and may also be conduct analysis under the Unfunded Mandates Reform Act of 1995. These analyses will be addressed in the proposed and final rules. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits, including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity. The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant economic impact of a rule on small entities. Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, when proposing a rule that would cost more than $100 million in a single year (adjusted for inflation). FDA will determine whether these rules meet the threshold for an Unfunded Mandates Reform Act analysis.

Mr. Kingston: The budget goes on to say that the outreach will be focused on small growers. Why the focus on small growers? Have the recent outbreaks occurred with small growers?

Response: FDA regards outreach to the farming community, including small and large growers, as an essential component in its produce safety rule implementation strategy. FDA recognizes that small growers are especially interested in training based on comments that FDA received through stakeholder engagements and a docket that FDA opened to solicit input on produce safety.

Outbreaks have been associated with operations across a variety of sizes and FDA believes that ensuring produce safety is the responsibility of all fresh produce growers, as food contamination which may lead to foodborne illnesses can occur on farms irrespective of size.

FDA intends to communicate the new fresh produce safety standards to farmers via numerous means including development and issuance of guidances as well as active participation in the Produce Safety Alliance. The Produce Safety Alliance is a public-private partnership charged with developing a national education and training program for growers and packers of fresh produce in anticipation of a produce safety rule from FDA. FDA will work with the Alliance to promote awareness of the new regulation and help farmers meet the standards.

DIETARY GUIDELINES

Dr. Georges Benjamin, executive director of the American Public Health Assn. describes you as "all about integrity and science". I appreciate and respect thoughtful decision making based on science rather than popular opinion. You have been a vocal supporter of efforts to reduce sodium intake – both in NY and now at the federal level. And just recently, FDA and USDA published their 2010 Dietary Guidelines for Americans which reduced the sodium target from 2,300 mg/day to 1500 mg/day.

In reviewing the Dietary Guidelines development, I was struck by the lack of consideration given to scientific studies that suggest that too little sodium might lead to adverse health consequences.

Mr. Kingston: In a couple of recent publications dealing with Diabetes, the authors note a link between a low sodium diet and increased mortality. I will note for you several of these recent and not so recent articles. I would appreciate your review and analysis of those articles for the record.

Thomas et al: *Diabetes Care 2011;* The Association Between Dietary Sodium Intake, ESRD and All-Cause Mortality and Morbidity in Patients with Type 1 Diabetes.

Ekinci et al: *Diabetes Care 2011;* Dietary Salt and Mortality in Patients with Type 2 Diabetes.

Paterna et al: *Clinical Science 2008:* Normal Sodium Diet Compared to Low-Sodium Diet in Compensated Congestive Heart Failure; Is Sodium an Old Enemy or New Friend?

Paterna et al: *American Journal of Cardiology 2009;* Medium Term Effects of Different Dosage of Diuretic, Sodium, and Fluid Administration on Neurohormonal and Clinical Outcome in Patients With Recently Compensated Heart Failure.

Willett and Bernstein: *American Journal of Clinical Nutrition 2010*; Trends in 24-h Urinary Sodium Excretion in the United States, 1957-2003: A Systematic Review.

McCarron et al: *Clinical Journal of the American Society of Nephrology 2009*; Can Dietary Sodium Intake be Modified by Public Policy.

Geerling and Loewy: *Experimental Physiology 2007*; Central Regulation of Sodium Appetite.

Response: The Dietary Guidelines for Americans are based on the preponderance of the most current scientific and medical evidence available at the time of publication. We also note that today the average American consumes nearly 3,500 milligrams of sodium per day. The vast majority of sodium in the U.S. diet comes from sodium added to processed foods. Because of the prevalence of sodium in processed foods, Americans who need to reduce their sodium intake to address medical issues or to improve their overall health have limited dietary options. FDA's approach to sodium reduction is intended to empower consumer choice and give the American consumer control over their intake of sodium. FDA believes that this approach will allow consumers with medical conditions that may be affected by sodium intake the best chance to work with their physicians to achieve good health. FDA thanks you for bringing these specific publications to FDA's attention and assures you that these and other studies will be considered in any future action FDA takes regarding sodium reduction.

Mr. Kingston: I understand that the first four studies cited appear to show harm from sodium reduction efforts in two high risk populations that were previously considered obvious targets for sodium reduction. Interestingly, the degree of sodium restriction associated with an increased risk is at levels higher than the current guideline. The next two studies cited demonstrate a remarkable stability in sodium intake across several decades, populations, and presumably, food environments. These data suggest homeostatic control of sodium intake which is apart from mere sensory effects of sodium reduction in food. They are consistent with the known existence of central neural regulatory mechanisms (Geerling and Loewy) and suggest modifying sodium content within the food environment may lead to changes in caloric and food intake patterns to maintain sodium intake. What are your views on this?

Response: As stated previously, the Dietary Guidelines for Americans are based on the preponderance of the most current scientific and medical evidence available at the time of publication. FDA recognizes the need for ongoing research in this area, which will guide future recommendations. However, at this time there is a broad consensus that current sodium intakes, which are well above the recommendations of the Dietary Guidelines, are detrimental to public health. FDA believes at this time that the preponderance of evidence supports actions that will expand options for consumers who may need to alter dietary choices to reduce their sodium intake, whether addressing medical needs or to improve their overall health. FDA will continue to seek out the most current scientific and medical evidence to guide our actions, and will also rely on relevant scientific expertise at other Federal agencies including the Centers for Disease Control and Prevention, the National Institutes of Health – especially the National Heart, Lung, and Blood Institute and the National Institute for Diabetes, Digestive and Kidney Diseases – and the U.S. Department of Agriculture.

MEDICAL DEVICES

FDA recently announced a planned change to the structure of the Global Harmonization Task Force (GHTF). This task force was conceived in 1992 in an effort to achieve greater uniformity between national medical device regulatory systems with two aims in mind: enhancing patient safety and increasing access to safe, effective and clinically beneficial medical technologies around the world.

Since its inception, GHTF was a partnership between regulatory authorities of five countries (EU, US, Canada, Australia and Japan) and the regulated industry. However, it's my understanding that FDA recently announced plans to change the structure of GHTF to dissolve the current structure and establish a regulators-only organization, with industry representatives being consulted on an as-needed basis.

Mr. Kingston: Why is this change being made?

Response: Achieving harmonization of regulatory activities is highly desirable in view of the pressures of a globalized manufacturing market and an increasing desire to streamline regulatory processes to deliver high quality products to the market with minimal delays. In a letter seeking direction from the medical device program heads, the Global Harmonization Task Force Steering Committee of regulators and industry acknowledged that while the objectives of the current Global Harmonization Task Force, or GHTF, had been accomplished, the highly regarded and significant guidances developed were most useful to developing device economies. The goals and mission of GHTF had not been fully achieved and the organization was not reflective of the market in 2011 and beyond. The change is designed to focus on information sharing and resource leveraging mechanisms within a more inclusive group of regulators that will be useful in implementing the documents developed, and to provide a forum for regulators to determine optimum ways to address harmonization and regulatory activities at an operational level.

Mr. Kingston: Would it be more beneficial if industry was included in the GHTF conversations given that the industry has as much of an interest in enhancing patient safety and increasing access to safe and effective medical technologies as the regulators do?

Response: Industry will continue to be included in the functions of Global Harmonization Task Force, or GHTF, as part of the new forum. In addition to industry, input and advice from other stakeholders such as health care professional groups and academia will be utilized in the future in GHTF functions to better enhance patient safety and increase access to safe and effective medical technologies.

Mr. Kingston: Given that industry will have to comply with the various device regulatory systems, isn't it important to include the industry perspective in all levels of GHTF discussion?

Response: Industry and all other appropriate stakeholders will have opportunities to provide their perspective in the discussions of Global Harmonization Task Force, or GHTF, functions, including document development and changes.

MEDICAL DEVICE REVIEW TIME

Delays in the FDA regulatory process are often cited as a concern of patients, doctors, investors and the medical device industry. A recent study by the California Healthcare Institute finds that there has been a 43 percent increase in 510(k) review times.

In FDA's MDUFA (Medical Device User Fee Agreement) report to Congress, FDA review performance is reported in FDA days--not calendar days. For example, for 510(k) reviews, FDA is meeting its performance goal, yet FDA has reported that the total time, in other words, calendar days, to a FDA decision continues to increase. This occurs because the number of FDA review cycles or number of times FDA reviewers stop the review clock is increasing, thus increasing the total review time. As another performance goal, FDA has committed to an interactive review process—the intent of which is to improve the review process and decrease the total review days.

Mr. Kingston: Please describe the steps you are taking to improve the interactive review process and to reduce the number of times reviewers stop the review clock--thus reducing the total days to a FDA decision.

Response: The Center for Devices and Radiological Health, or CDRH, is responsible for implementing the interactive review process for medical devices review. In 2008, CDRH published guidance describing the interactive review process for medical device submissions. CDRH is currently evaluating ways to improve the interactive review process. An element of the CDRH 2011 Strategic Priorities calls for the following:

By April 30, 2011, CDRH will obtain feedback from constituencies about the strengths and weaknesses of the interactive review process.

By June 30, 2011, CDRH will clarify CDRH roles, responsibilities, and workflow for the interactive review process and improve the business process, if necessary, as well as develop performance goals and accompanying tracking tools.

By September 30, 2011, CDRH will reassess the standard roles, responsibilities, practices, and procedures for the interactive review process and implement changes as necessary.

By November 30, 2011, CDRH will assess its interactive review process performance and modify as necessary to meet interactive review performance goals.

CDRH is currently meeting the 510(k) User Fee performance goals which specify that 90 percent of the 510(k) applications reach a decision within 90 days and that 98 percent reach a decision within 150 days. However, total time to decision is increasing due to longer manufacturer response times when CDRH asks questions. This outcome is undesirable to both CDRH and the industry. CDRH is looking at ways to address this issue.

Mr. Kingston: Is the FDA concerned that the US may lose medical device manufacturing to other countries due to the increased review times?

Response: FDA's goal is to provide consumers with safe and effective devices in a timely manner while fostering innovation. In accordance with that mission, FDA undertook a comprehensive evaluation of the 510(k) process to determine how the process could be more predictable. This evaluation included the use of new science in device review. Following this evaluation, FDA announced in January 2011, 25 actions it will take this year to improve the predictability, consistency, and transparency in our premarket device review programs.

Additionally, the Center for Devices and Radiological Health, or CDRH, has launched a Medical Device Innovation Initiative, or Innovation Initiative, to assure that American patients have timely access to important new technologies and next-generation products without compromising device safety. CDRH recognizes that transformative innovative devices typically present new scientific and regulatory challenges. The Innovation Initiative supports the development of innovative products by addressing some of the barriers that can impede a product's timely progress to market.

The Innovation Initiative proposes actions CDRH could take to reduce the cost of development and accelerate regulatory evaluation of innovative medical devices' safety and effectiveness based on sound science. These actions include facilitating the development and regulatory evaluation of pioneering medical devices, strengthening the United States research infrastructure and promoting high-quality regulatory science, and preparing for and responding to transformative innovative technologies and scientific breakthroughs.

We believe these actions will help facilitate innovation while assuring that devices are safe and effective, thereby helping to keep companies and jobs in the United States.

Mr. Kingston: The Food, Drug and Cosmetic Act provides for early meetings, a collaborative review process, and least burdensome requirements. Yet, we continue to hear it is difficult for manufacturers to avail of these basic concepts.

Why wouldn't your reviewers want to embrace these tools, all of which are aimed at resolving disputes and providing clarity for both sides as early in the review process as possible?

Response: FDA does embrace and use these tools. There is a pre-submission process that allows companies to obtain an early read of the information that would be necessary to support a marketing application. In 2010, the Center for Devices and Radiological Health, or CDRH, received more than 1,900 pre-submissions. CDRH is becoming increasingly interactive prior to submission of marketing applications. In 2005, there were approximately 900 pre-submission applications. Thus, between 2005 and 2010 the number of early interactions more than doubled. FDA also supports the least burdensome provisions of the statute. FDA is open to alternative ways to provide the same level of assurance of safety and effectiveness while reducing burdens on manufacturers. FDA deficiency letters typically reference that option as an alternative to our recommendations.

Additionally, FDA has become increasingly interactive prior to rendering a negative decision such as a Not Substantially Equivalent, or NSE, decision. Most of these NSE decisions are a result of the failure of the manufacturer to provide the needed performance information. FDA has become increasing interactive to try to work with the manufacturer to obtain the needed information for a particular submission. Thirteen percent of the submissions receive four or more review cycles before reaching the NSE decision. This is in contrast to 2006, when only 3 percent of the submissions received four or more review cycles before reaching an NSE decision.

Mr. Kingston: Wouldn't this save the agency and taxpayers time and money?

Response: FDA does not have the data that would allow us to say that these early interactions would save FDA and the taxpayers time and money. In fact, these early interactions consume considerable resources of the Center for Devices and Radiological Health's, or CDRH's, resources. Nonetheless, CDRH encourages these early interactions. An early understanding of the type of information needed to support a marketing application can, in theory, result in positive outcomes and improve submission quality for future submissions if the firm follows the advice that is provided in those early interactions. If, however, the issues are not addressed by the firm in the eventual marketing application, the benefits of early interaction diminish. CDRH is working on updates to existing guidance that describes the pre-submission and meeting processes. The goal of these updates is to provide greater clarity and transparency and improve the quality of these interactions. It is anticipated that a draft version of this guidance will publish later this year.

BLOOD SUPPLY

There is ongoing concern regarding the safety and availability of the nation's blood supply, due to problems with bacterial contamination and emerging infectious agents such as Babesia Microti, Dengue virus and the newly described Xenotropic Murine Related Viruses. In 2008, the HHS Advisory Committee on Blood Safety and Availability recommended implementation of pathogen inactivation technology for blood components when available. Technology for platelet and plasma components has been licensed in Europe for several years.

Mr. Kingston: What is FDA doing to facilitate the licensure of this technology in the U.S.?

Response: Thank you for the opportunity to respond to your question on blood safety. The safety of the blood supply is a top priority for FDA. Each year about 15 million blood donations are collected and made into components for about 4.5 million patients who need them. FDA is vigilant in its efforts to address threats to blood safety and has taken many actions to enhance blood safety. For example, FDA held recent public meetings of the Blood Products Advisory Committee, the BPAC, to discuss infectious agents and the risk to the blood supply. Specifically, the BPAC discussed Xenotropic Murine Related Viruses in December 2010, Dengue Virus in December 2010, and Babesia microti in June 2010, in addition to discussing other infectious agents. FDA also held public conferences on arboviruses in September 2010. One of the challenges regarding the development of donor screening tests is that in-vitro diagnostic device manufacturers may not have the interest in developing such tests.

We agree with the HHS Advisory Committee on Blood Safety and Availability that a safe and effective pathogen-inactivation system could improve blood safety by preventing transmission of emerging diseases. In November 2009, the FDA brought the issue of study designs -Phases 3 and 4- for product development of human platelets using the Cerus INTERCEPT Blood System for pathogen inactivation to the BPAC. The Committee discussed a potential safety signal and the reduced efficacy associated with INTERCEPT platelets. The BPAC recommended that additional large scale clinical studies be performed to address these issues. FDA continues to encourage manufacturers to discuss technologies for pathogen inactivation with FDA.

UNAPPROVED DRUGS ON THE MARKET

In November 2007, U.S. Marshals seized approximately $2 million worth of an unapproved eyelash growth promoter. The product contained bimatoprost, a prostaglandin analogue (PGA) and the active ingredient in prescription drugs for the treatment of hypotrichosis of the eyelashes.

Despite the 2007 seizure, unapproved products containing PGAs and derivatives of PGAs remain on the market. These products are not sold with the same warnings contained on the FDA-approved prescription drugs, do not require a doctor's consult, and are often marketed as "safer" to the public.

Mr. Kingston: Is the FDA taking steps to investigate the sale of unapproved, PGA-containing products?

Response: We appreciate your concerns and take potential safety issues very seriously. In 2007, U.S. Marshals seized approximately $2 million worth of an eyelash growth promoter sold by Jan Marini Skin Research Inc. The Jan Marini product contained bimatoprost, the active pharmaceutical ingredient in the approved drugs Lumigan and Latisse. Both Lumigan and Latisse have undergone extensive clinical trials

yielding extensive published data exposing safety risks and contraindications. Based on the safety profile of Lumigan - bimatoprost, FDA was able to take enforcement action against the Jan Marini product.

Currently, FDA is aware that there are numerous products on the market being sold as cosmetics that contain prostaglandin analogues. Typically, the prostaglandin analogue ingredients in these products are similar, but not identical, to the prostaglandin analogues in approved drug products for hypotrichosis of the eyelashes such as Latisse, and in drugs to lower intraocular pressure, such as Lumigan, Travatan, and Latisse. Therefore, they present unique regulatory and scientific challenges. We are currently evaluating the issues associated with these products and working on next steps to address them.

As you know, diabetes is the leading cause of kidney failure, blindness, and amputations, and accounts for $174 billion in direct and indirect costs to the U.S. I understand that the FDA is the process of moving to the next phase of the Artificial Pancreas Project, developed as a breakthrough technology to help individuals with diabetes, which could have the potential to help reduce this burden.

COCOA BEANS

It is my understanding that the FDA has recently changed long-standing practices regarding dead insect parts in imported cocoa and began applying strict application of the FDA's Regulatory Procedures Manual to the reconditioning of cocoa beans. If imported cocoa beans are found to contain live insects, the shipment is detained and required to undergo fumigation and cleaning at the port of entry. However, recently two FDA districts offices have begun to approve applications for reconditioning only with the condition that the tailings (waste) will be retained for FDA inspection.

This has created a bottleneck for two reasons:

- Cocoa beans are cleaned by the processes at the US processing plant – not the port. The importer often does not have the information about cleaning that is needed to complete the required forms
- Cocoa bean processers are unable to retain tailings for FDA inspection
    - Beans are often stored at the port for extended amounts of time, or sold through the Intercontinental Exchange many times before it reaches a processer
    - Beans are often mixed to created the right "blend" and truck loads often contains beans from more than one shipment
    - Good manufacturing practices requires that waste material be removed immediately after cleaning (which involves three intensive steps) to prevent contamination.

Mr. Kingston: Why was the long-standing practice changed?

Response: FDA did not change the long-standing practice, rather we have worked to ensure uniform implementation of the existing practice throughout our field offices. FDA's practice for reconditioning of apparently violative cocoa beans is outlined in FDA's Regulatory Procedures Manual, or RPM, and this practice has appeared in the RPM with the current language as far back as 1994. FDA does not require cocoa beans to be fumigated or cleaned at the Port of Entry. According to Chapter 9 of FDA's Regulatory Procedures Manual, the importer should provide to FDA details of the process that will be followed for fumigating and cleaning the cocoa beans. Chapter 9 describes two acceptable methods of reconditioning shipments of cocoa beans. Either one of the options, if correctly implemented, will result in a release of the shipment into U.S. commerce. There is no requirement stating these activities be carried out in any particular location or at the Port of Entry, though certain activities should occur before the cocoa beans are delivered to the roasting plant.

In 2010, FDA met with the National Confectioners Association – or NCA – regarding concerns over the fumigation and cleaning process. Some FDA Districts were requiring processors to hold 'tailings', such as sticks, rocks, and dead insects, for FDA to examine after the fumigation and cleaning process. NCA explained it was not feasible for industry to comply with this requirement because of current industry practice. After reviewing the information provided, FDA determined that it generally would not need processors to hold tailings to obtain release. FDA provided this information to the affected District offices and is in the process of reviewing the entire guidance regarding reconditioning of imported cocoa beans.

Mr. Kingston: What is FDA doing to find a solution that permits cocoa bean processing to remain a US operation while protecting food safety?

Response: FDA continues to work with regulated industry to address concerns related to processing cocoa beans while protecting food safety. In 2010 FDA met with the National Confectioners Association – or NCA – regarding concerns over the fumigation and cleaning process. One of the concerns that was discussed related to a practice that has been encountered in some FDA field offices in which FDA has required processors to hold 'tailings', such as sticks, rocks, and dead insects, for FDA to examine after the fumigation and cleaning process. NCA explained that it was not feasible for industry to comply with this requirement because of current industry practice. After reviewing the information provided, FDA determined that it generally would not need processors to hold tailings to obtain release and has provided this information to the affected field offices. FDA is in the process of reviewing the entire guidance regarding reconditioning of imported cocoa beans.

FDA continues its dialogue with NCA over the issue of processing the beans prior to their release into US commerce. We believe we have made clear our stance that the products can be released into US commerce if the importer shows the product is compliant or reconditions the product to successfully address the insect infestation problem. We have offered to review our timeframes for completion of such operations and if it is reasonable that the process will take longer, we are amenable to extending

those timeframes. We also believe the importers could avoid the issue by working with their foreign suppliers and possibly even foreign governments to adopt practices that resolve the infestation problem and, for those products subject to Detention Without Physical Examination, – or DWPE– that would allow removal from DWPE.

DOSE-DUMPING GUIDANCE

A constituent has raised a concern regarding the approval process for ATL001, a cough, cold and decongestant combination product. After four years of working with the FDA, the FDA introduced changes to the requirements for the clinical development program regarding the effect of alcohol on patient safety. These new requirements are significantly different from what was originally agreed upon in 2006 and not based upon science. In addition, the new requirements are not applicable when the product is used in accordance with the labeled directions for use. FDA appears to have translated a legitimate concern about the risk of dose dumping when taking medicine with alcoholic beverages into an unreasonable regulatory requirement.

Mr. Kingston: Does the FDA have written specific scientific information or guidance establishing how it is evaluating the actual risk to users in a dose-dumping situation as it relates to patients being treated for cough, cold, or allergy?

Response: There is no specific written guidance on this topic. However, FDA is well aware that food and alcohol can interact with drugs in ways that put patients at risk. Oral modified-release dosage forms, also known as MRDF, are particularly susceptible to these interactions. Alcohol can cause premature and rapid release of the entire dose of active ingredient in the MRDF. Alcohol can render both drugs in some MRDF and the excipients – also known as inactive ingredients – soluble, thus facilitating what is called dose-dumping. This effect can cause a significant health risk to patients depending on the intended use and therapeutic index of the medicine. Alcohol-MRDF interactions can shift the benefit-to-risk ratio of the product in an undesirable way.

Therefore, prior to approving these products, FDA requests that sponsors conduct specific food and alcohol studies in vitro and, in some cases, in healthy volunteers to look for dangerous interactions. If the in vitro testing shows that the release of the medicine from the MRDF is affected, then a clinical study in healthy volunteers may be warranted to confirm the in vitro findings.

SEAFOOD GUIDANCE

The 2010 Dietary Guidelines for Americans contain updated guidance for pregnant women regarding the consumption of seafood. The guidance recommend that pregnant women should consume 8 ounces of seafood per week to get receive necessary Omega 3s for brain and eye development. However, the 2004 FDA guidance on mercury suggests that pregnant women to reduce their seafood consumption to less than 2 ounces per week. I am concerned with the lack of consistent advice and federal guidance is confusing to pregnant women.

Mr. Kingston: What are your plans to update current FDA advisory with the new scientific data used to formulate the 2010 Dietary Guidelines?

Response: FDA is aware of concerns that the current fish consumption advice has become outdated because it does not take into account new science that has become available since 2004. The 2004 FDA and EPA advisory on fish consumption states that pregnant women may safely eat up to 12 ounces per week of most fish species. In a recent survey by the FDA, however, median fish consumption by the pregnant women surveyed was less than 2 ounces per week. The survey also indicated that many women reduce their seafood consumption when they become pregnant. The 2010 Dietary Guidelines for Americans recommends much greater fish consumption during pregnancy than what the survey results reflect in order to enhance neurodevelopment in the developing fetus and young children.

The 2004 FDA and EPA advisory were designed to be protective against neurotoxic effects from methylmercury in the developing fetus and young children. Both the 2010 Dietary Guidelines and the 2004 FDA and EPA advisory recommend that pregnant women consume a variety of seafood per week from choices that are lower in methyl mercury. FDA recognizes that guidelines for seafood consumption by pregnant women should also enable the developing fetus and young children to obtain the maximum neurodevelopmental benefits that fish can provide. FDA has been actively engaged in a quantitative risk and benefit assessment for commercial fish that takes into account the research germane to both risks and benefits, including research published since 2004 that was reflected in the 2010 Dietary Guidelines for Americans.

The FDA risk and benefit assessment was published in draft in January 2009. It has been under further development since that time to take into account comments from the public, other government agencies, and scientific peer reviewers, as well as to incorporate additional risk and benefit modeling as recommended by many who commented. When the assessment is completed, FDA will evaluate the 2004 FDA and EPA advisory, review new research, and determine if updates or modifications to the advisory may be appropriate based on the best science available. In so doing, we will continue to consult with scientific agencies and the public through a transparent process in which all views can be thoroughly aired and considered. FDA expects to complete its assessment in the coming year.

FDA ENFORCEMENT OF TITLE XXI

The principal obligation of the FDA is to implement and enforce the provisions of Title XXI. In its publicly available material, the FDA describes the investigative efforts of its Office of Criminal Investigations (OCI) to be as follows:

a. Counterfeit drugs;

b. Healthcare fraud;

c. Misbranded drugs;

d. Food contamination/poisoning;

e. Illegal drug diversion and importation; and

f. Faulty surgical devices

While I am not intimately familiar with the investigation that recently took your agents to Europe, I do not see a connection between the investigation being conducted by Agent Novitzky and any of these priorities.

Mr. Kingston: I am specifically interested in knowing whether Novitzky's investigation of Lance Armstrong and the conduct during the Tour de France is within the published Title 21 priorities I just described. If so, which of these fundamental missions does Novitzky's investigation advance?

Response: Yes, the investigation falls squarely within the Title 21 priorities. However, based on long-standing HHS policy, FDA cannot discuss any aspect of an ongoing criminal investigation. Even so, I want to emphasize that the introduction and distribution of misbranded and unapproved drugs, as well as the illegal dispensing of prescription drugs are prohibited criminal violations under the Federal Food, Drug, and Cosmetic Act. Performance enhancing drugs, which are often unapproved drugs from foreign sources, pose a serious public health risk to our nation's youth. Some of our nation's children who compete athletically are using performance-enhancing drugs that expose them to serious health risks.

Mr. Kingston: If the investigation is not in furtherance of the Tile 21 priorities above, what priority of the agency does it advance? Further, what was the decision-making process at the agency that resulted in the expenditure of the agency's time and resources to pursue an investigation falling outside the FDA's core mission?

Response: Again, I cannot comment on an ongoing criminal investigation based on long-standing HHS policy. However, I want to emphasize that the investigative priorities of FDA's Office of Criminal Investigations are completely aligned with the Title 21 priorities of the Food and Drug Administration.

Mr. Kingston: What other employees or contractors of the FDA have been involved in Novitzky's investigation?

Response: OCI has one primary case agent assigned to this investigation. This agent is occasionally supported by a few other agents on an as-needed basis.

Mr. Kingston: How much taxpayer money has been expended in the investigation of Lance Armstrong? I would like to know how the investigation is funded, what was the

rationale for the agency's decision to fund such an undertaking, and how the costs were calculated or arrived at by the FDA in answering this inquiry.

Response: OCI estimates that from mid-2009 through February 2011 it has expended $17,450 to cover investigative travel costs, which are the only expenditures allocated to this case from OCI's operating budget thus far. This does not include estimates of agent salaries. As we stated previously, OCI has one primary case agent assigned to this investigation, however, it is important to note that this agent is assigned to other investigations as well.

[CLERK'S NOTE.—The response provided by the Food and Drug Administration does not adequately address the question posed by the Chairman. The Chairman requested the full cost of the investigation and the FDA only provided travel costs for a 20 month period.]

Mr. Kingston: Are you aware of the following conclusions by the United States Court of Appeals for the Ninth Circuit and several Federal District Courts characterizing the investigative conduct of Agent Novitzky in the so-called BALCO investigation?

EXCERPTS FROM NINTH CIRCUIT DESCRIBING CONDUCT OF JEFF NOVITZKY:

a) Judge Cooper (trial judge) found, "[o]nce the items were seized, the requirement of the Warrant that any seized items not covered by the warrant be first screened and segregated by computer personnel was completely ignored."

b) (Novitzky) "himself reviewed the seized computer data and used what he learned to obtain the subsequent search warrants. (and) that, in conducting the seizure in the manner it did, "(Novitzky) demonstrated a callous disregard for the rights of those persons whose records were seized and searched outside the warrant."

c) Like Judges Cooper and Illston, Judge Mahan determined that "(Novitzky) callously disregarded the affected players' constitutional rights." Judge Mahan also concluded that the government "unreasonab[ly] . . . refuse[d] to follow (lawful) procedures

d) Novitzky also failed to comply with another important procedure specified in the warrant, namely that "computer personnel" conduct the initial review and segregate materials not the object of the warrant for return to their owner; "rather, (Novitzky) immediately rooted out information pertaining to all professional baseball players and used it to generate additional warrants and subpoenas to advance the investigation."

e) Judge Cooper found that (Novitzky) utterly failed to follow the warrant's protocol. Judge Illston found that the government's seizure was in "callous disregard of the Fourth Amendment"

f) Judge Cooper referred to "the image of quickly and skillfully moving the cup so no one can find the pea." And Judge Illston regarded (Notitzky's) tactics as "unreasonable" and found that they constituted "harassment."

Response: Yes, I have been made aware of the opinions of the United States Court of Appeals for the Ninth Circuit and other Federal District Courts. The actions of the OCI agent were coordinated with the United States Attorney's Office throughout the BALCO investigation.

Mr. Kingston: Given the many challenges and priorities the agency faces in this country and in the context of a very tight budget, is this an appropriate prioritization on FDA agent activity? If not, what has been done to address the abuses described by the United States 9th Circuit Court of Appeals?

Response: Yes, this is an appropriate prioritization of FDA activity. As previously stated, the distribution and abuse of unapproved drugs and the illegal dispensing of prescription drugs are prohibited criminal acts under the Federal Food, Drug, and Cosmetic Act and are serious crimes with dangerous public health consequences.

Mr. Kingston: Approximately one year ago, the GAO released its report on the FDA Office of Criminal Investigations ("OCI"). According to the GAO, OCI had operated autonomously for years with little or no accountability to top FDA officials. Yet, the office's budget rose 73% between 1999 and 2008, and the number of employees increased by about 40%.

GAO said the FDA "has relied largely on the OCI director to determine which aspects of OCI's operations and investigations are made known to FDA's top management" rather than ensuring that the OCI's activities are consistent with the FDA's core mission and the agency's priorities. Without effective oversight of OCI investigations, the agency cannot effectively evaluate OCI's performance, which would seem to frustrate FDA's efforts to strategically manage OCI's criminal investigative program to ensure its successful operation.

In August, the FDA said it wanted the criminal office to share information with FDA leaders regularly, and to do a better job picking cases that advance the agency's core mission.

What has the FDA done to implement the recommendations of the GAO? What has been done to accomplish the assurances concerning the OCI made by the agency in August, 2010?

Response: Since the issuance of the January 2010 GAO report, OCI is currently on track assessing its field office components in accordance with existing policy. The Los Angeles Field Office assessment was completed in May 2010. The Chicago Office assessment began in December 2010, and the final report is currently being reviewed. Additionally, OCI has established procedures for assessing the compliance by the Office of Internal Affairs with investigative policies, procedures and performance measures.

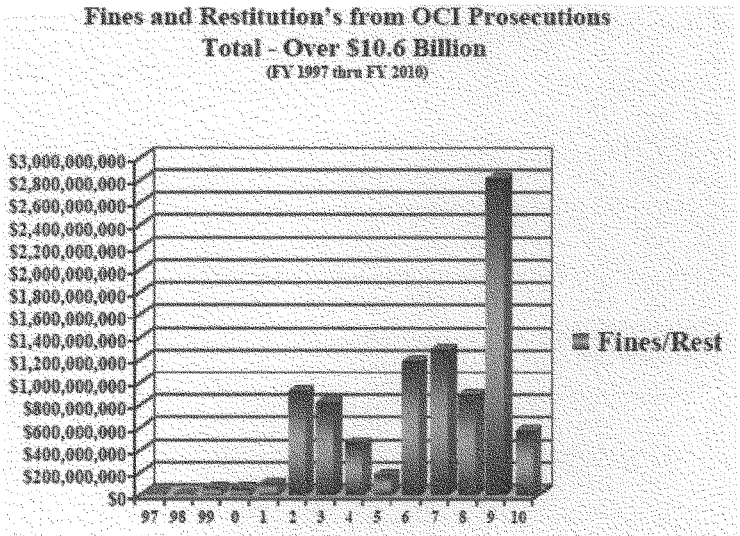
As recommended in the general comments from HHS regarding the GAO report, OCI agreed to develop meaningful performance measures to determine the extent to which results could be evaluated. These performance measures were developed and chosen by the Office of the Commissioner utilizing the FDA-wide initiative called FDA-Track. Under this performance program, OCI is required to report activities within three categories: Program Measures, Quality Improvement Measures, and Key Projects.

In response to the Program Measures category of FDA-TRACK, beginning in September 2010, OCI reports its monthly outreach and interactions with FDA Centers, the Office Regulatory Affairs, District Offices and senior level management. OCI posts the record of convictions, fines and restitutions on a quarterly basis, as a reflection of OCI's accomplishments.

In response to the Key Projects category of FDA-TRACK, OCI has been incorporated into and participates in all ORA New Hire Training courses as part of the curriculum to educate new employees about OCI's roles and responsibilities. Additionally, OCI has expanded its key projects to include outreach to all FDA Centers.

It is important to note that in addition to prosecuting organized criminal enterprises and individuals that target the nation's food, drugs, and other products that FDA regulates, OCI enforcement activities are responsible for collecting fines and restitutions that far surpasses the annual OCI budget. The experience of FY 2010 serves as a good example. OCI received a budget of $47,950,762 for FY 2010. During FY 2010, OCI was involved in cases that resulted in criminal fines and restitutions of $477,785,866. During FY 2009, the efforts of OCI yielded an even greater return on investment. With a budget of $45,172,534, OCI agents were involved in cases that yielded fines and restitutions of $2,815,417,522. This amount does not include more than $1.3 billion in criminally derived assets that have been identified and were deposited into the DOJ or Treasury accounts during FY 2009. Maintaining the FY 2012 funding level for OCI is essential to continue to sustain the FY 2009 and FY 2010 performance.

Two tables follow that illustrate recoveries from FY 1997 through FY 2010 realized as a result of prosecutions OCI was involved in.


Fines and Restitution's from OCI Prosecutions
Total - Over $10.6 Billion
(FY 1997 thru FY 2010)
$3,000,000,000
$2,800,000,000
$2,600,000,000
$2,400,000,000
$2,200,000,000
$2,000,000,000
$1,800,000,000
$1,600,000,000
$1,400,000,000
$1,200,000,000
$1,000,000,000
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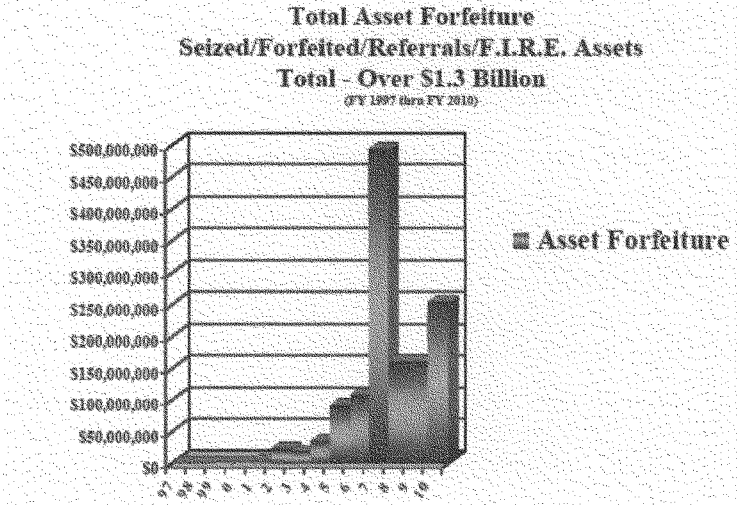
$400,000,000
$200,000,000
$0
97 98 99 0 1 2 3 4 5 6 7 8 9 10
Fines/Rest


Total Asset Forfeiture
Seized/Forfeited/Referrals/F.I.R.E. Assets
Total - Over $1.3 Billion
(FY 1997 thru FY 2010)
$500,000,000
$450,000,000
$400,000,000
$350,000,000
$300,000,000
$250,000,000
$200,000,000
$150,000,000
$100,000,000
$50,000,000
$0
Asset Forfeiture

Mr. Kingston: The fiscal year (FY) 2012 Budget request for FDA is $4,360,281,000. This represents a total program level increase of $1,076,215,000 above FY 2010.

Taxpayer resources are scarce. We need to ensure that FDA resources are devoted to the core FDA mission: namely, to protect the public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, cosmetics and our nation's food supply.

We have repeatedly been told that inadequate funding was inhibiting the agency's capacity to fulfill vital responsibilities. The growing backlog of generic drug approvals and the agency's inadequate response to the tragic loss of life from contaminated Chinese Heparin demonstrate that important aspects of the agency's core mission are being left unaddressed every day.

From a national security standpoint, the National Biodefense Science Board (NBSB) sought significant additional resources for FDA, stating in its March 2010 report that the NBSB "concludes that the FDA has not been able to fulfill its implicit national security mission, in large part because of lack of resources."

And yet, an Internet search of the names of Lance Armstrong and FDA Criminal investigator Jeff Novitzky returns over 100,000 hits about what must be one of the most highly public criminal investigations in memory. Most notably, the media has reported extensively on a trip by Novitzky and others to France, where they stayed in four star hotels, for the apparent purpose of obtaining Lance Armstrong's urine samples from 1998 and 1999 to determine whether he used performance enhancing drugs in the Tour de France.

As Americans are demanding that their government stop spending their money frivolously, please explain to this Committee how an investigation into cycling in France in the 1990's is essential to the FDA's core mission to protect the health and safety of the American people.

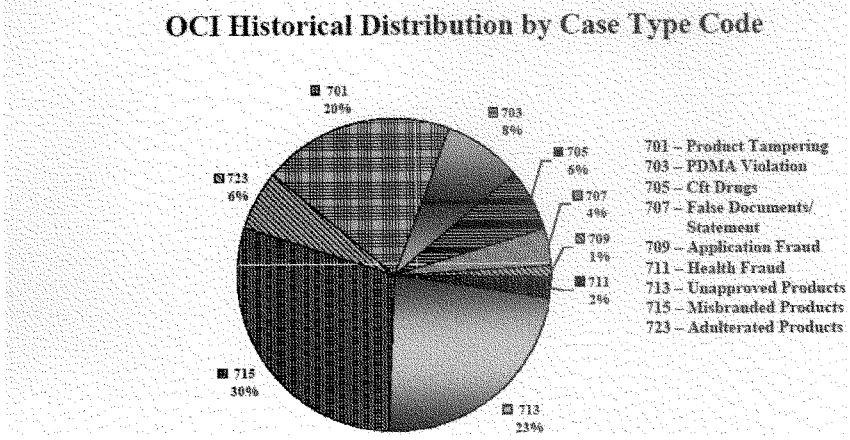
In light of the critical tasks that the FDA has left unaddressed, can you honestly assure this committee that engaging in a highly public and expensive investigation of professional cycling is truly a priority?

Response: As I stated previously, the illegal distribution of unapproved and misbranded drugs is a priority for FDA. FDA is very concerned that the use of these products presents a significant risk to all Americans, particularly our nation's youth. In addition to being a threat to the public health, such actions are prohibited criminal violations under the Federal Food, Drug, and Cosmetic Act.

Mr. Kingston: Do you agree, Dr. Hamburg that the FDA's efforts should be focused on the responsibilities and obligations set out in Title 21? If so, what criteria are

utilized at the agency in directing its enforcement and investigative activities to matters other than those mandated under Title 21?

Response: OCI's investigative priorities are based upon the Federal Food, Drug, and Cosmetic Act as established under Title 21, including cases involving the introduction and distribution of misbranded and unapproved drugs and the illegal dispensing of prescription drugs. In addition, FDA has investigative responsibilities under the Federal Anti-Tampering Act found under Title 18 USC 1365. The following chart displays the distribution of the types of cases that OCI has investigated.



QUESTIONS SUBMITTED BY REPRESENTATIVE LATHAM

ARTIFICIAL PANCREAS PROJECT

As you know, diabetes is the leading cause of kidney failure, blindness, and amputations, and accounts for $174 billion in direct and indirect costs to the U.S. I understand that the FDA is the process of moving to the next phase of the Artificial Pancreas Project, developed as a breakthrough technology to help individuals with diabetes, which could have the potential to help reduce this burden.

Mr. Latham: At what stage is FDA involved in the Artificial Pancreas Project? To what extent will you be taking input from outside entities – clinical experts and medical device stakeholders - as part of the regulatory process to develop guidance for device makers as clinical trials move forward?

Response: The artificial pancreas is a significant risk device, which requires the submission of an Investigational Device Exemption application, or IDE. FDA must approve the IDE before clinical research can begin.

FDA efforts to guide academicians and other researchers through the regulatory process for the artificial pancreas include issuing a publication that outlines information regarding software for the artificial pancreas, clinical study design, and other elements for developing an artificial pancreas. FDA has also developed a list of issues to consider for researchers who contact FDA and offering to meet with individual researchers to provide feedback on their study protocols.

To support the development of the artificial pancreas, FDA has sought input from outside entities such as clinical experts and medical device stakeholders. In particular, FDA, together with colleagues from NIH and academia, held two public workshops in 2008 and 2010 on the artificial pancreas as well as many meetings with individual or groups of stakeholders. FDA has developed scientific expertise – both internally and through consultation with outside experts – for aspects of each of the components of the artificial pancreas system in an effort to conduct an efficient review process. FDA plans to publish guidance that outlines an approach to designing a clinical study to assess the safety and effectiveness of an artificial pancreas in support of a marketing application. FDA also plans to solicit public comments, including input from outside clinical experts and medical device stakeholders, before finalizing guidance on the artificial pancreas.

FOOD USER FEES

As you know, CBO predicts it will take at least $300 million a year to implement the new food safety law, but the budget request targets funds for its implementation at $100 million for 2012. Furthermore, the request reflects the collection of "additional food safety fees" in 2013 and beyond.

The recently passed law already imposes fees in the case of a recall or re-inspection, and for companies participating in the Voluntary Qualified Importer Program. These fees would shift some of the cost of implementation to bad actors in the event of an incident, and to food companies who are voluntarily participating in a new import program. Congress, however, rejected "registration fees" as a way to pay for the law, in part because such fees would be little more than a tax that would lead to higher food prices for consumers at a time when many are struggling to make ends meet.

Mr. Latham: The budget request does not specify what "additional fees" FDA envisions collecting in 2013. Does the Administration intend to push this Congress to impose the same kind of food taxes that were rejected by the last Congress?

Response: Consistent with the Statement on Administration Policy on the FDA Food Safety Modernization Act, we hope to work with Congress to ensure that FDA has adequate resources to achieve our shared food safety goals, including resources from fee collections.

INSPECTIONS

Under the current budget restraints, FDA will need to do its import inspection job more efficiently. I have heard from a number of U.S. companies that import the exact same FDA certified product from the exact same facility abroad, sometimes at the exact same time each month. For several months these shipments are cleared quickly and sent on their way, but then, seemingly without cause, one month the FDA will decide to place a hold on these shipments.

Mr. Latham: What percentage of shipments that FDA places holds on are repetitive shipments, i.e. shipments that arrive on a regular schedule containing the same merchandise, from the same importer, from the same manufacturing facility? On what grounds does FDA detain such shipments? Is there a way to use inspection resources more wisely with respect to FDA-approved products, from companies that have averaged less than one refusal over the past five years for example?

Response: FDA does not maintain data in a manner that would allow us to readily determine the percent of shipments that are placed on hold and are repetitive shipments. There are a number of reasons that FDA may place a shipment on hold that had previously cleared without delay in the past. These reasons include routine surveillance, examination and analysis to ensure continued compliance with FDA regulations. FDA may also have identified a product for detention without physical examination based on evidence or data, or FDA may have recent information indicating public health safety concerns with a specific product area which would require increased sampling of the those commodities to ensure products are not injurious to health.

FDA is developing a new and improved IT program for imported products called PREDICT which will replace the current import screening system. PREDICT is a risk-based screening program that better reflects inherent product risks. PREDICT has the

ability to include a firm's record of compliance, which should result in an increased "may proceed" rate for firms and products based on past FDA testing or inspections. Therefore, firms that have demonstrated a high level of compliance with FDA requirements would be less likely to be sampled. Additionally, FDA is working to develop and implement portable instruments and quick screening tests that can be used by FDA inspectors in the field to conduct screening exams of foods when they are offered for import. These quick screening tests should help field staff assess the product's compliance by providing a limited screening result indicating if the product appears to be free of contaminants or adulterants. The screening tests could minimize the need for sample collection and full laboratory analysis.

SECURE SUPPLY CHAIN

On July 14, 2009, the Committee received a report on the FDA approach to medical product safety and the creation of the Secure Supply Chain program. FDA originally announced the program in January 2009, and two years later there is still no program.

Mr. Latham: When will FDA have this program up and running? Can you report back in 30 days on your progress towards making the program operational?

Response: FDA cannot at this time definitively say when this program will be up and running. FDA published its first notice regarding this proposed information collection in the Federal Register 74-FR-2605 and is in the process of preparing the second notice required by the Paperwork Reduction Act. After internal review is completed, FDA plans to publish a notice to discuss the submission of applications, including the date on which FDA will accept applications. Therefore, FDA cannot say when this program will be operational.

Mr. Latham: I have heard from participants in CBP's partnership programs, *Customs-Trade Partnership Against Terrorism and Importer Self-Assessment,* that while the programs are well intentioned, CBP does not coordinate them with other agencies that have stop and hold authority at the border, cancelling out much of the programs' incentives. What is FDA doing to coordinate with other agencies, CBP particularly, to ensure the upcoming Secure Supply Chain program complements those agencies' partnership programs?

Response: In 2005, FDA began working with Customs and Border Protection, or CBP, to develop the Secure Supply Chain proposal. These efforts continue to date and will continue through implementation of the program, should the pilot prove the program has benefits. The Secure Supply Chain program includes verification that participants meet certain requirements of CBP's Customs-Trade Partnership Against Terrorism, or CTPAT, program. Additional efforts are ongoing to ensure that FDA has access to the CBP information that is necessary to confirm CTPAT status of all participants in the Secure Supply Chain program.

BPCIA

I understand you are in the process of implementing the Biologics Price Competition and Innovation Act (BPCIA), a bill I cosponsored in the last Congress. This law struck an important balance by making lower cost biologics available to consumers while providing companies with adequate intellectual property protections so that they will continue to innovate.

Mr. Latham: Does FDA agree that, in order to ensure that intellectual property rights can be enforced, BPCIA requires a biosimilar applicant to provide a copy of its application and manufacturing information to the reference product's manufacturer within 20 days of the filing of a biosimilar application? If yes, will the Agency require each 351(k) application to contain a certification that the biosimilar applicant has done so?

Response: According to the statute, within 20 days after the applicant has been notified that its 351(k) application has been accepted for review by FDA, the applicant shall provide a copy of the 351(k) application and other information to the reference product manufacturer. We have not interpreted the scope and effect of the patent-related provisions of the statute and have not determined what, if any, information the 351(k) applicant would be required to provide FDA regarding the process described in the BPCIA for resolving patent disputes. Therefore, FDA is not in a position to agree or disagree with this statement in this question.

CTP MISSION

Mr. Latham: With regard to the infrastructure that has been developed to handle the ongoing mission of the Center for Tobacco Products, can you please tell us more about your Agency's plans to address tobacco product harm reduction? How will the Center create procedures for tobacco manufacturers to pursue modified risk tobacco product applications?

Response: The Family Smoking Prevention and Tobacco Control Act has a statutory requirement that FDA issue guidance or regulations by April 2, 2012 on the scientific evidence required for assessment and ongoing review of modified risk tobacco products. The guidance or regulations will describe the information needed for the Center for Tobacco Products to determine whether a product will significantly reduce harm and the tobacco-related disease risk to the individual user and benefit the health of the population as a whole. The Center for Tobacco Products has asked the Institute of Medicine for independent scientific advice and recommendations on the design and conduct of the studies that FDA should require of tobacco products proposed by their manufacturers to be marketed as having modified risk to consumers. All applications for modified risk will be submitted to the Tobacco Product Scientific Advisory Committee for its review and recommendations.

SUBSTANTIAL EQUIVALENCE

Mr. Latham: FDA's proposed rule for establishing a "substantial equivalence" exemption from reporting requirements for new tobacco products does not establish a timeframe for FDA to "grant or deny" an exemption request. What timeframe does the FDA intend to establish to issue its determination on a tobacco product's exemption from the substantial equivalence reporting requirements?

Response: FDA issued proposed regulations on exemptions from substantial equivalence requirements on January 6, 2011 for public comment. The 75-day public comment period ended on March 22, 2011. Among the comments received by FDA was a request for information on the timeframe within which the agency will review requests for an exemption. FDA is currently reviewing this and other comments received and will address these comments in a final regulation.

CORN SUGAR

Mr. Latham: On September 14, 2010, a petition was filed with FDA to allow producers to use "corn sugar" as an alternate name for high fructose corn syrup on product labeling. When does the FDA expect to publish a federal register notice?

Response: FDA is currently reviewing the petition and has not reached a decision at this time. If FDA were to decide to revise the relevant regulations as the petitioner requests, then FDA would need to publish a Federal Register notice. FDA is planning to send a tentative response to the petitioner, in accordance with Title 21 Code of Federal Regulations 10.30(e)(2), advising that FDA has not been able to reach a decision within 180 days.

QUESTIONS SUBMITTED BY REPRESENTATIVE ADERHOLT

PHARMACEUTICAL IMPORTERS

Mr. Aderholt: What are the proposals, and what merit do you give them, to create a fast lane for pharmaceutical importers who have a good track record and who undergo rigorous examination of their processes and controls by the agencies that regulate their imports?

Response: FDA currently has a proposal to create a fast lane for specific finished drug products and active pharmaceutical ingredients, or APIs, that apply and meet requirements of the program. The Secure Supply Chain Pilot Program would propose a facilitated entry for specific finished drug products and APIs imported into the United States that meet the criteria for approval under the program. The goal of the pilot is for FDA to assess the practicality of developing a secure supply chain program that would allow the agency to focus its resources on foreign-produced drugs that fall outside the program and that may not comply with FDA standards. Although an importer's compliance history will be a factor of this pilot program, it is not the only criteria. Moreover, the pilot may not establish a fast lane for all drug commodities for any participating pharmaceutical importer.

INSPECTIONS

Mr. Aderholt: Currently, how many inspector hours does FDA spend detaining FDA-approved products from companies that have averaged less than one refusal over the past five years?

Response: Our current data capturing and reporting systems does not allow FDA to determine the number of hours compliance officers spend processing a detention or the number of times firms have been previously refused for a specific product in the past five years. However, during FY 2010 FDA personnel spent more than 20,000 hours reviewing entry declarations for all pharmaceutical shipments offered for entry into the United States via commercial entries, courier facilities, and international mail facilities. During our entry review, FDA field staff made initial determinations to determine whether products meet the basic requirements for pharmaceuticals, including firm registration and product listing as well as the approval status, if appropriate. While these hours account for FDA's initial entry review activities, they do not include additional hours spent by field staff collecting a sample for analysis, analytical time in the laboratory, or hours spent by compliance staff determining the admissibility of individual shipments. Each of these additional activities may have occurred in any entry in which a detention was ultimately issued. Although we can determine the number of hours for sample collection and analysis, we cannot determine the numbers of hours spent in compliance.

IMPORTS

Mr. Aderholt: What coordination efforts and discussions have taken place between FDA and CBP to improve the import process?

Response: In November 2009, FDA's Office of Regulatory Affairs began an in-depth review of FDA's current import process to identify areas for improvement to aid in establishing a new national Import Operation Strategic Plan. This review included interviews with industry, trade associations, and other government agencies including various CBP offices to identify their concerns and needs. FDA has established several working groups, of which CBP is an active member, to evaluate the input, develop a strategy to address these concerns, and implement the improvements to the import process.

On August 19, 2010, Commissioner Bersin and I met at the National Targeting Center to view CBP and FDA co-located operations and discuss issues related to import security and safety. During our meeting, we identified several opportunities to improve data sharing, operational procedures, and communications. We remain committed to working together to address these issues.

On October 21, 2010, Commissioner Bersin, other Federal officials and I hosted the first Interagency Safety Conference. The meeting brought together agency heads and other senior leaders from 10 federal agencies to focus our efforts to protect the health and safety of the American consumer from unsafe products. From this meeting, the Border Interagency Executive Council (BEIC) was formed, a forum for interagency coordination on import safety related matters. The BEIC, comprised of executive members from all ten agencies that participated in the Interagency Conference, continues to meet and have identified several joint initiatives related to import safety.

In addition, the Import Safety Working Group, established in 2007 and comprised of FDA and CBP counterparts, continues to meet to address issues that affect both of the agencies. Finally FDA and CBP Headquarter and port locations meet regularly to discuss import operations and on-going initiatives that impact one or both agencies.

SECURE SUPPLY CHAIN

Mr. Aderholt: FDA announced the creation of a Secure Supply Chain program. Is this something that can help and if so when will it be implemented?

Response: The Secure Supply Chain Pilot Program may assist in expediting shipments of specific finished drug products and active pharmaceutical ingredients if they meet the criteria for selection under the program. Some of those criteria include: proof from the applicant that their drug products use a secure supply chain, proof that the applicant holds an FDA-approved drug application or is the foreign manufacturer identified in an FDA-approved application for the finished drug products, proof that the active pharmaceutical ingredients imported must be used only to make FDA-approved

drugs and validation that foreign drug manufacturers and U.S. establishments receiving drugs are FDA-registered and comply with good manufacturing practices.

This proposal was issued for public review and comment in the Federal Register, or FR, in January 2009. That FR has closed and the final document is under review by FDA. The agency anticipates the review process will be complete in 2011 and aims to implement the pilot by close of CY 2012.

IMPORTS

Mr. Aderholt: Who has the power to confiscate these substandard drugs at the time of importation?

Response: Both FDA and the Bureau of Customs and Border Protection, or CBP, have the authority to seize products that do not comply with applicable U.S. laws and regulations. Although FDA is the lead federal agency with authority over imported pharmaceutical products, CBP and FDA work together at international mail facilities to oversee the importation of pharmaceuticals.

PHARMACEUTICAL IMPORTS

Mr. Aderholt: How often does FDA intercept pharmaceuticals at the border that it knows are substandard but lacks the authority to confiscate or destroy these products and therefore simply refuses entry?

Response: While FDA will examine pharmaceutical products at the border, there is no official classification or violation referred to as substandard. FDA takes action on products that fail to comply with U.S. laws and regulations. The most common problems include, but are not limited to, charges of adulteration or contamination, unapproved pharmaceuticals and misbranded products. During FY 2010, FDA refused the entry of more than 2,200 commercial shipments of pharmaceutical products as well as more than 18,000 parcels of pharmaceutical products that were received through the international mail facilities and courier facilities. The majority of the refusals were due to the product being unapproved or misbranded.

Mr. Aderholt: Counterfeit or substandard pharmaceuticals that are simply refused entry, what percentage of the time do they show up at some other port to try to enter the system again?

Response: In FY 2010, FDA refused more than 20,000 shipments of pharmaceutical products that were in violation of our laws and regulations. Unfortunately, when a shipment has been refused entry into the United States, it is often not possible for FDA to know whether the shipment is offered for import a second time. Once a shipment is refused entry and is exported, FDA has very limited means for determining what happens to the shipment.

Mr. Aderholt: How effective are we in keeping these denied pharmaceuticals out of our country when they repeatedly try to gain access?

Response: FDA has no way of knowing how often attempts are made to import products that were previously refused and exported. Once a product is exported from the United States, FDA has very limited means of knowing the final outcome of that product. It is true that in a worst case scenario, a refused and exported shipment could be repackaged and submitted again for import into the United States.

Mr. Aderholt: What needs to happen in terms of laws and regulations for these drugs to be destroyed when seized?

Response: If FDA refused admission, FDA's authority currently allows the importer the option to export or destroy pharmaceutical product within 90 days of their refusal. Products that are seized, due to public health or other concerns, by FDA or CBP are ultimately destroyed.

QUESTIONS SUBMITTED BY REPRESENTATIVE LUMMIS

DRUG APPROVALS

Ms. Lummis: I understand that the FDA has increased requirements for drug approvals, including additional and larger clinical trials. How much have these new requirements increased the cost of introducing drugs to the market? How do you think we strike the right balance between access to life-saving products and safety?

Response: FDA is required to assess the safety and efficacy of a new drug before it can be sold to American patients and consumers. Assessing the safety of a new pharmaceutical product is becoming increasingly sophisticated. In some cases sponsors have been required to conduct larger, more comprehensive trials to allow FDA to determine if a drug's benefits outweigh its risks. These larger trials involve more patients and longer exposures to the drug product to demonstrate the safety of a new drug product. By definition these larger trials are more costly. However, without the data provided by these trials, it would be impossible for FDA to adequately evaluate the likely safety of the product.

It is difficult to determine the cost of these requirements for pharmaceutical companies. Estimates of such costs may be available from academic and private-sector entities.

FDA is acutely aware of and sensitive to the balance between the needs of patients for access to life-saving products, and the need to ensure that drug products are safe for their intended purpose. For this reason, FDA has been developing and formalizing its approach to balancing risks and benefits as part of assessing a new drug product's safety and efficacy profile. The risks associated with a treatment for a particular type of cancer, for instance, may be acceptable to the patients who would likely benefit from that treatment, whereas a treatment for something less severe such as a mild skin condition, would need to have a much more benign risk profile to pass FDA scrutiny. These trade-offs allow FDA to maintain its high standards for drug product safety without unnecessarily restricting access to important products for patients who knowingly accept the risks of those products.

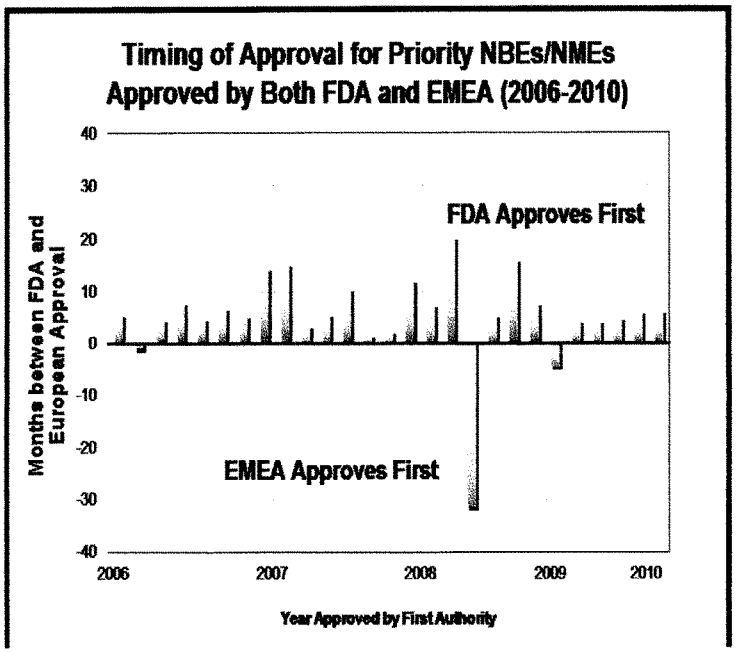
Ms. Lummis: The testimony submitted for the record states: "most new drugs are approved in the U.S. before they are approved in Europe." However, the California Healthcare Institute recently reported that FDA review times for drugs have increased. What is the main reason drug approvals have slowed in the U.S. and do you expect reviews to take even longer in the future? How do we ensure the U.S. continues to support innovation and be the top approver of drugs?

Response: Recent analyses have shown that the FDA generally approves more drugs more quickly than does the European Medicines Agency, also known as EMA. For instance, in the case of 27 new molecular or biologic entities approved on a priority basis

by both the FDA and the EMA between 2006 and early 2010, only three were approved by the EMA first.

Similarly, a review of 35 oncology drugs approved by the FDA or the EMA between October 2002 and December 2010 shows that 32 of the 35 were approved by the FDA with an average time to approval of 261 days, while the EMA approved 26 of those drugs with an average time to approval of 373 days. Finally, a steadily increasing proportion of new drugs are launched in the United States compared to the rest of the world. Between the early 1980s and 2009, the proportion of new active substances first launched in the U.S. rose from approximately 5% to almost 60%.

Drug approvals in the U.S. did slow down after the enactment of the FDA Amendments Act of 2007 also known as FDAAA. FDAAA included many new requirements that increased the amount of work required to review a new drug. For example, many more applications required an advisory committee meeting after FDAAA than before the enactment of FDAAA, particularly for priority reviews, while at the same time requiring a more stringent process for screening members of advisory committees. In the short term, these changes affected our ability to meet PDUFA performance goals. However, as the FDA has gained experience in implementing FDAAA, we have increasingly met our performance goals.



QUESTIONS SUBMITTED BY REPRESENTATIVE FARR

FOOD SAFETY MODERNIZATION ACT

As your know from your visit we grow over 85 specialty crops that gross over $4 billion in sales from the 17th District I represent. I want to thank you for visiting the valley with me to talk about food safety and fresh produce. As you will recall, spinach growers suffered a terrible blow in 2006 from a food borne illness outbreak. An outbreak that was traced to one farm that cost the entire industry hundreds of millions of dollars and sales have still not recovered. New legislation gives FDA responsibility for setting standards that ensure the safety of fresh produce.

Mr. Farr: Can you tell us where FDA is on completing the standards? How will you communicate these new standards to farmers and what steps does the agency plan to take to help farmers meet the standards?

Response: FDA is working diligently to complete produce safety standards. Although implementation of the Food Safety Modernization Act is in its early stages FDA has already made great progress on developing the produce safety rule. The schedule directed by Congress for issuing these standards is aggressive, with the proposed regulation due within one year of President Obama's signing of the bill into law, and the final rule due within one year of the close of the comment period on the proposed rule. Fortunately, FDA had already laid a foundation for the developing and implementing the new produce safety rule. FDA met extensively with numerous stakeholders and opened a Federal Register docket to formally solicit and receive comments from stakeholders regarding suggested best practices to effectively enhance the safety of fresh produce available to consumers. During the fall of 2009, FDA and USDA technical experts, scientists, and other staff engaged produce farmers by visiting 13 states across the country to participate in meetings, listening sessions, and tours of farms. During this time, FDA received more than 700 comments to an open docket from large and small growers, environmental groups, state and local government agencies, retail food chains, academia, and consumers.

FDA intends to communicate the new produce safety standards once a rule is finalized to farmers via numerous means including development and issuance of guidance as well as active participation in the Produce Safety Alliance. The Produce Safety Alliance is a public-private partnership charged with developing a national education and training program for farmers and packers of fresh produce in anticipation of a produce safety rule from the FDA. FDA will be working with the Alliance to promote awareness of the regulation and assist farmers in meeting the standards.

Mr. Farr: If we don't provide adequate funding to FDA, what is the impact on its efforts to improve the safety of fresh produce? Without funding what happens to programs that will assist our farmers in improving the safety of their crops?

Response: Without adequate funding, it will simply not be possible for FDA to engage in prolonged and extensive food safety educational outreach programs aimed specifically at fresh produce farmers. Secondly, without funding to conduct its inspection and verification activities, FDA will be prevented from adequately enforcing the new standards. It may also delay implementation of specific provisions associated with the Food Safety Modernization Act and delay improvements to the safety of our nation's food supply that Congress authorized in the Food Safety Modernization Act and that consumers and the produce industry are anxious for FDA to implement.

Mr. Farr: How much does FDA need for implementing the produce safety standards and can you give me a timeline for how that money will be spent this year and in future years?

Response: Education, outreach, and training for fresh produce growers will be a critical component of FDA's implementation strategy. This will require FDA to develop guidance documents to assist farms in compliance with the produce safety regulation. In the FY 2012 Budget FDA requests $10.5 million for efforts to improve produce safety. FDA will assess the value of specific preventive controls for safe produce growing and packing. FDA will also establish standards for key food safety risk factors to enhance produce safety and protect the health of consumers. FDA will develop practical risk-based preventive controls for small-scale agriculture operations.

With this investment, FDA will conduct food safety outreach, education and technical assistance to produce growers. FDA will develop a curriculum to train personnel assigned to produce safety compliance, inspection and enforcement activities. FDA will also provide training to FDA laboratory personnel on new methods and detection protocols developed by FDA science programs. These protocols relate to produce safety on farms and to environmental sampling to identify contamination. FDA will provide this training to FDA field personnel and other Federal, state, local, tribal, and territorial regulatory and public health partners.

In addition, the funding will also support the Produce Safety Alliance, a public-private partnership charged with developing a national education and training program for farmers and packers of fresh produce in anticipation of a produce safety rule from the FDA. The alliance is located at Cornell University's National GAPs Program and is funded by USDA and the FDA.

RISK COMMUNICATION SYSTEM AND TRACEABILITY

Commissioner Hamburg, you will recall how in 2008 we had an outbreak that began with warnings about tomatoes but eventually contaminated peppers were found to be the culprit. That outbreak exposed problems with our risk communication system and traceability. I know FDA took a lot of blame from our tomato farmers for the losses they suffered. Putting aside the blame issue –

Mr. Farr: What lessons were learned from the way CDC and FDA handled that outbreak, and what of those lessons has been incorporated into the surveillance and traceability provisions that are in the FDA Food Safety Modernization Act?

Response: Following the 2008 Salmonella Saintpaul multistate outbreak, FDA held an internal "lessons learned" exercise to examine how intra- and inter-agency collaboration and response procedures were handled. Some of the significant lessons learned are:

FDA's Office of Crisis Management, also known as OCM, has coordinated the revision of FDA Emergency Operations Plan that establishes a single, comprehensive framework for FDA's management of incidents.

FDA's OCM, in collaboration with FDA's Office of Regulatory Affairs, has developed Incident Command System training for field and headquarters emergency responders and managers to facilitate FDA compliance with the National Incident Management System.

FDA has enhanced its collaboration with the Centers for Disease Control and Prevention, also known as CDC, to improve outbreak investigation and response efforts beginning at the earliest point in the outbreak—signal detection and notification. FDA continues to strengthen this relationship with CDC, as well as USDA/FSIS, in all aspects of outbreak detection, investigation and response.

FDA is creating a new team whose full-time job is to improve and enhance FDA's capacity to manage food- and feed-related outbreaks from start to finish. The group will be responsible for surveillance and outbreak detection; outbreak response and investigation; and post-response activities. The new team, led by a Chief Medical Officer, will be a multidisciplinary, designated group of experts representing all disciplines of FDA's Foods Program.

Enhancements have been made to the FDA Emergency Operations Network Incident Management System, utilized to capture incident information the response generates in near real-time, including Geographic Information System maps related to emergency activities.

All of these lessons learned will be incorporated into the delivery of the relevant provisions of the Food Safety Modernization Act.

Mr. Farr: What levels of funding are needed to implement improvements in the surveillance program? How much is needed for the high-risk traceability program?

Response: The 2012 budget request includes $50 million for improving the integrated food safety system. With these funds, FDA will improve rapid response and recovery by strengthening FDA preparedness, surveillance and outbreak detection, outbreak response and investigation, and post response activities under the FDA

Foodborne Outbreak Team. Improving the ability to detect and respond to foodborne outbreaks will require improvements at all levels of government since Federal, State, and local agencies have a role to play. Since most disease and outbreak detection is done by state and local health departments, these stakeholders would need support. At a time when state and local funding is being cut for these activities, federal dollars may be the only remaining resource. FDA will improve food and feed safety response by integrating the capabilities of Federal, State, and local partners. FDA will also pursue pilot studies with industry using track and trace technology.

BIOSIMILARS

In regard to the Biologics Price Competition and Innovation Act the President's FY 2012 budget calls for modifying the years of "market exclusivity" from twelve to seven years. However, there is an ample record that shows Congressional intent applied to data exclusivity, not market exclusivity.

Mr. Farr: Does the FDA acknowledge Congressional intent in its implementation of the Biologics Price Competition and Innovation Act to provide for data exclusivity, not market exclusivity?

Response: Thank you for your question. FDA is still considering how to implement the exclusivity provisions of the Biologics Price Competition and Innovation Act.

Mr. Farr: Does the FDA have a timetable for issuing guidance to implement the new biosimilars pathway? What is it?

Response: FDA plans to issue guidance on biosimilars during 2011.

Mr. Farr: In a related vein, at a November, 2010 public meeting on biogenerics, FDA focused on the names to be given to biogeneric and biosimilar products. Can you comment on FDA plans to have a brand company change the chemical name of a biogeneric or biosimilar after making changes to the product?

Response: A robust postmarketing pharmacovigilance plan can be an important component in ensuring the safety and effectiveness of biological products. In general, the pharmacovigilance plan for biosimilar and interchangeable biological products should have adequate mechanisms in place to differentiate any adverse events attributable to one biosimilar or interchangeable biological product from those attributable to the reference or other biosimilar or interchangeable biological products. FDA is exploring all feasible options to ensure that a biological product can be identified when and if an adverse event has taken place. One of these involves the naming of biological products. FDA anticipates that any general decisions reached regarding the naming of biosimilar or interchangeable biological products will be published in guidance or rulemaking, both of which provide an opportunity for comment from the public. No matter what decision the

FDA recommends, the decision will reflect our mission to protect and promote the public health.

QUESTIONS SUBMITTED BY REPRESENTATIVE DELAURO

MENU LABELING

I am sure you are aware of recent reports that movie theater chains are fighting the new menu labeling requirements that were enacted into law last year. As you know, it would require chain restaurants with at least 20 U.S. locations to post calorie content of menu items.

Move theater chains are fighting this because they are concerned about disclosing the calorie content of their popcorn – which can contain as many as 1,460 calories, or equal to almost three Big Macs.

Carving out any exemption to the menu labeling requirement clearly would counter legislative intent.

Also opposed to any exemptions would be the National Restaurant Association who was an integral part in negotiating the final language.

Ms. DeLauro: What is the status of the proposed rule and what can be done to avoid any exemptions to the calorie posting requirement?

Response: FDA will issue the proposed rule on menu labeling soon. The proposed rule outlines FDA's interpretation of restaurants and similar retail food establishments that would be covered under menu labeling requirements recently enacted by Congress. In the proposed rule, FDA proposes one interpretation but also puts forth alternative interpretations. Since this is a proposed rule, FDA welcomes comment from Congress, industry, public health organizations, advocacy groups, and consumers on their interpretation of covered establishments as well as alternative approaches. FDA is publishing a separate rule for the vending machine requirements.

FDA CUTS IN H.R. 1

Commissioner Hamburg, three years ago the Science Board reported that FDA was so underfunded it could not perform its public health mission. Congress responded by increasing funding in FY 2009 and FY 2010. That progress stalled with this year's CR, and the House passed H.R. 1, which would cut FDA funding by $241 million.

Ms. DeLauro: How would FDA accommodate that kind of cut and what would it do to efforts to address problems identified by the Science Board in 2008?

Response: Under the proposed cuts to the FDA budget in H.R. 1 FDA would not be able to fulfill commitments to implement important Science Board findings of November, 2007. For example, FDA would not be able to adequately perform new science activities in certain areas because of H.R. 1 funding levels. In 2009, the FDA took action to develop scientific priority areas to be evaluated by the Science Board, established support and leadership on new scientific activities and began an in-depth

review of the information technology capabilities of FDA. In 2010, strides were made in advancing regulatory science by defining the priorities and publishing a white paper entitled "Advancing Regulatory Science for the Public." The budget levels in the House-passed version of H.R. 1, will limit FDA's efforts to strengthen science-based decision making, will impair FDA's ability to build regulatory science to improve public health outcomes, and to speed innovative products to patients.

Ms. DeLauro: Specifically, if the cuts in H.R. 1 were implemented, would it lead to fewer food safety and medical product inspections? How many?

Response: FDA estimates that the reductions to the FDA budget in the House-passed version of H.R. 1 will result in approximately 1,250 fewer FDA inspections of firms that provide or manufacture food and medical products. In addition, House-passed version of H.R. 1 will result in a decline in funding that we could provide to our state counterparts to support development of an integrated national food safety system as well as state contract inspections that FDA supports. In addition, FDA also estimates that the reductions for FDA in the House-passed version of H.R. 1 would result in 7,500 fewer FDA import inspections to assure that imported foods and medical products meet safety standards.

Ms. DeLauro: Would the cuts impact the amount of imported foods and medical products that gets inspected? How many?

Response: Yes, the House-passed version of H.R. 1 will affect food and medical product inspections. FDA estimates it would result in 7,500 fewer FDA import inspections needed to assure that imported foods and medical products meet safety standards. The reduced number of inspections could result in an increase in the number of manufacturing and safety incidents that threaten the health of patients and consumers. A lower inspection rate makes it difficult for FDA to monitor the safety of a growing manufacturing volume of food and medical product imports. The result is that Americans could suffer increased foodborne illness and experience greater medical product safety problems resulting in more sickness and deaths.

Ms. DeLauro: Given that cuts would have to be enacted in a short amount of time, would furloughs or reductions in the FDA inspection force be necessary?

Response: Cuts to FDA's budget that you describe could lead to furloughs or a reduction in FDA's inspection force or furloughs of the professionals that conduct medical product safety and effectiveness reviews.

Ms. DeLauro: The President's budget closes some of the gap on needs identified by the Science Board. Where does it leave us if we lose ground in FY 2011 and then fail to fund FDA adequately in FY 2012?

Response: Failure to fund FDA at the level of the President's budget request for FY 2011 and FY 2012 could delay FDA's implementation of the Science Board

recommendations. Specifically, in the following areas -- accomplishing Science Board recommendations in Science Capacity, Capability Organization, Securing Critical Scientific Capability and Capacity, Information Technology and Infrastructure, and other critical areas.

Ms. DeLauro: What would that do to the agency's ability to perform its mission?

Response: Failure to fund FDA at the level of the President's budget request for FY 2011 and FY 2012 could delay the ongoing implementation of the Science Board recommendations. FDA will not be able restore FDA's eroded scientific base and organizational structure, upgrade the capacity and capability of its scientific workforce, and modernize the IT infrastructure from systems that have exceeded their usual life cycles.

Ms. DeLauro: What are the risks to public health if FDA Is not able to perform its mission?

Response: All aspects of the FDA mission support America's public health. FDA's ability to assure the safety of America's food supply and medical products will be substantially reduced under the H.R. 1 funding levels for FDA.

As a result of the $400 million budget reduction, FDA estimates that the agency will conduct 1,250 fewer FDA inspections of firms that provide or manufacture food and medical products. In addition, the House-passed version of H.R. 1 will result in a significant decline in FDA-funded state contract inspections.

In addition, FDA also estimates that the reductions for FDA under H.R. 1 would result in 7,500 fewer FDA import inspections to assure that imported foods and medical products meet safety standards. A lower inspection rate makes it difficult for FDA to monitor the safety of a growing volume of food and medical product imports. The result will be less analysis of imports, which means that Americans could suffer increased foodborne illness and experience greater medical product safety problems associated with imports that do not meet safety standards.

In addition, FDA also estimates that it may conduct 3,300 fewer analyses of food and medical product samples to identify safety problems. Furthermore, FDA's ability to implement the food safety legislation that Congress recently enacted will be severely limited.

Overall, cuts of this magnitude could limit FDA's ability to stimulate and support industry innovation that offers promising new opportunities to diagnose, treat, cure, and prevent disease. These lost opportunities could diminish industry innovation and compromise the development of new products that would improve the lives of patients.

FDA FOOD SAFETY MODERNIZATION ACT IMPLEMENTATION

With the enactment of the FDA Food Safety Modernization Act, FDA will for the first time have mandated inspection frequencies of food facilities under its jurisdiction. As you know, the legislation calls for the inspection of high-risk food facilities once every five years initially and then dropping to a frequency of once every three years. Low-risk plants would initially be inspected every seven years and then drop to once every five years.

Ms. DeLauro: Based on the information you currently have, how many food facilities would fall into the high-risk category and how many would fall into the low-risk category?

Response: With regard to inspection frequency, the Food Safety Modernization Act provides criteria to be considered in determining whether a particular facility is considered to be a part of the high or non-high risk category. The criteria include the known safety risk of a food, compliance history of the facility, rigor and effectiveness of the facility's hazard analysis and preventive controls, and other criteria. Currently, the FDA is refining its definition of high and non-high risk facilities and is performing the necessary analysis to categorize food facilities. FDA will not have reliable estimates of the numbers of facilities in each of the categories until the agency completes this work.

Ms. DeLauro: In order to meet the mandate, how much more funding would FDA need to reach those inspection frequencies and how many more inspectors would you need to hire?

Response: At this time, FDA is studying the new legislation, including opportunities to work with Federal, State, local, tribal, and foreign regulatory partners and 3rd party organizations, to determine how best to leverage all available resources to best assure the safety of the food supply. We are not currently in a position to say how many resources we will be able to leverage. Therefore, we cannot say at this time how many additional resources FDA will need to meet the expectations of the new law.

Ms. DeLauro: The President's budget request provides a budget increase of $183 million as an investment to implement the FDA Food Safety Modernization Act.

Could you detail what we will see implemented with this request and what will be needed to complete implementation in FY 2013-2015?

Response: With the requested increase of $183 million to implement the Food Safety Modernization Act, also known as the FSMA, FDA expects to make substantial progress in building the science-based, prevention-oriented and efficient food safety system mandated by Congress. FDA would issue the key regulations required by the Food Safety Modernization Act, including produce safety standards, preventive controls in food processing facilities, and standards for preventing intentional adulteration. In addition, we would strengthen the scientific basis for the Foods Program, including the

ability to make the design and implementation of our prevention standards more risk-based and effective in preventing food safety problems.

FDA plans to train FDA investigators in the latest inspection techniques that take advantage of the preventive controls regulatory framework. FDA will also build state capacity and create a national inspection work plan so that state inspections can be leveraged to meet FDA's domestic inspection frequency requirements.

FDA plans to design and implement a new import safety framework for carrying out the FSMA mandates. The new framework will include stronger importer accountability through the foreign supplier verification program, an accredited third-party certification program, comparability assessments to determine if foreign governments have food safety systems comparable to the United States, a voluntary qualified importer program to expedite review and importation of food by qualified importers, and expanding the foreign inspection program. Finally, FDA will need to rely on better information technology to support more efficient domestic inspection and effective oversight of imports.

In future years, FDA will need to continue to invest in implementing these programs, including increasing FDA science capacity, strengthening the integrated food safety system, and implementing the import safety framework. We hope to work with Congress to ensure that FDA has adequate resources to achieve our shared food safety goals, including resources from fee collections.

Ms. DeLauro: We were already increasing funding for FDA's food safety program just to catch up to where the agency needed to be under prior law. If you have make cuts, how do you balance the prior problems that the Science Board identified in 2008 against the need to implement the new law? What programs win and what programs lose and who pays the price in terms of health and economic impacts?

Response: Efforts to bolster FDA's science capacity must occur in tandem with implementing the Food Safety Modernization Act. The new law envisions an increase in FDA's scientific expertise to implement the preventive controls framework and engage in risk-based public health decision making. This will include additional staff with microbiological and chemical safety expertise and risk analysis expertise. Decreased funding to supplement FDA's scientific expertise will negatively impact FDA's ability to implement the Food Safety Modernization Act.

Ms. DeLauro: The FDA Food Safety Modernization Act authorizes the FDA to recognize private third party certifiers to vouch for the safety of imported products. Would you describe how FDA plans to implement that provision of the new law?

Response: FDA has assembled a workgroup of technical experts on auditing, third-party programs, and imported foods to establish the system for accrediting third-party auditors of foreign food facilities. FDA is conducting a public meeting on March 29, 2011, to seek input on the third-party system and implementing regulations. FDA has

opened a docket to solicit public comment as well. This input will help inform FDA's regulations and other activities in implementing the program for accreditation of third-party auditors who perform regulatory audits of foreign food entities and, based on audit results, issue import certifications for high-risk foods and facility certifications required for participation in the Voluntary Qualified Importer Program. The implementing regulations will include measures to protect against conflicts of interest through unannounced audits, public disclosure of fees, and limits on financial affiliations. FDA also will issue user fee regulations and model accreditation standards that third-party auditors and their audit agents must meet.

Ms. DeLauro: How much FDA will be assigned to provide oversight over any private third party certifiers recognized?

Response: We are not currently in a position to determine how many FDA FTE will be assigned to oversight of private third party certifiers—referred to as third-party auditors in the Food Safety Modernization Act, or FSMA. Whether third- party auditors are accredited directly by FDA or by accreditation bodies recognized by FDA, FDA will retain its full inspection and oversight authorities. FSMA requires FDA oversight of third-party auditors by, among other things, requiring FDA to periodically evaluate the performance of each third-party auditor and conduct on-site audits of certified entities—with or without the certifier present. Moreover, FSMA directs FDA to withdraw accreditation of a third-party auditor under certain circumstances, such as when FDA evaluates an auditor and finds that the auditor no longer meets the requirements for accreditation. The Office of Regulatory Affairs will play a significant role in the third-party program, including all of the activities described above.

Ms. DeLauro: How much funding will you need to implement that provision of the Act?

Response: FDA is in the process of developing and implementing processes in support of the FSMA implementation. During this process FDA will be evaluating the funding that will be required to fully implement the new law.

Ms. DeLauro: The FDA Food Safety Modernization Act requires that FDA double its inspection of foreign food facilities every year for the next five years, so by FY 2016, FDA will need to inspect over 19,000 foreign food establishments that export to the U.S. How does FDA plan to achieve that requirement?

Response: Achieving the foreign inspection mandate will require a substantial investment of resources. FDA intends to determine the most efficient way to use its resources and consider ways to leverage the resources of others, such as foreign governments, to fulfill the objective of this mandate.

Ms. DeLauro: How much money will be required to fund those inspections?

Response: At this time, FDA is studying the new legislation, including opportunities to work with our Federal, State, local, territorial, tribal, and foreign regulatory partners and 3rd party organizations, to determine how best to leverage all available resources to best assure the safety of the food supply. We are not currently in a position to say how many resources we will be able to leverage versus how many additional resources FDA will need to meet the expectations of the new law.

Ms. DeLauro: The FDA Food Safety Modernization Act requires FDA to take certain steps to improve the recall program, in addition to having new authority to order recalls if necessary. One improvement is creating a consumer friendly website so that the public can get quick and accurate information about recalls. That is supposed to be operational within 90 days. While the funds needed for the recall website is very minor, could you tell me where progress is on getting that website up?

Response: At the current time, we are on track to meet the statutory deadline of having an improved consumer search engine for recalls within 90 days of enactment of the Food Safety Modernization Act.

Ms. DeLauro: What, if you know, will it look like when a consumer goes to it?

Response: Though we plan to have the improved website operational by the statutory deadline, FDA is still developing the final details of what the website will look like.

Ms. DeLauro: Many grocery stores use customer loyalty cards where they give you a discount in return for information about yourself that they use to sell you products. Would it be a good use of those cards to also use the information to alert you when you've purchased a product that is subsequently recalled?

Response: FDA is aware that some retail outlets use loyalty cards to contact their customers when a product they have purchased has been subsequently recalled, so it is a method that is being used to notify consumers of recalls. FDA will consider this use of loyalty cards in its implementation of the Food Safety Modernization Act.

Ms. DeLauro: Will FDA make that part of its rule when it implements the notice provisions in the Food Safety Modernization Act?

Response: Section 211 of the Food Safety Modernization Act requires, among other things, that grocery stores display certain information about reportable foods in a prescribed manner. FDA is in the process of implementing this provision. It is not possible to say at this time whether customer loyalty cards will play a role in FDA's implementation of this requirement.

Ms. DeLauro: The FDA Food Safety Modernization Act provides protection to consumers, but the food industry supported the new food safety law, too. If

appropriations for implementation are slashed, what will the impact be on food companies, in terms of competitiveness in overseas markets?

Response: If funding for implementation is not available, FDA will be able to put new regulations on the books, but we will not be able to build the new system called for by the Food Safety Modernization Act and produce the benefits Congress envisioned for both consumers and the food industry. We will not be able to effectively implement the new prevention standards and take full advantage of our new administrative enforcement tools. We would also be unable to credibly implement the new import oversight tools contained in the law.

It is implementation of the new law, with its broad preventive controls framework, that will provide further food safety protections to US consumers and those consuming US products abroad. FDA is in the process of beginning a public dialogue on the idea of "comparable" countries, i.e.., countries with a robust food safety system similar to that of the US, where we can be confident that certain safeguards and oversight are in place. There is value in knowing that a food product was produced under a robust system and there is value in the US being a food safety leader.

RECENT FOOD SAFETY RECALLS

FDA announced two food recalls just within the past week. One involved Skippy Peanut Butter that was contaminated with salmonella and the other hazel nut that were contaminated with e-coli 0157:H7 that were distributed by DeFranco and Sons of Los Angeles, CA.

Ms. DeLauro: Would you tell us the last time FDA inspection personnel visited the facilities involved in these recalls?

Response: Prior to the recall, FDA personnel had previously inspected DeFranco and Sons, Los Angeles, CA in December 2008 and October 2009. FDA personnel conducted an inspection at the Unilever in Little Rock, AR, in November 2009 that produces the Skippy Peanut Butter.

Ms. DeLauro: Were any of the inspections for these facilities contracted to states to perform?

Response: FDA has a contract with the State of California, and state inspectors inspected DeFranco and Sons in March 2008. FDA has a contract with the State of Arkansas, and state inspectors inspected the Unilever facility that produces the Skippy Peanut Butter under that contract. The State of Arkansas inspected this establishment in May 2007, April 2006, August 2005, August 2004, and June 2002.

RECENT FOOD SAFETY RECALLS

Ms. DeLauro: Can you supply the subcommittee with copies of all inspection reports for the facilities involved in these recalls dating back to January 1, 2006?

Response: The following documents are Establishment Inspection Reports, also known as an EIR, are enclosed for the inspections of Unilever, Little Rock, Arkansas, facility: [The information follows:]

Attached is the April 27, 2006 (state contract inspection);

Food and Drug Administration Establishment Inspection Report

Date Assigned: 11/21/2005 **Inspection Start Date:** 04/27/2006 **Inspection End Date:** 04/27/2006

Firm Name & Address: Unilever Best Foods , 8201 Frazier Pike Little Rock, AR 72206-3871 US

Firm Mailing Address: 8500 Frazier Pike, Little Rock, AR 72203 United States

FEI: 2316570 **JD/TA:** 80 **County:** PULASKI **Est Size:** (b) (4)

Phone: (501)490-1441 **District:** DAL-DO **Profiled:** No

Conveyance Type: **% Interstate:** **Inspectional Responsibility:** State

Endorsement

Unilever Foods North America dba BestFoods, 8201 Frazier Pike, Little Rock, Arkansas, manufactures Skippy brand peanut butter. Products produced include creamy, crunchy, reduced fat, low carbohydrate and honey-nut peanut butters. The firm is under (b) (4) (b) (4) and received a Superior rating from that organization during its last inspection b(3) b(3) Mr. Patrick Mathieu is the Plant Manager. Ms. Tawana Walker is the Technical Manager.

Detail description of the process, including a flow chart, were provided in a previous EI. No changes to the operation or plant have occurred since that time. The previous inspection revealed no objectionable conditions. The current inspection was conducted for routine surveillance purposes. The firm has a written HACCP plan.

The firm has gross annual sales of approximately $(b) (4)

The firm has a contract with (b) (4) for its pest control program.

Endorsement Location:

Inspector Name	Date & Time of Signature	Supervisor Name	Date & Time of Signature
	ET	Frederic W French Iii	07/20/2006 03:26 PM ET

FMD Letter sent 8/21/06

Food and Drug Administration Establishment Inspection Report

FEI:2316570 **Inspection Start Date:** 04/27/2006 **Inspection End Date:** 04/27/2006

Firm Name & Address: Unilever Best Foods , 8201 Frazier Pike Little Rock, AR 72206-3871 US

Related Firm FEI: **Name & Address of Related Firm:**

b(3) [redacted]

Establishment Type		Industry Code	
M	Manufacturer	23	Nuts/Edible Seed
M	Manufacturer	26	Vegetable Oils
M	Manufacturer	36	Food Sweeteners (Nutritive)
M	Manufacturer	71	Byprodcts For Animal Foods

District Use Code:

Food and Drug Administration Establishment Inspection Report

FEI: 2316570 **Inspection Start Date:** 04/27/2006 **Inspection End Date:** 04/27/2006

Firm Name & Address: Unilever Best Foods , 8201 Frazier Pike Little Rock, AR 72206-3871 US

Inspection Basis: Surveillance

Inspected Processes & District Decisions

PAC	Establishment Type	Products/ Process	MQSA	Reschedule Insp Date	Re-Inspection Priority	Inspection Conclusions
03S001	Manufacturer	23 C H T				No Action Indicated (NAI

Final Decision?	District Decision Date	District Decision Type	District Decision Made By	Org Name
	05/16/2006	No Action Indicated (NAI)	Agency, State	DAL-DO

Remarks:

Food and Drug Administration Establishment Inspection Report

FEI: 2316570 **Inspection Start Date:** 04/27/2006 **Inspection End Date:** 04/27/2006

Firm Name & Address: Unilever Best Foods , 8201 Frazier Pike Little Rock, AR 72206-3871 US

Products Covered

Product Code	Est Type	Description	Additional Product Description
23 C H T 07	Manufacturer	Peanut, Butter; Nonflex Plastic; Packaged Food (Not Commercially Sterile)	

Assignees Accomplishment Hours

Employee Name	Position Class	Hours Credited To	PAC	Establishment Type	Process	Hours
Agency, State	STA	DAL-DO	03S001	Manufacturer	23 C H T	2.5
					Total Hours:	2.5

Food and Drug Administration Establishment Inspection Report

FEI: 2316570 **Inspection Start Date:** 04/27/2006 **Inspection End Date:** 04/27/2006

Firm Name & Address: Unilever Best Foods , 8201 Frazier Pike Little Rock, AR 72206-3871 US

Inspection Result

EIR Location **Trips Num**

Inspection Summary
Credentials were presented to Mr. Patrick Mathieu, Plant Manager, and Ms. Tawana Walker, Technical Manager. Both individuals were very freindly and helpful. Ms. Walker accompanied the inspector during the inspection and answered all questions freely.

The results of the inspection were discussed with Ms. Walker. Ms. Walker displayed a high level of knowledge and professionalism. She discussed with the inspector FDA complaint #36036, concerning glass purported to have been found in a container of product. Ms. Walker explained the investigation the firm conducted which included viewing of video of the entire shift during which the product was made. Attention was focused on the filler machines. Ms. Walker were informed that no violative conditions were noted. A form FDA483 was not issued and the discussion ended.

[illegible]B Suggested Actions

[illegible]ction **Remarks**

Referrals

Org Name **Mail Code** **Remarks**

Refusals

Inspection Refusals: No refusal

Samples Collected

Sample Number

Recall Numbers

Recall Number

Related Complaints

Consumer Complaint Number

FDA 483 Responses

483 Issued?: **483 Location:**

Response Type	Response Mode	Response Date	Response Summary

Food and Drug Administration Inspection Report

Summary

Date Assigned: 05/16/2006 **Inspection Start Date:** 04/27/2006 **Inspection End Date:** 04/27/2006

Firm Name & Address : Unilever Best Foods, 8201 Frazier Pike Little Rock, AR 72206-3871 US

FEI: 2316570 **County:** PULASKI **Phone:** (501) 490-1441 **District:** Dallas District Office

Endorsements

Endorsement

Unilever Foods North America dba BestFoods, 8201 Frazier Pike, Little Rock, Arkansas, manufactures Skippy brand peanut butter. Products produced include creamy, crunchy, reduced fat, low carbohydrate and honey-nut peanut butters. The firm is under AIB inspection services and received a Superior rating from that organization during its last inspection. b(3) b(3) Mr. Patrick Mathieu is the Plant Manager. Ms. Tawana Walker is the Technical Manager. Detail description of the process, including a flow chart, were provided in a previous EI. No changes to the operation or plant have occurred since that time. The previous inspection revealed no objectionable conditions. The current inspection was conducted for routine surveillance purposes. The firm has a written HACCP plan. The firm has gross annual sales of approximately $(b) (4) The firm has a contract with (b) (4) for its pest control program.

Endorsement Location

Supervisor	Date of Approval
frenchfw	07/20/2006

Registration

Registration Type
Food

Registration Date
11/25/2003

Establishment Type
Manufacturer

Industry Code
71 Byprodcts For Animal Foods

Inspection

Inspection Basis: Surveillance

Inspected Processes

PAC	Establishment Type	Products/Process	Inspection Conclusion
CONTRACT FOOD SANITATION INSPECTIONS	Manufacturer	23CHT	No Action Indicated

Products

Products Covered

Product Code	Establishment Type	Description
23CHT07	Manufacturer	Peanut, Butter; Nonflex Plastic; Packaged Food (Not Commercially Sterile)

Investigator

Investigator Accomplishment Hours

Employee Name	PAC	Establishment Type	Process	Hours
Hastings	CONTRACT FOOD SANITATION INSPECTIONS	Manufacturer	23CHT	2.5

Results

Inspection Result

Inspection Summary

Credentials were presented to Mr. Patrick Mathieu, Plant Manager, and Ms. Tawana Walker, Technical Manager. Both individuals were very freindly and helpful. Ms. Walker accompanied the inspector during the inspection and answered all questions freely. The results of the inspection were discussed with Ms. Walker. Ms. Walker displayed a high level of knowledge and professionalism. She discussed with the inspector FDA complaint #36036, concerning glass purported to have been found in a container of product. Ms. Walker explained the investigation the firm conducted which included viewing of video of the entire shift during which the product was made. Attention was focused on the filler machines. Ms. Walker were informed that no violative conditions were noted. A form FDA483 was not issued and the discussion ended.

Samples Collected

Sample Number	Sample Description

Consumer Complaints

Consumer Complaint Numbers

37095

36706

26011

Refusals

Refusals

Inspection Refusals

No refusal

Adverse Observations

Adverse Inspectional Observations Issued to the Firm? No

Attached is the May 3, 2007 (state contract inspection);

Food and Drug Administration Establishment Inspection Report

Date Assigned: 11/02/2006 **Inspection Start Date:** 05/03/2007 **Inspection End Date:** 05/03/2007

Firm Name & Address: Unilever Best Foods , 8201 Frazier Pike Little Rock, AR 72206-3871 US

Firm Mailing Address: 8500 Frazier Pike, Little Rock, AR 72203 United States

FEI: 2316570 **JD/TA:** 80 **County:** PULASKI **Est Size:** (b) (4)

Phone: (501)490-1441 **District:** DAL-DO **Profiled:** No

Conveyance Type: **% Interstate:** **Inspectional Responsibility:** State

Endorsement

A routine surveillance inspection was conducted of this facility under assignment #782886. The facility manufactures peanut butter under the Skippy brand name. The business is (b) (4) % wholesale and [redacted] % of the production is shipped out of state. The firm does approximately $(b) (4) in gross annual sales. The previous inspection was made on 04/27/2006 and no adverse findings were noted. The current inspection was conducted by me for surveillance purposes. No adverse conditions were observed. No infested or defiled food products were noted. No samples were collected (b)(3) [redacted]. A sample of nutrition facts labeling was collected for NLEA surveillance purposes. The firm has a written HACCP plan. SCM Remarks for State Inspection:

Endorsement Location:

Inspector Name	Date & Time of Signature	Supervisor Name	Date & Time of Signature
	ET		ET

Food and Drug Administration Establishment Inspection Report

FEI:2316570 **Inspection Start Date:** 05/03/2007 **Inspection End Date:** 05/03/2007

Firm Name & Address: Unilever Best Foods , 8201 Frazier Pike Little Rock, AR 72206-3871 US

Related Firm FEI: **Name & Address of Related Firm:**

b(3) [redacted]

Establishment Type		Industry Code	
M	Manufacturer	23	Nuts/Edible Seed
M	Manufacturer	26	Vegetable Oils
M	Manufacturer	36	Food Sweeteners (Nutritive)
M	Manufacturer	71	Byprodcts For Animal Foods

District Use Code:

Food and Drug Administration Establishment Inspection Report

FEI: 2316570 **Inspection Start Date:** 05/03/2007 **Inspection End Date:** 05/03/2007

Firm Name & Address: Unilever Best Foods , 8201 Frazier Pike Little Rock, AR 72206-3871 US

Inspection Basis: Surveillance

Inspected Processes & District Decisions

PAC	Establishment Type	Products/ Process	MQSA	Reschedule Insp Date	Re-Inspection Priority	Inspection Conclusions
03S001	Manufacturer	23 C H T				No Action Indicated (NAI

Final Decision?	District Decision Date	District Decision Type	District Decision Made By	Org Name
	05/21/2007	No Action Indicated (NAI)	Agency, State	DAL-DO

Remarks:

Food and Drug Administration Establishment Inspection Report

FEI: 2316570 **Inspection Start Date:** 05/03/2007 **Inspection End Date:** 05/03/2007

Firm Name & Address: Unilever Best Foods , 8201 Frazier Pike Little Rock, AR 72206-3871 US

Products Covered

Product Code	Est Type	Description	Additional Product Description
23 C H T 07	Manufacturer	Peanut, Butter; Nonflex Plastic; Packaged Food (Not Commercially Sterile)	

Assignees Accomplishment Hours

Employee Name	Position Class	Hours Credited To	PAC	Establishment Type	Process	Hours
Agency, State	STA	DAL-DO	03S001	Manufacturer	23 C H T	2.5
					Total Hours:	2.5

Food and Drug Administration Establishment Inspection Report

FEI: 2316570 **Inspection Start Date:** 05/03/2007 **Inspection End Date:** 05/03/2007

Firm Name & Address: Unilever Best Foods , 8201 Frazier Pike Little Rock, AR 72206-3871 US

Inspection Result

EIR Location **Trips Num**

Inspection Summary

I presented my credentials to Mr. Patrick Mathieu, Plant Manager, Tawana Ogeto, Technical Manager, Tracy Feldman, Operations Manager, and (b) (6) Quality/Environmental Specialist. All the individuals were very cordial. We discussed two consumer complaints that had been received since the previous inspection. Ms. Ogeto stated that the object described in Complaint #39159, could not have come from the plant since no false fingernails are allowed on the workers there. The other complaint, #36300, was not in the company's files. After discussing the complaints, and previous EI, the inspection was allowed to proceed, with Ms. Ogeto, Ms. (b) (6) and Mr. Feldman accompanying. The processing of Skippy Natural Super Chunk was observed during the inspection. Shelled peanuts are recieved in rail cars. Peanuts are blown by air into silos. From the silos the peanuts cleaned and sorted. The peanuts then go into large ovens for roasting. After roasting, [redacted]% of the stream is shunted to choppers to make peanuts that will be added back to make Chunky type product. The main flow continues to mills and kettles. Sugar, palm oil and salt are added at the kettles. The peanut butter is run through more milling and the cooled in (b) (4) chillers for packaging. Plastic jars, manufactured at [redacted] (b) (4) specifically for Unilever, are transferred to the filler machines. The jars are inverted and blown out with air prior to filling. Fillers deposit peanut butter in the jars, machines then cap and label the jars. Lot identification codes are put on the jars by ink jet printers and the jars are cased and palletized for shipping. Product is immediately placed on trucks for shipping. Management provided me with a label containing nutrition facts. A discussion took place with Mr. Mathieu, Mr. Feldman, Ms. Ogeto, and Ms. (b) (6) during which they were informed that no adverse inspectional observations were noted. A 483 was not issued and the discussion ended.

IB Suggested Actions

Action **Remarks**

Referrals

Org Name **Mail Code** **Remarks**

Refusals

Inspection Refusals: No refusal

Samples Collected

Sample Number

Recall Numbers

Recall Number

Related Complaints

Consumer Complaint Number

FDA 483 Responses

483 Issued?: **483 Location:**

Response Type	Response Mode	Response Date	Response Summary

Food and Drug Administration Inspection Report

Summary

Date Assigned: 05/21/2007 **Inspection Start Date:** 05/03/2007 **Inspection End Date:** 05/03/2007

Firm Name & Address : Unilever Best Foods, 8201 Frazier Pike Little Rock, AR 72206-3871 US

FEI: 2316570 **County:** PULASKI **Phone:** (501) 490-1441 **District:** Dallas District Office

Endorsements

Endorsement

A routine surveillance inspection was conducted of this facility under assignment #782886. The facility manufactures peanut butter under the Skippy brand name. The business is [redacted]% wholesale and [redacted]% of the production is shipped out of state. The firm does approximately $[redacted] in gross annual sales. The previous inspection was made on 04/27/2006 and no adverse findings were noted. The current inspection was conducted by me for surveillance purposes. No adverse conditions were observed. No infested or defiled food products were noted. No samples were collected [redacted] A sample of nutrition facts labeling was collected for NLEA surveillance purposes. The firm has a written HACCP plan.

SCM Remarks for State Inspection

Endorsement Location

Supervisor	Date of Approval

Registration

Registration Type	**Registration Date**
Food	11/25/2003
Establishment Type	**Industry Code**
Manufacturer	71 Byprodcts For Animal Foods

Inspection

Inspection Basis: Surveillance

Inspected Processes

PAC	Establishment Type	Products/Process	Inspection Conclusion
CONTRACT FOOD SANITATION INSPECTIONS	Manufacturer	23CHT	No Action Indicated

Products

Products Covered

Product Code	Establishment Type	Description
23CHT07	Manufacturer	Peanut, Butter; Nonflex Plastic; Packaged Food (Not Commercially Sterile)

Investigator

Investigator Accomplishment Hours

Employee Name	PAC	Establishment Type	Process	Hours
Hastings	CONTRACT FOOD SANITATION INSPECTIONS	Manufacturer	23CHT	2.5

Results

Inspection Result

Inspection Summary

I presented my credentials to Mr. Patrick Mathieu, Plant Manager, Tawana Ogeto, Technical Manager, Tracy Feldman, Operations Manager, and (b) (6) Quality/Environmental Specialist. All the individuals were very cordial. We discussed two consumer complaints that had been received since the previous inspection. Ms. Ogeto stated that the object described in Complaint #39159, could not have come from the plant since no false fingernails are allowed on the workers there. The other complaint, #36300, was not in the company's files. After discussing the complaints, and previous EI, the inspection was allowed to proceed, with Ms. Ogeto, (b) (6) and Mr. Feldman accompanying. The processing of Skippy Natural Super Chunk was observed during the inspection. Shelled peanuts are recieved in rail cars. Peanuts are blown by air into silos. From the silos the peanuts cleaned and sorted. The peanuts then go into large ovens for roasting. After roasting [redacted] of the stream is shunted to choppers to make peanuts that will be added back to make Chunky type product. The main flow continues to mills and kettles. Sugar, palm oil and salt are added at the kettles. The peanut butter is run through more milling and the cooled in (b) (4) chillers for packaging. Plastic jars, manufactured at (b) (4) specifically for Unilever, are transferred to the filler machines. The jars are inverted and blown out with air prior to filling. Fillers deposit peanut butter in the jars, machines then cap and label the jars. Lot identification codes are put on the jars by ink jet printers and the jars are cased and palletized for shipping. Product is immediately placed on trucks for shipping. Management provided me with a label containing nutrition facts. A discussion took place with Mr. Mathieu, Mr. Feldman, Ms. Ogeto, and (b) (6) during which they were informed that no adverse inspectional observations were noted. A 483 was not issued and the discussion ended.

Samples Collected

Sample Number	Sample Description

Consumer Complaints

Consumer Complaint Numbers

37095

36706

26011

Refusals

Refusals

Inspection Refusals

No refusal

Adverse Observations

Adverse Inspectional Observations Issued to the Firm? No

Attached is the November 27, 2007(FDA inspection);

Food and Drug Administration Establishment Inspection Report

Date Assigned: 10/15/2007 **Inspection Start Date:** 11/26/2007 **Inspection End Date:** 11/27/2007

Firm Name & Address: Unilever Best Foods , 8201 Frazier Pike Little Rock, AR 72206-3871 US

Firm Mailing Address: 8201 Frazier Pike, Little Rock, AR 72206 United States

FEI: 2316570 **JD/TA:** 80 **County:** PULASKI **Est Size:** (b) (4)

Phone: (501)490-1441 **District:** DAL-DO **Profiled:** No

Conveyance Type: **% Interstate:** (b) (4) **Inspectional Responsibility:** State

Endorsement

This CFSAN initiated assignment, DFP&G #07-21, ORA Concurrence #2007061901, includes the inspection of a peanut butter manufacturer, a ready-to-eat food, using processing methods that are typically carried out in a dry environment. Establishments were included that produce peanut butter by dry or oil roasting methods as well as other manufacturing facilities that produce other ready-to-eat foods in a dry processing environment. The objective was to determine whether or not Salmonellae are present in the food processing environment of these plants and thus present a risk of product contamination. CFSAN requested ?Environmental? samples to be collected (not ?for cause?) from atypical areas that are not generally sampled.

The previous inspection was conducted 5/3/07 and was classified NAI. No FDA-483 Inspectional Observations form was issued.

The current inspection covered the entire plant area including manufacturing and non-manufacturing areas. The inspection did not result in the issuance of an FDA-483, Inspectional Observations form.

There were 66 environmental samples collected at the firm which were submitted to ARL for analysis of the presence of Salmonella. Sample #420919.

No part of the inspection was refused.

All correspondence including FMD-145 should be addressed to:
Unilever Foods
Mr. Patrick Mathieu, Supply Leader
8201 Frazier Pike
Little Rock, AR 72206

Classification: VAI;
Reschedule
P-10, I-8, W-16

FACTS # 851520

Distribution:
DAL-DO M&F
cc w/exhibits & attachments: DAL-DO DCB
cc: LR-RP
cc: SA-RP

Endorsement Location: DAL-DO M&F

Inspector Name	Date & Time of Signature	Supervisor Name	Date & Time of Signature
Torrance J Slayton	12/12/2007 04:12 PM ET	Elvia J Cervantes	01/10/2008 02:27 PM ET
Torrance J Slayton	12/12/2007 04:12 PM ET	Elvia J Cervantes	01/10/2008 02:23 PM ET

Food and Drug Administration Establishment Inspection Report

FEI: 2316570 **Inspection Start Date:** 11/26/2007 **Inspection End Date:** 11/27/2007

Firm Name & Address: Unilever Best Foods , 8201 Frazier Pike Little Rock, AR 72206-3871 US

Related Firm FEI: **Name & Address of Related Firm:**

b(3)

Establishment Type		Industry Code	
M	Manufacturer	23	Nuts/Edible Seed
M	Manufacturer	26	Vegetable Oils
M	Manufacturer	36	Food Sweeteners (Nutritive)
M	Manufacturer	71	Byprodcts For Animal Foods

District Use Code:

Food and Drug Administration Establishment Inspection Report

FEI: 2316570 **Inspection Start Date:** 11/26/2007 **Inspection End Date:** 11/27/2007

Firm Name & Address: Unilever Best Foods , 8201 Frazier Pike Little Rock, AR 72206-3871 US

Inspection Basis: Surveillance

Inspected Processes & District Decisions

PAC	Establishment Type	Products/ Process	MQSA	Reschedule Insp Date	Re-Inspection Priority	Inspection Conclusions
03803	Manufacturer	23 C H T		11/2008	Surveillance	Correction Indicated (CI)

Final Decision?	District Decision Date	District Decision Type	District Decision Made By	Org Name
Y	01/10/2008	Voluntary Action Indicated (VAI)	Cervantes, Elvia J	DAL-TM3

Remarks: Subs 21, 33, 56 indicate positive results for salmonella spp

Food and Drug Administration Establishment Inspection Report

FEI: 2316570 **Inspection Start Date:** 11/26/2007 **Inspection End Date:** 11/27/2007

Firm Name & Address: Unilever Best Foods , 8201 Frazier Pike Little Rock, AR 72206-3871 US

Products Covered

Product Code	Est Type	Description	Additional Product Description
23 C H T 07	Manufacturer	Peanut, Butter; Nonflex Plastic; Packaged Food (Not Commercially Sterile)	Skippy Peanut Butter

Assignees Accomplishment Hours

Employee Name	Position Class	Hours Credited To	PAC	Establishment Type	Process	Hours
Norris, Carla A	MBI	ARL	03803	Manufacturer	23 C H T	10
Slayton, Torrance J	CIN	DAL-DO	03803	Manufacturer	23 C H T	34
					Total Hours:	44

Food and Drug Administration Establishment Inspection Report

FEI: 2316570 **Inspection Start Date:** 11/26/2007 **Inspection End Date:** 11/27/2007

Firm Name & Address: Unilever Best Foods , 8201 Frazier Pike Little Rock, AR 72206-3871 US

Inspection Result

EIR Location
DAL-DO M&F

Trips Num

Inspection Summary
This CFSAN initiated assignment, DFP&G #07-21, ORA Concurrence #2007061901, includes the inspection of a peanut butter manufacturer, a ready-to-eat food, using processing methods that are typically carried out in a dry environment. Establishments were included that produce peanut butter by dry or oil roasting methods as well as other manufacturing facilities that produce other ready-to-eat foods in a dry processing environment. The objective was to determine whether or not Salmonellae are present in the food processing environment of these plants and thus present a risk of product contamination. CFSAN requested ?Environmental? samples to be collected (not ?for cause?) from atypical areas that are not generally sampled.

The previous inspection was conducted 5/3/07 and was classified NAI. No FDA-483 Inspectional Observations form was issued.

The current inspection covered the entire plant area including manufacturing and non-manufacturing areas. The inspection did not result in the issuance of an FDA-483, Inspectional Observations form.

There were 66 environmental samples collected at the firm which were submitted to ARL for analysis of the presence of Salmonella. Sample #420919.

No part of the inspection was refused.

IB Suggested Actions

Action	Remarks

Referrals

Org Name	Mail Code	Remarks

Refusals

Inspection Refusals: No refusal

Samples Collected

Sample Number
420919

Recall Numbers

Recall Number

Related Complaints

Consumer Complaint Number

FDA 483 Responses

483 Issued?: **483 Location:**

Response Type	Response Mode	Response Date	Response Summary

DEPARTMENT OF HEALTH AND HUMAN SERVICE

Food and Drug Administration — Dallas District

Memorandum

Date 12/12/07

From Torrance J. Slayton, Investigator

Subject Salmonella Sampling Assignment at Unilever Foods
(aka Skippy Peanut Butter) DFP&G #07-21, ORA
Concurrence #2007061901, FACTS Assignment #851520

To Elvia J. Cervantes, Supervisory Investigator

Ref: Unilever Foods
8201 Frazier Pike
Little Rock, AR 72206
FEI: 2316570

Background:
This CFSAN initiated assignment includes the inspection of a food manufacturing establishments that produce ready-to-eat foods using processing methods that are typically carried out in a dry environment. Establishments were included that produce peanut butter by dry or oil roasting methods as well as other manufacturing facilities that produce other ready-to-eat foods in a dry processing environment. The objective was to determine whether or not Salmonellae are present in the food processing environment of these plants and thus present a risk of product contamination. CFSAN requested "Environmental" samples to be collected (not "for cause") from atypical areas that are not generally sampled **(Attachment 2).**

All parts of the memo were written by Investigator Slayton, except where noted in Area of Concern, preceding each paragraph in bold type face.

Initiation of Inspection:
On 11/26/07, Investigator Torrance J. Slayton and Analyst Carla A. Norris (Arkansas Regional Lab) entered the firm and displayed credentials to Mr. Tracy D. Feldman, Operations Manager. An FDA 482, Notice of Inspection was issued to Mr. Feldman, and in addition, Resources for FDA Regulated Businesses was provided. Mr. Feldman was the most responsible person present during the initiation of the inspection. Also present was Ms. Tawana J. Walker Ogeto, Safety, Health, Environmental and Quality Manager. Mr. Patrick Mathieu, Supply Leader is the most responsible individual at the firm. Mr. Mathieu was present during the second day of the inspection and participated in the closeout of the assignment. Mr. Feldman and Ms. Ogeto provided copies of all documents requested and answered all questions concerning the inspection. The firm was manufacturing peanut butter during both days of the inspection. The firm was manufacturing the following: (b) (4) - Skippy Super Chunk 20 oz jar code #FEB 18 09 R3, (b) (4) - Skippy Creamy 48 oz jar code #FEB 18 09 R2. (b) (4) was not observed in operation. Sixty-six (66) environmental sub-samples were collected during the inspection. The firm collected duplicate samples of all samples collected. The firm collected their samples duplicate samples with (b) (4) which appeared identical to the ones utilized by the FDA; however, it is not known if the (b) (4) were pre-moistened (which are available) as the firm did not use separate tubes of neutralizing broth as did the FDA, see attached copy of the Collection Report. A copy of the firm's identification of sample sites was provided **(Exhibit 1).** The firm also provided a diagram of the plant area **(Exhibit 2).** The location of each sub sample collected is noted on the diagram to assist in identification.

ENDORSEMENT Date: 1/10/08

To: DAL-DO M&F

ARL will submit analytical packages to DAL-DO CB for review and additional follow-up as necessary.
Samples 21, 33 and 56 confirmed positive for salmonella spp.
Elvia J. Cervantes, SCSO

Dist: DAL-DO M&F
cc w/exhibits & attachments: DAL-DO DCB
cc: LR-RP
cc: SA-RP

Firm History:
The firm is a manufacturer of bulk and retail size peanut butter in a variety of blends (smooth, chunky, extra chunky, etc.). All retail size products are packed under the "Skippy" brand. The firm has been inspected by the State of Arkansas Department of Health under contract for the past several years. The most recent inspection was conducted on 5/3/07 and no adverse conditions were noted. The firm ships (b) (4) % of its products in interstate commerce.

Manufacturing/design operations:
Ms. Ogeto and Mr. Feldman provided the information for manufacturing. The peanuts are in a closed system starting when they are unloaded from a railcar and continuing until the peanut butter is filled into jars. There are isolated instances where the product is exposed to the environment. Only (b) (4) occasions occur after the roasting process; blanching and sorting, but even in those instances, the exposure remains very limited. As the blanching process occurs, the peanuts fall through what can best be described as a chute. There are areas on two of the sides which are approximately 6 inches in height which were open to the environment. These areas exist at approximately chest level of the machine which is located on a solid floor platform above the sorters near the east wall of the process area. During the sorting process (located below the blanching process), the peanuts fall down what resembles a slide a sort distance, approximately two to three feet. The peanuts are exposed to the environment as they descend **(Exhibit 2)**.

Receiving - The firm receives bulk raw peanuts in rail cars. Each load is checked for moisture, filth, and Aflatoxins prior to acceptance. Once accepted, the peanuts are blown via a closed system to one of (b) (4) silos, each capable of holding approximately (b) (4) lbs. Sub sample #10 was collected on floor in front of a door accessing the rail dock **(Exhibit 2)**.

Screening - Once peanuts are to be processed, they are passed though a (b) (4) then a Stoner. The two machines are screening devices. The (b) (4) removes foreign material and the Stoner removes peanut fines. The (b) (4) and Stoner are cleaned (b) (4) in a dry cleaning process and the floors in the same general area are mopped (b) (4) with a wet mop and bucket.

Roasting - The peanuts proceed into the Roasting Room and into one of (b) (4) Roasters. The Roasters are continually roasting peanuts via a system of a belt and tunnels which operate at various temperatures. It takes approximately (b) (4) minutes for peanuts to pass through the Roaster and the peanuts are exposed to a maximum temperature of approximately (b) (4) °F. Each Roaster is capable of processing (b) (4) lbs of peanuts/hour. The Roasters are dry cleaned (b) (4) and the belt is wet cleaned with (b) (4) every (b) (4) The floor is wet cleaned with a mop and bucket on a (b) (4) basis. Sub sample #'s 11 through 18 were collected from the Roaster Room. The samples were collected from the floor (3), floor drains (3), roaster oven door handle, and high pressure hose wand **(Exhibit 2)**.

Sugar Room - The firm receives (b) (4) sugar in (b) (4) totes. The firm uses (b) (4) to (b) (4) (b) (4) (powdered sugar) for use as an ingredient for peanut butter. The sugar is blown to the production area via a closed system. The (b) (4) are dry cleaned (b) (4) and the floors are wet cleaned (b) (4) with a mop and bucket. Sub sample #22 was collected from the Sugar Room. The sample was collected from the floor in front a support column **(Exhibit 2)**.

Bulk Jar Lid – The firm receives jar lids in bulk. The firm has (b) (4) machines (for different lid sizes) on the outside of the process area which the lids are dumped into a hopper. The machines align the lids for use in packaging and the lids enter the production area. Sub sample #25 was collected from the handle to the hopper of which supplies lids to packing line (b) (4) **(Exhibit 2)**.

(b) (4) **Area** – The area referred to as (b) (4) by the firm includes the area outside the process area where empty jars enter the process area and then filled, capped, labeled jars exit (b) (4) separate lines). Empty jars are received palletized and an automated system places each layer of jars from the pallet on a conveyor system to be filled. The filled jars exit the process area and are cased and shrink wrapped. An automated system conveys the cased product to another area of the firm where the product is palletized. The (b) (4) area equipment is dry cleaned and the floor is wet cleaned with a mop and bucket on a (b) (4) basis. Sub sample #'s 27 through 31 were collected from the (b) (4) Area. The samples were collected from the floor in front of four separate doors (4) which access the process area and from the conveyor supplying empty jars to Line (b) (4) **(Exhibit 2)**.

Other Areas Outside Processing Room - Other areas outside the processing room include the equipment cleaning rooms, mechanical/maintenance areas, finished product storage (limited), other storage areas (for labels, empty jars, lids, minor ingredients, etc). Sub sample # 9 was collected from a floor drain in the forklift battery storage area. Sub sample #'s 1 through 3 were collected from the floor and floor drain in the room which food contact equipment is cleaned. Sub sample #'s 4 through 8 were collected from the room used for non-food contact cleaning storage such as mops, squeegee's, mop buckets,

plastic scoop shovels and also a floor drain. Sub sample #19 was collected from a cracked portion of concrete floor entering the dry additives storage room. Sub sample #20 was collected from the floor in front of an entry door to the processing area. Sub sample #21 was collected from a tire of forklift which was sitting in front of the Sugar Room. Sub sample #'s 23, 24 & 26 were collected from the floor, a door seal, and a cart which are associated with [redacted] separate Clean Rooms. The Clean Rooms are used to provide access, other than regular employee admittance, to the processing area for items such as carts **(Exhibit 2)**.

Processing Area - see **Exhibit 2** for location of each sub sample identified within this section.
The roasted peanuts enter the process area via the closed system. The peanuts are passed through one of [redacted] Blanchers to remove the skin. Sub sample #41 was collected from a broom near the Blanchers. The peanuts are then sorted and peanuts which do not meet color specifications are rejected. Sub sample #'s 42 through 44 were collected from the steps and handrail of Sorter #[redacted] The peanuts are next transported via the closed system to the Primary Grinders. Sub sample #45 was collected from an air intake filter which moves the peanuts from the sorting area to the Primary Grinders. The firm uses [redacted] identical grinders for the first grind of the peanuts. For the production of "crunchy" varieties of peanut butter, a portion of the peanuts are reserved after the first grind to be incorporated into the final product. Sub sample #38 was collected from a support column near Primary Grinder #[redacted] The peanuts are then passed to one of [redacted] bulk kettles which can hold up to [redacted] lbs each. The product remains here until needed later in the production cycle. A [redacted] Kettle is used to supply the Slurry machine. Sugar, salt, and any other ingredients are added in the Slurry machine. Sub sample #'s 47 & 48 were collected from the wheels and a steel plate directly underneath the Slurry machine. The product is transported via the closed system to a Mixing Kettle. The last step before packaging is the Final Grind. The Final Grand takes place in a room within the process area and is accomplished by approximately [redacted] separate grinders which produce the final form to be packaged (except crunchy variety's which have partially ground peanuts added for the texture). Sub sample #'s 50 through 52 were collected from the floor area near the Final Grind.

The retail size packaging area is divided into [redacted] separate lines, each packaging different sizes and being fully automated. The empty jars enter on a conveyor from the [redacted] area. The jars are inverted and "puffed" with air to remove any foreign material. When the jars are inverted, the opening is approximately 18" from the floor. The air is intended to remove any debris from the empty jars. The machine is open on the bottom, exposing the jars directly to the floor. The jars are then filled, capped, and labeled. Any jar which has not been adequately filled is emptied [redacted] and the product reenters the filling system. All jars pass through metal detection prior to leaving the processing area. Employees are present in the packaging area to perform such task as ensuring jars are full, checking cap torque, and ensuring proper label application. The finished product exits the processing area to be cased for shipment. Sub sample #'s 54, 55 & 59 through 64 were collected from packaging Lines #1 through #3.

The firm wet cleans the floors of the processing area [redacted] Wet cleaning is accomplished with a floor scrubber and mops. No hoses were observed in the processing area during the assignment. During both days of the assignment, we observed periodic dry cleaning with brooms. The firm dry cleans the Blancher and Sorter [redacted] in a dry process only. The Primary Grinders through the point of filling are wet cleaned [redacted] A wet clean involves a detergent, then sanitizer, and finally a rinse with [redacted] The firm maintains a separate cleaning SOP for each piece of equipment. The SOP includes the floor area in relative proximity to the equipment. No separate floor cleaning SOP exists.

Sub samples #'s 32 through 34, 36, 39, 40, 49, 53, 57, 58, 65 & 66 were collected from the floor in front of all exit and entry points to the processing area, including boot dip mats, except the Clean Rooms which were sampled. Sub sample #'s 35 & 37 were collected from door handles within the processing area. Sub sample #46 was collected from the floor directly underneath a water valve near the [redacted] are used to cool the product.

Quality – The firm has implemented an environmental sampling program. The firm has [redacted] sample sets which are rotated so that each sample set is collected every [redacted] **(Exhibit 3)**. Many of the sample sites which are located within the production area are part of each sample set, and are thus sampled every [redacted] The lab analysis is performed by [redacted] located in [redacted] conducts the following test on each set of samples: Salmonella, Coliforms, and Aerobic Plate Count. Ms. Ogeto stated the firm last had a positive environmental sample for Salmonella in 1995.

The firm also samples each lot of finished product. A composite is created and sent to [redacted] for the same analysis as the environmental samples. Ms. Ogeto stated it had been many years prior to the positive environmental sample since any product tested positive for Salmonella.

Management Discussion
At the conclusion of the assignment, a meeting was held with the facility management. Present was Mr. Mathieu - Supply Leader , Mr. Feldman - Operations Manager, and Ms. Ogeto - Safety, Health, Environmental and Quality Manager. Also present were various plant personal which were not materially involved in providing information for the assignment. I summarized the assignment and indicated that results of the sample analysis should be available in approximately one week. I indicated to the firm that barring positive results to any of the environmental sub samples, I did anticipate a return trip to the firm would be required. I indicated to the firm that if any of the samples were positive, it might require a return visit and additional samples and/or information, but what exact course of action could not be determined until the situation arose.

Area of Concern
(T. Slayton, CSO) The assignment indicated that gloves would be provided and sterile gloves should be used to collect each sub. The day prior to the initiation of the assignment, I spoke to Analyst Norris concerning the assignment and discovered that sterile gloves had not been provided as specified. I inquired as to the availability of sterile gloves from ARL. She indicated that ARL did not have sterile gloves available that she was aware of. She inquired to the availability of exam gloves here at the RP. I indicated we had none. She indicated that she could locate an unopened box of exam gloves for use at ARL. I inquired as to the issue of assuring we were not introducing Salmonella in to the samples. She indicated we would include an exam glove as a control and that should be sufficient.

(T. Slayton, CSO) After the sample collection was complete, I (T. Slayton) was preparing the Collection Report re-read the Biotrace instructions for use of the Spongesicle's. I realized our sample collection did not follow the directions presented. For example, the Biotrace instructions directed the user to push the stick up and grasp above the thumb stop (step 3). The sticks were grasped by reaching into the bag and pulling out the stick. Additionally, step 7 directs the user to return the Spongesicle to the whirl-pak, stopping short of the thumb stop. The user was to break off the Spongesicle stick at this point and seal the bag. The entire stick was returned to the whirl-pak, unbroken. It should noted that the Biotrace instructions are demonstrated w/out the use of gloves, we; however, did wear gloves

(C. Norris, Analyst) In lieu of not having sterile gloves available I (C. Norris) felt that we made every effort to ensure an aseptic collection of the environmental collection process was performed. My experience with Spongecicles has always been that the handle remains with the sponge, having numerous other occasions where I have analyzed this type of environmental swab, the handles have to my knowledge always been intact. Although this collection method is not in keeping with the directions of Bio Trace I feel that Investigator Slayton and myself collected the samples in such a manner that the integrity of the sample was not compromised in any way and illustrated by the results of the numerous environmental controls that were collected and analyzed to ensure no potential cross contamination could occur.

Samples collected:
Control sub samples:
Spongesicle Control Open – 1 Spongesicle, Lot #2007010, was submitted after being opened in firm and submitted in whirl-pak bag provided. Distributed by: Biotrace International.

Spongesicle Control Closed – 1 Spongesicle, Lot #2007010, was submitted after being opened in firm and submitted in whirl-pak bag provided. Distributed by: Biotrace International.

CultureSwab Control Closed – 1 BBL CultureSwab Liquid Amies Single Applicator, Lot #9PV793, remained closed and was submitted sealed in poly wrap from manufacturer. Distributed by: Becton, Dickinson and Compnay, 7 Loveton Circle, Sparks, MD 21152. Expires 6/30/08.

CultureSwab Control Open – 1 BBL CultureSwab Liquid Amies Single Applicator, Lot #9PV793, was submitted after being opened in firm and submitted in whirl-pak bag. Distributed by: Becton, Dickinson and Compnay, 7 Loveton Circle, Sparks, MD 21152. Expires 6/30/08.

Neutralizing Broth Control – 1 10 ml vial of Reditube Neutralizing Broth, Lot #V07124, submitted unopened in whirl-pak bag. Distributed by: Biotrace International. Expires 8/8/09.

Exam Glove Control Open – 1 X-Large Vinyl Exam Glove (Powder Free, Latex Free), Lot # 51110SHR-2336, submitted in whirl-pak bag. Manufactured for: Fisher Scientific, 2000 Park Lane Dr., Pittsburgh, PA 15275.

Exam Glove Control Open – 1 Medium Nitrile Exam Glove (Powder Free, Latex Free), Lot # 2569F, submitted in whirl-pak bag. Manufactured for: High Five Products Inc., Chicago, IL 60610.

Subs 1 through 8 collected from equipment cleaning rooms:
Sub 1 - Sub was collected from the floor drain under the sink in the center of the room which was identified as Food Contact Equipment Cleaning Room. Sub was collected by swabbing the drain cover and perimter of drain with a Spongesicle and neurtalizing broth. Site identified by firm as Perimeter of Food Contact Drain.

Sub 2 - Sub was collected from the floor area immediately in front of air handling unit identified as AIR COND 28 and contacting support structure located in NE corner of the room identified as Food Contact Equipment Cleaning Room. Sub was collected by swabbing the floor area in front of the unit with a Spongesicle and neutralizing broth. Site identified by firm as Air Cond28 Base.

Sub 3 - Sub was collected from the floor drain under the sink in the center of the room which was identified as Food Contact Equipment Cleaning Room. Sub was collected by removing the floor drain cover and trap and swabbing the interior of the drain with a Spongesicle and neutralizing broth. This sub was collected by Investigator Slayton due to the difficulty in reaching the sample site inside the drain pipe, beneath the sink. Analyst Norris handed a pre-moistened Spongesicle to Investigator Slayton. Investigator Slayton collected the sample and returned the Spongesicle to Analyst Norris, who returned the Spongesicle to the whirl-pak bag. Site identified by firm as Food Contact Steam Room Drain (Trap Removed).

Sub 4 - Sub was collected from the floor drain in the center of the room identified as Non-Food Contact Equipment Cleaning Room. Sub was collected by removing the floor drain cover and trap and swabbing the interior of the drain with Spongesicle and neutralizing broth. Site identified by firm as Non-Food Contact Steam Room Drain (Trap Removed).

Sub 5 - Sub was collected from a damp floor mop hanging on S wall in room identified as Non-Food Contact Equipment Cleaning Room. Sub was collected by swabbing the dangling mop head with a Spongesicle and neutralizing broth. Site identified by firm as Mop in Non-Food Contact Steam Room.

Sub 6 - Sub was collected from a yellow plastic scoop shovel hanging on the N wall in room identified as Non-Food Contact Equipment Cleaning Room. Sub was collected by swabbing the part of the shovel used to handle materials when in use with a Spongesicle and neutralizing broth. Site identified by firm as Shovel in Non-Food Contact Steam Room.

Sub 7 - Sub was collected from a long handled floor squeegee hanging on the N wall in room identified as Non-Food Contact Equipment Cleaning Room. Sub was collected by swabbing the rubber squeegee surface which is in contact with floor when in use with a Spongesicle and neutralizing broth. Site identified by firm as Squeegee in Non-Food Contact Steam Room.

Sub 8 - Sub was collected from a damp floor mop bucket which was inverted and stacked along the S wall of the room which was identified as Non-Food Contact Equipment Cleaning Room. Sub was collected by inverting and swabbing the inside of the bucket with a Spongesicle and neutralizing broth. Site identified by firm as Bucket in Non-Food Contact Steam Room.

Subs 9 & 10 collected in non-production areas:
Sub 9 - Sub was collected from the floor drain in the NE corner of the room identified as Forklift Battery Recharge Area. Sub was collected by removing the floor drain cover and trap and swabbing the interior of drain with a Spongesicle and neutralizing broth. Site identified by firm as Drain in Battery Charging Area.

Sub 10 - Sub was collected from the floor area in front of an outside access door (sample taken on interior side) which was identified as Rail Dock Exit Door. Sub was collected by swabbing an area approximately 18" sq. with a Spongesicle and neutralizing broth. Site identified by firm as Floor in front of Rail Dock Exit Door.

Subs 11 through 18 collected in the peanut roasting room:
Sub 11 - Sub was collected from the floor area adjacent to vertical support beam for Roaster [redacted] near Roaster [redacted] access door # R17) which was identified as Roaster Room. Sub was collected by swabbing an area approximately 24" sq. with a Spongesicle and neutralizing broth. Site identified by firm as Base under Roaster [redacted] Door R#17.

Sub 12 - Sub was collected from a round grooved cover measuring approximately 5" in diameter on the floor near door #R9 of Roaster [redacted] which was identified as Roaster Room. Sub was collected by swabbing the drain cover, grooves, and perimeter of drain cover with a Spongesicle and neutralizing broth. Site identified by firm as Drain Cover between Roaster [redacted] Doors 9 & 10.

Sub 13 - Sub was collected from the floor underneath a ceiling mounted exhaust near the SW corner of the room which was identified as Roaster Room. Sub was collected by swabbing an area approximately 24" sq. with a Spongesicle and neutralizing broth. Site identified by firm as Roaster [redacted] Floor across barrier underneath Door 2".

Sub 14 - Sub was collected from the handle of Roaster [redacted] access door #R2 which was located in area identified as Roaster Room. Sub was collected by swabbing the door handle with a CultureSwab. Site identified by firm as Roaster [redacted] Door 2 Handle.

Sub 15 - Sub was collected from the floor drain located between Roaster #[redacted] and #[redacted] (near Roaster #[redacted] access door #L5 and Roaster #[redacted] access door #R6) in the area which was identified as Roaster Room. Sub was collected by removing the floor drain cover and trap and swabbing the interior of the drain with a Spongesicle and neutralizing broth. Site identified by firm as Floor Drain between Roaster Doors Roaster[(b) (4)] & Roaster[(b) (4)] (trap removed).

Sub 16 - Sub was collected from the floor drain located between Roaster #[redacted] and #[redacted] (near Roaster #[redacted] access door #L11 and Roaster #[redacted] access door #R12) in the area which was identified as Roaster Room. Sub was collected by removing the floor drain cover and trap and swabbing interior of the drain with a Spongesicle and neutralizing broth. Site identified by firm as Floor Drain between Roaster Doors Roaster[(b) (4)] & Roaster[(b) (4)] (trap removed).

Sub 17 - Sub was collected from the floor area directly beneath a water valve near access door #R11 of Roaster #[redacted] in the area which was identified as Roaster Room. Sub was collected by swabbing an area approximately 24" sq. directly beneath the water valve with a Spongesicle and neutralizing broth. Site identified by firm as Roaster[redacted] Steel Post Floor Door #12.

Sub 18 - Sub was collected from wand attached to high pressure hose hanging in the center of the N wall in the area which was identified as Roaster Room. Sub was collected by swabbing exterior of wand opposite of handle end with a Spongesicle and neutralizing broth. Site identified by firm as High-pressure Hose Roaster Room.

Sub 19 through 26 collected in areas related to, or in close proximity to, the processing area:
Sub 19 - Sub was collected from a cracked portion of concrete floor located at the entry point to the Dry Additive Storage area. Sub was collected by scraping cracked area approximately 8" x 16" with sterile spatula and then swabbing the same area with a Spongesicle and neutralizing broth. Site identified by firm as Cracks in Floor under Curtains to Dry Additive Room.

Sub 20 - Sub was collected from floor area in front of door entering into hand sanitizing room. Room leads into NE corner of processing area. Sub was collected by swabbing floor area approximately 18" sq. in front of door with a Spongesicle and neutralizing broth. Site identified by firm as Floor by Day Tank Side Entry to[(b) (4)] Ante Room.

Sub 21 - Sub was collected from left rear tire of forklift identified with #T6819. Forklift was parked (not in use at time of sampling) in front of sugar[(b) (4)] room. Sub was collected by swabbing surface area of tire which comes into contact with floor when in use with a Spongesicle and neutralizing broth. Site identified by firm as Forklift #2 Right-rear Tire.

Sub 22 - Sub was collected from floor area in front of support column for sugar[(b) (4)] stand identified as "200 WEST". Sugar [(b) (4)] stand is located in sugar room which is approximately centered on the N exterior wall. Sub was collected by swabbing floor area approximately 18" sq. with a Spongesicle and neutralizing broth. Site identified by firm as Floor under 200 West Hopper in Sugar Room.

Sub 23 - Sub was collected from the bottom door seal of an overhead door leading into a Clean Room which provides access for items such as carts to the processing area. The Clean Room is located near holding area #6. Sub was collected by opening over head door and swabbing door seal which contacts floor when closed with a Spongesicle and neutralizing broth. Sub was collected by Investigator Slayton due to the sample site of the overhead door floor seal being raised out of the reach of Analyst Norris. Analyst Norris handed a pre-moistened Spongesicle to Investigator Slayton. Investigator Slayton collected the sample and returned the Spongesicle to Analyst Norris, who returned the Spongesicle to the whirl-pak bag. Site identified by firm as Bottom of Roll-up Door seal (by bay #6).

Sub 24 - Sub was collected from wheels of hand cart found in Clean Room referenced in Sub 23. Cart is routinely taken in and out of the process area. Sub was collected by swabbing surface area of one of four wheels which comes into contact with floor when in use with a Spongesicle and neutralizing broth. Site identified by firm as Wheels on Add-back Cart.

Sub 25 - Sub was collected from handle cover of hopper which holds lids intended for use in production of finished product on Line #[redacted] Cover is frequently opened in the course of production to add lids. Sub was collected by swabbing black handle which comes into contact with employee's hands when in use with a Spongesicle and neutralizing broth. Site identified by firm as Line[redacted] Cap Hopper Handle.

Sub 26 - Sub was collected from floor area within the Clean Room near the N over head door. Clean Room is located near holding area 4. Sub was collected by swabbing area approximately 18" sq. with a Spongesicle and neutralizing broth. Site identified by firm as Floor under Roll-up Door behind Line[redacted] Filler.

Subs 27 through 31 were collected in the area referred to as[(b) (4)] The[(b) (4)] area is where empty, unlabeled jars enter the processing area for filling and filled, closed, labeled jars exit and are cased for shipment:
Sub 27 - Sub was collected from conveyor belt which moves empty plastic jars into the production area for use on Line #[redacted] Sub was collected by swabbing surface area of belt which comes into contact with empty jars prior to filling with a Spongesicle and neutralizing broth. Site identified by firm as CNVRJAR304 Belt.

Sub 28 - Sub was collected near a door which accesses the NW corner of the processing area near Packing Line[redacted] Sub was collected by swabbing an area approximately 18" sq. to the exterior of the processing area with a Spongesicle and neutralizing broth. Site identified by firm as Floor by[redacted] Side Door to Line[redacted]

Sub 29 - Sub was collected from the floor in front of a door which accesses the processing area through the W wall near Packing Line[redacted] Sub was collected by swabbing an area approximately 18" sq. to the exterior of the processing area with a Spongesicle and neutralizing broth. Site identified by firm as Floor by[redacted] Side Door to Line[redacted]

Sub 30 - Sub was collected in front of a door which accesses the processing area through the SW corner near Packing Line[redacted] Sub was collected by swabbing the floor (approximately 18" sq.) area to the exterior of the processing area with a Spongesicle and neutralizing broth. Site identified by firm as Floor by[redacted] Side Door to Line[redacted]

Sub 31 - Sub was collected in front of a double door which accesses the processing area through the extreme NW corner near the Tube Packing Line. Sub was collected by swabbing the floor (approximately 18" sq.) area to the exterior of the processing area with a Spongesicle and neutralizing broth. Site identified by firm as Floor by[redacted] Side Door to[redacted] Line.

Subs 32 through 37, 39 & 40 were collected from the processing area, in front of, or related to, entrance and exit doors:
Sub 32 - Sub was collected in front of a door which accesses the processing area via a hand sanitation room on the S wall of the process area and is located near Packing Line[redacted] Sub was collected by swabbing the floor (approximately 18" sq.) area to the interior of the processing area with a Spongesicle and neutralizing broth. Site identified by firm as Floor by Process Ante Room (line side).

Sub 33 - Sub was collected in front of a door which exits the processing area on the S wall of the process area. The door opens out of the processing area only and is located immediately E of the door identified in sub 32. Sub was collected by swabbing the floor (approximately 18" sq.) area to the interior of the processing area with a Spongesicle and neutralizing broth. Site identified by firm as Floor by Exit Door by[redacted] Kettles.

Sub 34 - Sub was collected in front of a door which accesses the processing area via a hand sanitation room on the S wall of the process area and is located near Primary Mill (peanut grinders). The door opens into the processing area facing the W wall. Sub was collected by swabbing the floor (approximately 18" sq.) area to the interior of the processing area with a Spongesicle and neutralizing broth. Site identified by firm as Floor by Exit Door by[redacted] Electrical Panel.

Sub 35 - Sub was collected of the handle associated with the door referenced in sub 34. Sub was collected by swabbing the handle on the interior side of the door with a Spongesicle and neutralizing broth. Site identified by firm as Exit Door Handle by[redacted] Electrical Panel.

Sub 36 - Sub was collected in front of a door which accesses the processing area via a hand sanitation room on the S wall of the process area and is located near Primary Mill (peanut grinders). The door opens into the processing area facing the E wall. Sub was collected by swabbing the floor (approximately 18" sq.) area to the interior of the processing area with a Spongesicle and neutralizing broth. Site identified by firm as Exit Door Floor by Chunk Cutter.

Sub 37 - Sub was collected of the handle associated with the door referenced in sub 36. Sub was collected by swabbing the handle on the interior side of the door with a Spongesicle and neutralizing broth. Site identified by firm as Exit Door Handle by Chunk Cutter".

Sub 39 - Sub was collected on floor by in front double blue sliding doors located in the S wall of the processing area. Sub was collected by swabbing the floor (approximately 24" sq.) area in front of the doors on the processing area side with a Spongesicle and neutralizing broth. Site identified by firm as Floor by Blue Exit Double Doors to Main Hallway (sorting side).

Sub 40 - Sub was collected on floor by in front double doors located in the E wall of the processing area. Sub was collected by swabbing the floor area (approximately 24" sq) in front of the doors on the processing area side with a Spongesicle and neutralizing broth. Site identified by firm as Floor by Double Doors to old Roaster Room (sorting side)".

Sub 38 & 41 through 52 were collected from the part of processing area that milling, blending, holding occurs:
Sub 38 - Sub was collected on floor by the SE support column which holds Primary Mill [redacted] in the processing area. Sub was collected by swabbing the floor area (approximately 18" sq) adjacent to the SE support column with a Spongesicle and neutralizing broth. Site identified by firm as Primary Mill [redacted] Support Pole.

Sub 41 - Sub was collected from push broom against wall by[redacted] Blancher, which is near the E wall of the processing area. Sub was collected by swabbing the bristles of the broom with a Spongesicle and neutralizing broth. Site identified by firm as Broom from Blancher Floor.

Sub 42 - Sub was collected from floor in front of steps which accesses Sorter #[redacted] which is near the E wall of the processing area. Sub was collected by swabbing the floor area (approximately 24" sq) in front of the first step with a Spongesicle and neutralizing broth. Site identified by firm as Floor in front of [redacted]

Sub 43 - Sub was collected from the top step which accesses Sorter #[redacted] which is near the E wall of the processing area. Sub was collected by swabbing the step area (approximately 8" X 12") with a Spongesicle and neutralizing broth. Site identified by firm as [redacted] Step Ladder.

Sub 44 - Sub was collected from the left rail which is attached to the steps that accesses Sorter #[redacted] which is near the E wall of the processing area. Sub was collected by swabbing the area which a hand would come in contact with while climbing with a Spongesicle and neutralizing broth. Site identified by firm as Left Handle to [redacted] Step Ladder.

Sub 45 - Sub was collected from the air intake filter of the [redacted] Blower which moves roasted peanuts to the [redacted] Sorter, which is near the E wall of the processing area. Sub was collected by swabbing the filter with a Spongesicle and neutralizing broth. Site identified by firm as [redacted] Blower Filter.

Sub 46 - Sub was collected from the floor directly beneath a water valve marked Chilled Water near the [redacted] cool the product). Sub was collected by swabbing an area approximately 18" sq. with a Spongesicle and neutralizing broth. Site identified by firm as Floor under [redacted] Mill [redacted] by [redacted].

Sub 47 - Sub was collected from a steel plate on the floor and the wheels resting on the plate which were attached to the left side of the slurry tank, which is near the NE corner of the processing area. Sub was collected by swabbing the area with a Spongesicle and neutralizing broth. Site identified by firm as Wheel Plates under Mixing Slurries.

Sub 48 - Sub was collected from a steel plate on the floor and the wheels resting on the plate which were attached to the left side of the slurry tank, which is near the NE corner of the processing area. Sub was collected by scraping debris from the plate, wheels, and attached support structure into a whirl-pak bag with a sterile spatula. The whirl-pak bag contained a Spongesicle and neutralizing broth. Site identified by firm as Stabilizer Buildup inside Wheels to West Mixing Slurry.

Sub 49 - Sub was collected in front of a door which accesses the processing area via a hand sanitation room on the NE wall of the process area and is located near the slurry tank. Sub was collected by swabbing an area approximately 18" sq. to the interior of the processing area with a Spongesicle and neutralizing broth. Site identified by firm as Floor in front of [redacted] Ante Room [redacted] side).

Sub 50 - Sub was collected from floor at exit point of [redacted] which is located near the NE corner of the processing area. Sub was collected by swabbing an area approximately 18" sq. with a Spongesicle and neutralizing broth. Site identified by firm as Floor under Entrance Door to [redacted]

Sub 51 - Sub was collected from floor at exit point of [redacted] (door faces holding area), which is located near the NE corner of the processing area. Sub was collected by swabbing an area approximately 18" sq. with a Spongesicle and neutralizing broth. Site identified by firm as Floor under Entrance Door to [redacted]

Sub 52 - Sub was collected from floor mat at entry point of [redacted] (door faces packaging area), which is located near the center of the N wall of the processing area. Sub was collected by swabbing an area approximately 18" sq. with a Spongesicle and neutralizing broth. Site identified by firm as [redacted] Floor Mat.

Subs 53 through 66 were collected near Packing Lines [redacted] through [redacted]

Sub 53 - Sub was collected in front of a door which exits the Packing Line [redacted] and opens into [redacted] area of Line [redacted] in the E wall of the process area. Sub was collected by swabbing an area approximately 18" sq. to the interior of the processing area with a Spongesicle and neutralizing broth. Site identified by firm as Floor in front of Line [redacted] Exit to [redacted] Area.

Sub 54 - Sub was collected from floor and support column of conveyor system of Packing Line [redacted] The sample site was after the equipment [redacted] and before equipment [redacted] Sub was collected by swabbing the floor area, approximately 12" sq., which was adjacent to the conveyor support column and also the lower part of the support column with a Spongesicle and neutralizing broth. Site identified by firm as Floor around support by Line [redacted] Jar Cleaner.

Sub 55 - Sub was collected from floor near the reprocess vacuum of Line [redacted] Sub was collected by swabbing an area approximately 18" sq. with a Spongesicle and neutralizing broth. Site identified by firm as Floor by Line [redacted] Add-Back Station Trashcan.

Sub 56 - Sub was collected from floor directly underneath equipment [redacted] located on Packing Line [redacted] Sub was collected by swabbing an area approximately 18" sq. with a Spongesicle and neutralizing broth. Site identified by firm as Floor under Line [redacted] Jar Cleaner (outside line).

Sub 57 - Sub was collected in front of a door which exits the Packing Line [redacted] and opens into [redacted] area of Line [redacted] in the E wall of the process area. Sub was collected by swabbing an area approximately 18" sq. to the interior of the processing area with a Spongesicle and neutralizing broth. Site identified by firm as Floor in front of Line [redacted] Exit to [redacted] Area.

Sub 58 - Sub was collected from mat next to boot dip in Packing Line [redacted] Mat was next to conveyor on Line [redacted] near point before [redacted] which is close to the E wall of the process area. Sub was collected by swabbing an area approximately 18" sq. with a Spongesicle and neutralizing broth. Site identified by firm as Line [redacted] Foot Sanitizer Mat.

Sub 59 - Sub was collected from inside the cabinet of equipment [redacted] located on Packing Line [redacted] Sub was collected by accessing the cabinet from the rear and swabbing the base of the peanut butter jar filling machine with a Spongesicle and neutralizing broth. Site identified by firm as Line [redacted] Filler Base.

Sub 60 - Sub was collected from wheel of stainless steel push cart holding product labels, which was setting near Packing Line [redacted] Sub was collected by swabbing one of the wheels with a Spongesicle and neutralizing broth. Site identified by firm as Wheel of the [redacted] Wrap Cart.

Sub 61 - Sub was collected in front of a door which exits the Packing Line [redacted] and opens into [redacted] area of Line [redacted] in the E wall of the process area. Sub was collected by swabbing an area approximately 18" sq. to the interior of the processing area with a Spongesicle and neutralizing broth. Site identified by firm as Floor in front of Line [redacted] Exit to [redacted] Area.

Sub 62 - Sub was collected from inside the cabinet of equipment [redacted] located on Packing Line [redacted] Sub was collected by accessing the cabinet from the front and swabbing the part of the machine resembling a gear approximately 24" in diameter with a Spongesicle and neutralizing broth. The purpose of the gear is to move the jars through the filler as they are filled with peanut butter. Site identified by firm as Line [redacted] Filler Discharge Star Wheel.

Sub 63- Sub was collected from inside the cabinet of equipment [redacted] located on Packing Line [redacted] Sub was collected by accessing the cabinet from the front and swabbing the part of the machine resembling a gear approximately 18" in diameter with a Spongesicle and neutralizing broth. The purpose of the gear is to move the jars through the capper as the caps are affixed on the jars. Site identified by firm as Line [redacted] Capper Discharge Star Wheel.

Sub 64 - Sub was collected from conveyor moving filled jars on Packing Line [redacted] Sample was collected from section of conveyor after [redacted] and before labeling machine with a Spongesicle and neutralizing broth. Site identified by firm as Line [redacted] Belt after Ladder to Labeler.

Sub 65 - Sub was collected in front of a double door which exits the processing area and opens into [redacted] near the SW corner of the processing area. Sub was collected by swabbing an area approximately 18" sq. to the interior of the processing area with a Spongesicle and neutralizing broth. Site identified by firm as Floor by [redacted] Exit Door to [redacted]

Sub 66 - Sub was collected in front of a door which exits the processing area through the S wall near the Tube Filling Line. Sub was collected by swabbing an area approximately 18" sq. to the interior of the processing area with a Spongesicle and neutralizing broth. Site identified by firm as [redacted] Exit Door to Hallway Outside Lab.

Attachments:
FDA 482 dated 11/26/07
Copy of CFSAN assignment, DFP&G #07-21, ORA concurrence #2007061901, FACTS 851520
Copy Biotrace directions for use of Spongesicle
Copy of C/R #420919

Exhibits:
1. A copy of the firm's identification of sample sites, 3 pgs.
2. An original copy of a diagram of the firm.
3. A copy of the firm's environmental sample sites, 10 pgs.

Attached is the November 6, 2009 (FDA inspection).

Food and Drug Administration Establishment Inspection Report

Date Assigned: 10/21/2009 **Inspection Start Date:** 11/02/2009 **Inspection End Date:** 11/06/2009

Firm Name & Address: Unilever , 8201 Frazier Pike Little Rock, AR 72206-3871 US

Firm Mailing Address: 8201 Frazier Pike, Little Rock, AR 72206-3871 United States

FEI: 2316570 **JD/TA:** 80 **County:** PULASKI **Est Size:** (b) (4)

Phone: (501)490-1441 **District:** DAL-DO **Profiled:** No

Conveyance Type: **% Interstate:** (b) (4) **Inspectional Responsibility:** State

Endorsement

The CFSAN initiated inspection of this peanut butter manufacturer was performed as part of the FY '10 DAL-DO Food Program PG, FACTS Assignment #1101846 and conducted pursuant to CFSAN High Priority assignment, DFPG #10-03, ORA Concurrence #2009092802 for inspections and environmental sampling for Salmonellae at firms that manufacture nuts and nut products. Additionally, the cGMP inspection was accomplished following CP 7303.803 - Domestic Food Safety.

The previous inspection conducted in 11/07 was classified VAI and included 66 environmental sub-samples. Three of the sub-samples indicated positive for Salmonella spp. and resulted the firm voluntarily holding all product and suspending production for approximately (b) (4) while the firm conducted extensive cleaning and sanitization. According to the firm, no held product tested positive for Salmonellae.

The current inspection revealed the firm continues to operate as manufacturer of peanut butter from raw peanuts and distribute under the Skippy brand. Only minor cGMP deviations were noted and no FDA 483, Inspectional Observations Form, was issued.

Sample numbers 479697, 479698 and 479699 were collected during the inspection which are comprised a total of 103 environmental sub-samples. All samples were determined to be negative for Salmonellae.

No refusals were encountered during the inspection.

b(3)

All FDA correspondence including the FMD-145 letter should be directed to:
Unilever
Mr. Patrick J. Mathieu, Supply Leader
8201 Frazier Pike
Little Rock, AR 72206

Classification: NAI
Reschedule: per CPGM

Distribution:
O. DAL-DO M&F
cc w/o exhibits: LR-RP
c/s: DAL-IB BOC (Cervantes)
FMD-145

Endorsement Location: DAL-DO M&F

Inspector Name	Date & Time of Signature	Supervisor Name	Date & Time of Signature
Torrance J Slayton	11/30/2009 02:39 PM ET	Brenda G Stewart Munoz	01/28/2010 11:44 PM ET

Food and Drug Administration Establishment Inspection Report

FEI:2316570 **Inspection Start Date:** 11/02/2009 **Inspection End Date:** 11/06/2009

Firm Name & Address: Unilever , 8201 Frazier Pike Little Rock, AR 72206-3871 US

Related Firm FEI: **Name & Address of Related Firm:**

b(3) [redacted]

Establishment Type		Industry Code	
M	Manufacturer	23	Nuts/Edible Seed
M	Manufacturer	26	Vegetable Oils
M	Manufacturer	36	Food Sweeteners (Nutritive)
M	Manufacturer	71	Byprodcts For Animal Foods

District Use Code:

Food and Drug Administration Establishment Inspection Report

FEI: 2316570 **Inspection Start Date:** 11/02/2009 **Inspection End Date:** 11/06/2009

Firm Name & Address: Unilever , 8201 Frazier Pike Little Rock, AR 72206-3871 US

Inspection Basis: Surveillance

Inspected Processes & District Decisions

PAC	Establishment Type	Products/ Process	MQSA	Reschedule Insp Date	Re-Inspection Priority	Inspection Conclusions
03803	Manufacturer	23 C H T		(b)(7)(A)	Surveillance	No Action Indicated (NAI

Final Decision?	District Decision Date	District Decision Type	District Decision Made By	Org Name
	01/28/2010	No Action Indicated (NAI)	Stewart Munoz, Brenda G	DAL-TM1

Remarks:

PAC	Establishment Type	Products/ Process	MQSA	Reschedule Insp Date	Re-Inspection Priority	Inspection Conclusions
03803E	Manufacturer	23 C H T		(b)(7)(A)	Surveillance	No Action Indicated (NAI

Final Decision?	District Decision Date	District Decision Type	District Decision Made By	Org Name
	01/28/2010	No Action Indicated (NAI)	Stewart Munoz, Brenda G	DAL-TM1

Remarks:

Food and Drug Administration Establishment Inspection Report

FEI: 2316570 **Inspection Start Date:** 11/02/2009 **Inspection End Date:** 11/06/2009

Firm Name & Address: Unilever , 8201 Frazier Pike Little Rock, AR 72206-3871 US

Products Covered

Product Code	Est Type	Description	Additional Product Description
23 C H T 07	Manufacturer	Peanut, Butter, Nonflex Plastic; Packaged Food (Not Commercially Sterile)	

Assignees Accomplishment Hours

Employee Name	Position Class	Hours Credited To	PAC	Establishment Type	Process	Hours
Slayton, Torrance J	INV	DAL-DO	03803	Manufacturer	23 C H T	40
Peters, Christophe T	MBI	ARL	03803	Manufacturer	23 C H T	24
Slayton, Torrance J	INV	DAL-DO	03803E	Manufacturer	23 C H T	4
Peters, Christophe T	MBI	ARL	03803E	Manufacturer	23 C H T	2
					Total Hours:	70

Food and Drug Administration Establishment Inspection Report

FEI: 2316570 **Inspection Start Date:** 11/02/2009 **Inspection End Date:** 11/06/2009

Firm Name & Address: Unilever , 8201 Frazier Pike Little Rock, AR 72206-3871 US

Inspection Result

EIR Location
DAL-DO M&F

Trips Num

Inspection Summary
The CFSAN initiated inspection of this peanut butter manufacturer was performed as part of the FY '10 DAL-DO Food Program PG, FACTS Assignment #1101846 and conducted pursuant to CFSAN High Priority assignment, DFPG #10-03, ORA Concurrence #2009092802 for inspections and environmental sampling for Salmonellae at firms that manufacture nuts and nut products. Additionally, the cGMP inspection was accomplished following CP 7303.803 - Domestic Food Safety.

The previous inspection conducted in 11/07 was classified VAI and included 66 environmental sub-samples. Three of the sub-samples indicated positive for Salmonella spp. and resulted the firm voluntarily holding all product and suspending production for approximately (b) (4) while the firm conducted extensive cleaning and sanitization. According to the firm, no held product tested positive for Salmonellae.

The current inspection revealed the firm continues to operate as manufacturer of peanut butter from raw peanuts and distribute under the Skippy brand. Only minor cGMP deviations were noted and no FDA 483, Inspectional Observations Form, was issued.

Sample numbers 479697, 479698 and 479699 were collected during the inspection which are comprised a total of 103 environmental sub-samples. All samples were determined to be negative for Salmonellae.

No refusals were encountered during the inspection.

b(3)

IB Suggested Actions

Action	Remarks

Referrals

Org Name	Mail Code	Remarks

Refusals

Inspection Refusals: No refusal

Samples Collected

Sample Number
479697
479698
479699

Recall Numbers

Recall Number

Related Complaints

Consumer Complaint Number

FDA 483 Responses

Food and Drug Administration Establishment Inspection Report

FEI: 2316570 **Inspection Start Date:** 11/02/2009 **Inspection End Date:** 11/06/2009

Firm Name & Address: Unilever , 8201 Frazier Pike Little Rock, AR 72206-3871 US

483 Issued?: **483 Location:**

Response Type	Response Mode	Response Date	Response Summary

Establishment Inspection Report	FEI:	**2316570**
Unilever Best Foods	EI Start:	11/02/2009
Little Rock, AR 72206-3871	EI End:	11/06/2009

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SUMMARY

The CFSAN initiated inspection of this peanut butter manufacturer was performed as part of the FY '10 DAL-DO Food Program PG, FACTS Assignment #1101846 and conducted pursuant to CP 7303.803 – Domestic Food Safety. The CFSAN High Priority assignment, DFPG #10-03, ORA Concurrence #2009092802, requested GMP inspections and environmental sampling for Salmonellae at firms that manufacture nuts and nut products. Also covered per CFSAN was DFPG #10-01, ORA Concurrence #2009082801 for foods containing a major allergen.

The previous inspection conducted in 11/07 was classified VAI and included 66 environmental sub-samples. Three of the sub-samples indicated positive for *Salmonella spp* and resulted the firm voluntarily holding all product and suspending production for approximately (b) (4) while the firm conducted extensive plant cleaning and sanitization. According to the firm, no held product tested positive for *Salmonella*.

Establishment Inspection Report	FEI:	**2316570**
Unilever Best Foods	EI Start:	11/02/2009
Little Rock, AR 72206-3871	EI End:	11/06/2009

The current inspection revealed the firm continues to operate as manufacturer of peanut butter from raw peanuts and distribute under the Skippy brand. Only minor GMP deviations were noted and no FDA 483, Inspectional Observations Form, was issued.

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No refusals were encountered during the inspection.

ADMINISTRATIVE DATA

Inspected firm:	Unilever
Location:	8201 Frazier Pike Little Rock, AR 72206-3871
Phone:	501-490-1441
FAX:	
Mailing address:	8201 Frazier Pike Little Rock, AR 72206
Dates of inspection:	11/2/2009, 11/3/2009, 11/4/2009, 11/5/2009, 11/6/2009
Days in the facility:	5
Participants:	Torrance J. Slayton, Investigator Christopher T. Peters, Analyst

Upon arrival, we displayed credentials and issued a FDA-482, Notice of Inspection, to Mr. Patrick J. Mathieu, Supply Leader. Also present was Ms. Tawana J. Walker Ogeto, Safety, Health, and Environmental and Quality Manager and (b) (6) Quality and Environmental Specialist. Ms. Ogeto provided a copy of a document dated 11/2/09 and addressed to "Dear Investigators" (Exhibit 1). The document specified the firm's policy concerning photographs, signing documents, affidavits, trade secrets, samples and employee contact.

Investigator Slayton and Analyst Peters completed the inspection jointly. The report was written by Investigator Slayton with input by Analyst Peters.

HISTORY

The firm history remains essentially unchanged. The firm is part of the Unilever global operations with U.S. based corporate offices located in Englewood Cliffs, NJ.

The previous inspection did not result in the issuance of an FDA 483, Inspectional Observations Form; however, three environmental sub-samples did test positive for the presence of *Salmonella spp* DAL-CB informed the firm of the results, and in response, the firm suspending production and placed all products on hold. According to the firm, private laboratory testing did not detect *Salmonella* in the product. The firm hired a consultant, (b) (4) Ph.D to provide guidance in the extensive cleaning and sanitization of the entire facility. The facility was closed (b) (4) weeks in which a total equipment teardown occurred. The inspection was classified VAI.

The firm has previously been audited by (b) (4) and received superior ratings. Ms. Ogeto stated the (b) (4) had been selected as the new third-party auditor and began their initial audit on 11/5/09.

The firm operates (b) (4) with (b) (4) full-time employees and (b) (4) contract employees. Annual sales and unit production figures were not available, but Ms. Ogeto stated the firm produces on average (b) (4) (b) (4) pounds of peanut butter per week.

b(3) We verified that the firm was aware of the RFR requirements.

All FDA correspondence including the FMD-145 letter should be directed to:

Unilever
Mr. Patrick J. Mathieu, Supply Leader
8201 Frazier Pike
Little Rock, AR 72206

INTERSTATE COMMERCE

The firm distributes peanut butter (PB) throughout (b) (4) (b) (4) % of product for the U.S. market is sent to one of (b) (4) out-of-state Unilever distribution centers located throughout the country (Exhibit 2). From there, the product is distributed to customers. The firm's three largest customers are (b) (4)

JURISDICTION

The firm manufactures a variety of PBs. At least (b) (4) % of product is for the retail market and the remaining amount is packed in 25 lb pails and 550 lb drums for further processing by other manufacturers. All products are distributed under the Skippy brand.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

Mr. Patrick J. Mathieu, Supply Leader – Mr. Mathieu is the most responsible person at the plant. His responsibilities include employee and product safety and environmental concerns. He has an annual operating budget of (b) (4) that excludes raw materials and packaging. His budget must

be submitted to the corporate office for approval. He can hire employees but firing employees requires input from the legal department. Engineering, finance, and HR functions do not report to him, but rather the corporate office. Mr. Mathieu demonstrated his authority by accepting the FDA 482.

Ms. Tawana J. Walker Ogeto, Safety, Health, and Environmental and Quality Manager – Ms. Ogeto is responsible for all quality issues. There are (b) (4) quality employees who report to Ms. Ogeto. She can hire quality employees but the legal department must approve any firing. She can request expenditures for up $(b) (4). Ms. Ogeto demonstrated her authority by directing employees (quality and production). We observed employees comply with her directions. She also facilitated all documentation during the inspection. According to Ms. Ogeto, the corporate legal department reviewed and approved all documents prior to our review. Ms. Ogeto reports to Mr. Mathieu.

Ms. Alicia (b) (6) Quality and Environmental Specialist (b) (6) is responsible for the review of laboratory results (PB and environmental) and release/rejection of finished lots of PB. She has input on the hiring/firing of employees, but can't make any final decisions. She can not authorize expenditures, but can authorize the destruction of product (b) (6) reports to Ms. Ogeto.

FIRM'S TRAINING PROGRAM

All employees receive annual GMP training. Employees are shown photos of what not to do, as observed in the plant, and they discuss why they do certain actions as they relate to GMPs. New employees receive GMP training before they are allowed to enter the production area with a (b) (4) day follow-up. The firm administers a quiz at the end of orientation and (b) (4) days.

Roaster operators must have in-plant experience before they can learn to operate the roasters. To be selected, the employee must pass a critical interview conducted by management and must have held previous leadership roles. It takes from (b) (4) mo'ns to be fully trained as an operator.

MANUFACTURING/DESIGN OPERATIONS

The manufacturing of peanut butter is divided into the raw and cooked areas. The firm prohibits employees dedicated to the raw and cooked area from entering each others area at all times. The peanuts are in a predominantly closed system starting when they are unloaded from a railcar and continuing until the peanut butter is filled into jars. There are isolated instances where the product is minimally exposed to the environment. (b) (4) occasions occur after the roasting process; blanching and sorting, but those instances the exposure remains very limited; and the troughs associated with the Primary Grinders, Mixing Slurrys and the (b) (4) brand mills, but the troughs are covered with a Lexan cover (a polycarbonate resin thermoplastic similar to plexiglass).

Bulk raw peanuts - The firm receives bulk raw peanuts in rail cars from one of (b) (4) different suppliers. Each load is checked for aflatoxins prior to acceptance. Each lot is accompanied by a

USDA issued CoA. Any aflatoxin test failed must be repeated twice per USDA regulation before it can be rejected. Qualities such as moisture, filth, foreign objects, flavor, infestation, damage (immature or mold) are checked every (b) (4) lot. A railcar contains enough peanuts to fill (b) (4) approximately (b) (4) lbs. Once accepted, the peanuts are blown via a closed system to one of (b) (4) silos. The firm processes about (b) (4) railcars (b) (4) Peanuts to be processed are passed though a (b) (4) and then a Destoner. The two machines are screening devices. The (b) (4) removes foreign material and the Destoner removes rocks and stones.

The peanuts proceed into the Roasting Room and into one of (b) (4) continuous roasters. The roasters are approximately (b) (4) long and can roast a maximum of (b) (4) lbs of peanuts/hour/each. The belt speed has a maximum set point of (b) (4) /minute and is continuously monitored. The peanuts are exposed to (b) (4) heating zones (b) (4) and then (b) (4) cooling zones. The corporate R&D conducted a validation of the firm's roasting process approximately six months ago and confirmed a (b) (6) reduction occurred at the kill step. A revalidation was completed approximately two weeks ago. The temperatures are recorded via data logger and the operators take a manual reading every (b) (4) minutes which is recorded in a log book. The log book is reviewed daily by the quality department. The roaster (b) (4) s are calibrated by (b) (4) on (b) (4) basis. The roaster is operated by software which has been validated. The program can only be changed by the contractor.

Also present in the Roaster Room is a batch roaster, referred to as the Mini Roast. The mini roast is used to roast peanut nibs, the heart of the peanut. A batch is comprised of (b) (4) lbs of nibs roasted to an internal product temperature of (b) (4) F for (b) (4) minutes. The firm has validated the roasting process. Nibs are incorporated into all PB blends at varying percentages.

Other raw ingredients - The firm receives (b) (4) sugar in (b) (4) totes. The firm uses (b) (4) (powdered sugar) for use as an ingredient in PB (except natural). The Dry Additive Room houses the sugar (b) (4) (b) (4) along with salt, soy (for reduced fat), corn syrup solids (for reduced fat), vitamin blend (for reduced fat) and (b) (4) (a stabilizer for full fat). The firm also uses bulk honey and molasses for honey-nut flavored PB. The molasses and honey are received with a CoA and undergo micro testing, but the honey is not tested for pesticides or chemicals.

(b) (4) area – The area referred to as (b) (4) by the firm includes the area outside the process area where empty jars enter the process area and then filled, capped, labeled jars exit (b) (4) separate lines). Empty jars are received palletized and an automated system places each layer of jars from the pallet on a conveyor system to be filled.

Packaging and labeling are received in bulk. The firm has (b) (4) bins on the outside of the process area where the lids are dumped into a hopper. The machines align the lids for use in packaging and the lids enter the production area via a track system. Labels are brought into the processing area via clean rooms. The clean room has a two roll-up doors and only one can be opened at a time. The

labels are brought into the clean rooms via forklift and then each roll is carried into the processing area by an employee who must step in a footbath to return to the processing area.

The filled jars exit the process area and are cased and shrink wrapped. An automated system conveys the cased product to another area of the firm where the product is palletized.

Processing area - The roasted peanuts enter the process area via the closed system from the roasters. The peanuts are passed through one of (b) (4) Blanchers to remove the skin. The peanuts are passed over a magnet. The magnet is checked and challenged on each shift. Any foreign objects found are taken to the lab for identification and description. The peanuts are then sorted by (b) (4) brand sorters and peanuts which do not meet color specifications are rejected. The rejected peanuts are subjected to metal detection which is checked and challenged (b) (4) The rejected peanuts are passed through another (b) (4) brand sorter. All acceptable peanuts are next transported via the closed system to the Primary Mills (first grind). (b) (4) product temperature at exit of approximately (b) (4) (b) (4) F. For the production of "crunchy" varieties of peanut butter, (b) (4) % of the peanuts are reserved after the first grind to be incorporated into the final product. The peanuts are then passed to one of (b) (4) bulk kettles which can hold up to (b) (4) lbs each. The product remains here for approximately (b) (4) until needed to feed the (b) (4) Kettle, which in turn is used to supply the Mixing Slurry. The product in the kettles remains at approximately (b) (4) F. (b) (4) (b) (4) a sample is pulled from the kettles for micro analysis. Ms. Ogeto stated the firm has never had a positive sample.

Sugar, salt, and any other ingredients are combined with the PB in the Mixing Slurry (b) (4) . The product is transported via the closed system to one of (b) (4) (b) (4) lb Mixing Kettles (b) (4) for each (b) (4) . The Mixing Kettles are only to ensure a uniform blend. The product exits the Mixing Kettles at approximately (b) (4) F and is cooled by one of (b) (4) (b) (4) (each kettle feeds (b) (4) , referred to as (b) (4) Coolers. The final consistency is accomplished by one of (b) (4) (b) (4) brand mills, each connected to a (b) (4) The product is accumulated in the (b) (4) Kettles (approximately (b) (4) lb capacity) to (b) (4)

The product is transported to the (b) (4) filling lines. Each line has (b) (4) (b) (4) to lower the product temperature to approximately (b) (4) (b) (4) F. An in-line magnet is in place as the product leaves the (b) (4) and travels to the filling machine. The magnet is checked (b) (4) unless the filling line metal detector is activated. The empty jars enter on a conveyor from the (b) (4) area. The jars are inverted and "puffed" with air to remove any foreign material. The jars are then filled, capped, and labeled. Any jar which has not been adequately filled is manually emptied via a (b) (4) system and the product reenters the filling system. All jars pass through metal detection prior to leaving the processing area. The metal detector is challenged (b) (4) and the results recorded. The firm screens for ferrous, non-ferrous, and stainless steel. The metal detector is challenged (b) (4) and documented. Employees are present in the packaging area to perform such task as ensuring jars are full, checking cap torque, and ensuring proper label application. The finished product exits the processing area to be cased for shipment.

Employees must enter the processing area through an ANTE room. The ANTE room contains an automated hand wash/sanitizing station and a boot dip. There are exit only doors from the process which are clearly marked as exit only.

Other Areas Outside Processing Room - Other areas outside the processing room include food contact and non-food contact cleaning rooms, mechanical/maintenance areas, and finished product storage (limited). The non-food contact cleaning room houses items such as mops, squeegees, mop buckets, plastic scoop shovels for use in the raw areas on non-food contact surfaces. The mechanical and maintenance areas are just that, areas where tools and materials are stored which are used in the maintenance and upkeep of the facility and equipment. The food-contact cleaning room is used to clean equipment from the production area, which are taken across the hall to a temporary area for drying and sanitization. A small room inside the food-contact cleaning room is designated to prepare mops/buckets for use in the production area.

The firm will rework product only due to flavor or color issues. The product to be reworked is stored in drums and clearly labeled. The product is added to the Back Kettle for full fat PB and the Add Back Kettle for the reduced fat PB. A log is kept of the add backs separate from production. The log is reviewed daily by the quality department.

CLEANING & SANITIZATION

Day-to-day cleaning and sanitation is conducted by (b) (4) full-time and (b) (4) part-time contract employees. A contract supervisor is (b) (4) and the supervisors report to (b) (6) At the (b) (4) the firm conducts a thorough cleaning and sanitization of the plant. Unilever employees who work in production during (b) (4) are responsible for cleaning their own areas.

The employees are trained as part of their OJT how to clean and sanitize. They are taught what to do and what not to do. They are instructed on the when/where to use specific cleaners/sanitizing agents and also discuss what microorganisms are. The firm provided a list of all sanitizers used, where used, and the application strength (Exhibit 3). The firm documents what specific cleaning and sanitizing agents are used, where used, and the diluted strength. Ms. Ogeto stated the firm did not add any additional sanitizers in response to the positive sample results found during the previous inspection.

Raw area - The (b) (4) and Stoner are cleaned (b) (4) in a dry cleaning process utilizing a combination of shop vacs, brushes, and (b) (4) (b) (4) the floors in the Raw area are cleaned with floor scrubbers dedicated to the Raw area and areas unreachable by floor scrubbers are mopped with a wet mop and bucket.

Roaster Room – The belts on the tunnel roasters are CIP (b) (4) The sanitizer is an (b) (4) (b) (4) delivered at (b) (4) and followed by a drying step (b) (4) the inside walls and ceiling are cleaned with a high-pressure hose (detergent/sanitize). The exterior of the roasters are

wiped down (b) (4) The Mini Roast is cleaned (b) (4) The inside walls of the tunnel roasters are scrapped down to remove build up. The screens are removed and taken to the food-contact cleaning room for cleaning and sanitization. The floor is cleaned/sanitized with a mop and bucket on a (b) (4) basis.

Production area - The firm maintains a separate cleaning SOP for each piece of equipment. The SOP includes the floor area in relative proximity to the equipment. No separate floor cleaning SOP exists.

The firm wet cleans the floors of the production area (b) (4) Wet cleaning is accomplished with a floor scrubber and mops. No hoses were observed in the processing area during the assignment. During the assignment, we observed periodic dry cleaning with brooms. The floors are cleaned with a floor scrubber and the areas which can not be reached by the scrubber are moped with a solution of soap/water. All floor areas are sanitized by mopping with a bleach/water solution. The bleach is mixed at a ratio of (b) (4) gallon of water. The sanitizer is allowed a (b) (4) minute contact time and then rinsed mopped with a clean mop. The supplies (mops/buckets/squeegees, etc.) are dedicated to either the production area or the raw area.

The firm cleans equipment prior to the primary grind, such as the Blancher and Sorter, (b) (4) (b) (4) in a primarily dry process. The equipment is brushed and a shop vac is used. The exterior surface is surfaces are then sanitized by wiping with (b) (4) which contains (b) (4) (b) (4)

The Primary Mills (Grinders) and the Mixing Slurry are cleaned (b) (4) The exterior surfaces are scrapped of any product and sanitized by wiping with (b) (4) The food contact surfaces that can be reached without disassembling are scrapped of product (Lexan covered troughs), then the entire system is flushed with (b) (4) (b) (4) all Primary Mill CIP pipes are broken down and the grinders are opened for inspection (b) (4) the Mixing Slurry CIP lines are torn down for cleaning. The (b) (4) brand mills and attached (b) (4) are cleaned (b) (4) in the same manner.

The Bulk Kettles and the Front Kettle are cleaned (b) (4) and the Mixing Kettles and (b) (4) Kettles are cleaned (b) (4) by circulating (b) (4) at (b) (4) for (b) (4) hours. The firm collects a product sample (b) (4) from the kettles to screen for micro. According to Ms. Ogeto, the firm has never had a positive sample.

The filling lines are cleaned (b) (4) The filling machine is CIP, except Line [redacted] after reduced fat PB (allergen). The filling heads are completely broken down in this case. Additionally, any time the filling line is down for (b) (4) hours or more the filling machine is cleaned. The line conveyors are sprayed (b) (4) with a spray sanitizer and (b) (4) they are removed from the line to be steam cleaned.

Establishment Inspection Report	FEI:	**2316570**
Unilever Best Foods	EI Start:	11/02/2009
Little Rock, AR 72206-3871	EI End:	11/06/2009

ALLERGENS

The firm has a potential for allergen cross-contamination from a soy product used in the reduced fat PB. The allergen is Soy Concentrate (Exhibit 4) and is added to replace the protein lost do to the lower fat content (b) (4) reduced fat PB is manufactured on the (b) (4) brand mixer/grinder and (b) (4) lines and equipment are dedicated to the reduced fat PB until the (b) (4) affiliated with Fill line # (b) (4) The reduced fat PB is only filled (b) (4) . The firm manufactures reduced fat PB (b) (4) (b) (4) and then follows a written procedure to complete the product changeover. The changeover includes changing some piping configurations on the (b) (4) and then a cleaning via a validated cleaning procedure. The firm documents the changeover and cleaning. The firm conducts bio trace swabbing following each allergen cleaning to ensure no soy residue remains. The allergen checklist was completed (attached).

QUALITY CONTROL & ENVIRONMENTAL MONITORING

Ms. Ogeto is head of the quality department. All laboratory analysis are conducted by (b) (4) at various locations. Finished product testing occurs in (b) (4) Environmental swab testing occurs in (b) (4) and Nutritional analysis occurs in (b) (4)

The in-house quality functions include verification of physical attributes of in-process PB (fill wt., container closure, etc.), releasing raw materials for use, label and packaging material review at receipt, release of product, and review of environmental sample results. Only Ms. Ogeto or Ms. (b) (6) may release product or review environmental test results. The other quality functions are conducted by quality unit employees in Ms. Ogeto's department.

The firm collects a representative sample from each lot of PB and ships to (b) (4) (b) (4) screens each lot for APCs, coliforms, and *Salmonella* according to AOAC methods. Additionally, at the (b) (4) (b) (4) is screened for the presence of yeast and mold. Ms. Ogeto reported no failures since the previous inspection.

The firm collects environmental samples on a (b) (4) basis. There are (b) (4) sample sites, but only (b) (4) samples are collected (b) (4) . The firm rotates the sample sites over a (b) (4) period with some sites being sampled only once per cycle and other sites on a more frequent basis (Exhibit 5). The samples are collected by (b) (4) an outside contractor. The contract employees are trained by (b) (4) and (b) (6) randomly observes sample collection. The firm uses (b) (4) brand pre-moistened sponge sticks and adds a (b) (4) broth manufactured by (b) (4) Ms. Ogeto reported no failures since the previous inspection.

Analyst Peters reviewed laboratory results for environmental swabs and finished product dated 9/25/09- 10/31/09. He found no discrepancies and the results to be within the firm's specifications. The finished product specifications are: Negative for *Salmonella*, (b) (4) maximum for coliforms, (b) (4) maximum for APCs, and (b) (4) maximum for Yeast and Mold. The firm has never isolated *Salmonella* in either environmental swabs or finished product. Ms. Ogeto stated the firm would hold

the affected product and initialize a thorough cleaning of the processing line if the laboratory results ever approach the stated specifications or show spikes in microorganism counts.

MANUFACTURING CODES
The firm applies an expiration date (b) (4) days from the date of production for U.S. market products. An example is 450 (b) (4) LR0220:02. The breakdown would be:

- 450 – (b) (4)
- (b) (4) – (b) (4) days from the date of production
- LR – production site, Little Rock
- 02 – (b) (4)
- 20:02 – TOD stamp

PEST CONTROL
The firm contracts all pest control. The contractor monitors the stations on a (b) (4) basis and treats as necessary. A record is provided to the firm detailing the results. No pest control is conducted inside the processing room, but the firm does monitor the area for pest. The previous 90 days pest log was reviewed. One reoccurring item was observed concerning a door seal which was included in the management discussion at the conclusion, below.

COMPLAINTS
All complaints are received by an 800 number operated by Unilever. All complaints are transmitted to the plant. Top management, legal, or the plant quality department can initiate an investigation. All complaint records are maintained electronically and Ms. Ogeto or (b) (6) have access to all information. Most foreign object complaints are investigated and all injury/illness complaints are investigated. The firm follows a written complaint procedure.

The complaint trending from March 2008 to present was reviewed. All complaint levels remained constant over the time period. The firm averages (b) (4) complaints/month for injury/illness. Ms. Ogeto stated none of the injury/illness complaints could be confirmed as a result of the firm's product.

RECALL PROCEDURES
The firm has a written recall plan. They conduct a mock recall (b) (4) No product has been recalled since the previous inspection.

REFUSALS
There were no refusals.

Establishment Inspection Report	FEI:	**2316570**
Unilever Best Foods	EI Start:	11/02/2009
Little Rock, AR 72206-3871	EI End:	11/06/2009

GENERAL DISCUSSION WITH MANAGEMENT

At the conclusion of the inspection, a discussion with management was held. Present were:

- Mr. Patrick J. Mathieu, Supply Leader
- Ms. Tawana J. Walker Ogeto, Safety, Health, and Environmental and Quality Manager
- (b) (6) Quality and Environmental Specialist
- Mr. Alfred Martin, Maintenance Manager
- (b) (6) Safety Specialist
- Mr. Robert Moellers, Manufacturing Manager
- (b) (6) Manufacturing Specialist

Two items were discussed with the firm:

1. We observed a container used to store and transport (b) (4) used for the roaster CIP system in the roaster room. The container had been emptied but had not been properly stored after use. The container was removed prior to the conclusion of the inspection.
2. While review the pest log, we observed that monitoring site # (b) (4) a door sweep by the security desk, had been noted in disrepair since April 2009.

I stated to the firm that in the event any of the samples were to test positive for *Salmonella*, DAL-CB would most likely be responsible for alerting the firm. I also stated I would expect, but could not guarantee, that if positives results were found the firm would be contacted within two to three weeks. I stated that if the no sample was positive and management agreed with our findings, the firm should receive a courtesy copy of the report in 60-90 days. The firm had no questions and the inspection was closed.

SAMPLES COLLECTED

During the current inspection sample numbers 479697, 479698 and 479699 were collected which totaled 103 environmental sub-samples (Attached). All samples were determined to be negative for Salmonellae

VOLUNTARY CORRECTIONS

During the previous inspection, three FDA collected environmental samples tested positive for *Salmonella* spp. Upon notification, the firm suspending production and placed all products on hold. According to the firm, private laboratory testing did not detect *Salmonella* in any product. The firm hired a consultant, (b) (4) Ph.D, to provide guidance in the extensive cleaning and sanitization of the entire facility. The facility was closed (b) (4) weeks in which a total equipment teardown occurred. The firm added additional environmental sample sites after the cleaning. According to the firm, no product or environmental sample has tested positive for *Salmonella* since the cleaning

Establishment Inspection Report	FEI:	**2316570**
Unilever Best Foods	EI Start:	11/02/2009
Little Rock, AR 72206-3871	EI End:	11/06/2009

EXHIBITS COLLECTED

1. Original document dated 11/2/09 specifying the firm's policy concerning photographs, signing documents, affidavits, trade secrets, samples and employee contact.
2. Original document listing all Unilever distribution centers
3. Original document listing of all sanitizers used, where used, and the application strength
4. Photocopy of label for Soy Concentrate
5. Copy of document listing all environmental sample sites and sample schedule. 5 pgs

ATTACHMENTS

- FDA 482, dated 11/2/09
- Copy of CFSAN High Priority assignment for inspections and environmental sampling for Salmonellae at firms that manufacture nuts and nut products, DFPG #10-03, ORA Concurrence #2009092802
- Allergen checklist
- Copy of C/R #479697
- Copy of C/R #479698
- Copy of C/R #479699

Torrance J. Slayton

Torrance J. Slayton, Investigator

Torrance J. Slayton
for

Christopher T. Peters, Analyst

FDA has not completed the EIR for the March 18, 2011, inspection as of this time.

The attached documents are the EIRs for the DeFranco and Sons inspections:

March 13, 2008 (state contract inspection);

State of California—Health and Human Services Agency

Department of Health Services

NOTICE OF VIOLATION

Food and Drug Branch

Direct responses to: (562) 590-5394 FAX

Supervisor	Telephone number
Sharron Cavert Smith	(562) 590-5387

Address (number, street)	City	ZIP code
11 Golden Shore, Suite 420	Long Beach	90802

Firm name	Date
D. De Franco & Sons	3/13/2008

Address (number, street)	City	ZIP code
1000 Lawrence St.	Los Angeles	90021

Person interviewed	Position
Mr. Jerry De Franco Richard De Franco Paul De Franco	Vice President Secretary President / Production Manager

The conditions or practices noted below were observed on subject premises this date. These are alleged to be violations of one or more provisions of California law pertaining to the manufacture, processing, holding, sale, labeling, or advertising of a food, drug, medical device, cosmetic, or hazardous substance. The Department may seek administrative, civil, or criminal action for each of the violations. This report has been prepared to alert the management of the investigator's findings. It is the responsibility of the firm to assure compliance with all applicable laws and regulations.

1) Visible rust and peeling paint were noted on the wire top cover of corn husker machine in the corn processing room.

2) Physical facility of the processing rooms are not maintained in good repair.

(a) Ceiling directly above area of green bean processing line & packing was observed with holes.

(b) Aluminum ceiling material near the corn husker was observed to be loose and hanging, exposing insulation material.

3) Two employees working at the corn sorting conveyor line prior packaging were observed without beard covers.

4) The firm failed to verify HACCP critical control monitoring records (Refrigeration units and daily thermometer calibration logs) on a (b) (4) basis according to the firm's HACCP plan for produce.

Signing this notice does not indicate admission of a violation but only receipt of the Notice of Violation.

Firm's authorized representative signature	Authorized representative position
[signature]	PLANT MANAGER
Authorized agent signature	**Authorized agent name and badge number (printed)**
[signature]	CHARLENE KIM TRAN #119

Exhibit 1
Page 1 of 1 pages
Inv. KT Date 3/24/08

EH 82 A (12/06)

OSP 07 99722

ate of California —Health and Human Services Agency | Department of Health Services

NOTICE OF VIOLATION

Food and Drug Branch

Direct responses to:

Supervisor: Hugo Conejo			Telephone number: (213) 580-5720
Address (number, street): 1449 W. Temple St. Rm 724	City: LA		ZIP code: 90026
Firm name: D. De Franco & Sons		Date: 10/28/05	
Address (number, street): 1600 Lawrence St.	City: LA		ZIP code: 90021
Person interviewed: Paul de Franco	Position: Supervisor		

The conditions or practices noted below were observed on subject premises this date. These are alleged to be violations of one or more provisions of the California Health and Safety Code, Division 104, pertaining to the manufacture, processing, holding, sale, labeling, or advertising of a food, drug, device, cosmetic, or hazardous substance. Criminal conviction on these charges carries the penalty of imprisonment for up to one year in county jail and/or a maximum fine of $1,000 per violation. A second or subsequent conviction carries the penalty imprisonment for up to three years and/or a maximum fine of $10,000 per violation. Additionally, the Department may seek administrative or civil action, with maximum civil penalties of up to $1,000 per violation. This report has been prepared to alert the management of the investigator's findings and act as a permanent record of conditions noted.

Temporary repair work using tape, cardboard, string, and stainless was observed on the walk-in packaging line and the one powder mix packaging line. Equipment was not smooth and easily cleanable

2) Hair nets were improperly worn by employees in that hair was exposed. Employees were observed working at all the processing lines

3) Employees working at the processing lines were observed lacking facial hair protection in that facial hair was exposed

Signing this notice does not indicate admission of a violation but only receipt of the Notice of Violation.

Firm's authorized representative signature: Paul de Franco	Authorized representative position: Supervisor
Authorized agent's signature: [illegible]	Authorized agent's name and badge number (printed): [illegible] 131

Exhibit 2
Page 1 of 2 pages
Inv. KT Date 3/24/06

Page 1 of 2

4624 (7/05)

State of California—Health and Human Services Agency

Department of Health Services

NOTICE OF VIOLATION—Continued

(a) Used paper hand towels were observed on the floor of the mens restroom. This provides for an insanitary condition.

EH 32 (3/03)

FOOD & DRUG

PublicHealth

CALIFORNIA ESTABLISHMENT INSPECTION REPORT FOR FOOD

FIRM INFORMATION

Name: D. De Franco and Sons formerly "New England Tomato Co."
Address: 1000 Lawrence Street, Los Angeles, CA 90021
Phone: (213) 627-9575

Inspection Date: 3/13/2008

FEI Number: 3004655865

FDB Firm Number (if applicable): F36-00095

INSPECTIONAL HISTORY

DATE(S) OF PREVIOUS INSPECTIONS

FDA (Attach 483) None.
CDPH/FDB: Last inspection 10/28/2005. A 4-item Notice of Violation was issued to the firm. Firm repaired the bulk nut packaging line and removed tape, cardboard, and shoelace off the machine. According to Mr. Paul De Franco, the firm discontinued repacking mixed nuts in 1-pound repacking line. During the inspection on 3/13/2008, employees working in the corn processing area were observed without beard covers (repeated item). The men's restroom was observed to be clean. Used hand paper towels were noted in the trash receptacle.
List corrective actions from last FDA inspection (if any):

b(3)

FIRM DESCRIPTION

Type of business: The firm operates as a wholesale manufacturer of refrigerated produce such as washed and trimmed fresh corn, beans, green beans & carrots, and tomatoes. The firm also warehouses and distributes bulk nuts in 50-pound bags to customers. The firm repacks bulk mixed nuts in shells from September to December.
List of corporate officers in the firm: Paul De Franco/President, Jerry De Franco/Vice President, Richard De Franco/Secretary, and (b) (6)
Name of most responsible person present at the time of inspection: Paul De Franco/President, Jerry De Franco/Vice President, Richard De Franco/Secretary, and (b) (6)
Products produced / re-packed / wholesaled, and type of packaging used (i.e. LACF): Washed and trimmed produce such as beans, green beans & carrots packed in preprinted plastic bags, fresh corn packed in retail size Styrofoam trays with sealed plastic wrap, tomatoes packed in boxes, and bulk whole mixed nuts in 50-pound sacks.

CALIFORNIA ESTABLISHMENT INSPECTION REPORT FOR FOOD

Code(s) from FDA Product Code List: 23 GG T 99
Supplier(s) for ingredients used in product(s) produced (Include firm name, city and state): (b) (4)
(b) (4)
Legally related firms (Include name, city and state): None.
Geographic area served by the firm: Los Angeles areas, Stockton, Utah and Oregon.
Description of firm's customers (markets, restaurants, etc.): (b) (4)
(b) (4)
Gross annual sales: $ Approx (b) (4)
Percent of product sold outside California: (b) (4)
Percent sold wholesale: (b) (4)
Number of employees: Full-time (b) (4) **Part-time** **Seasonal**
Hours of operation: (b) (4)
Days of operation: (b) (4)
Seasonal operation (describe): The firm repacks bulk mixed nuts in shells from September to December.
Other governmental agencies that regulate and inspect the firm: State Food and Drug Branch and Local County Health Department (LA County).

NUTRITION LABELING

	YES	NO
Is the Nutritional Labeling and Education Act (NLEA) required?	☒	☐

Why is NLEA required / not required? Fresh produce is sold in retail packages at retailers. Mixed nuts are sold in 50 pound bags to be repacked into retail packages.
Number of labels reviewed: 2
Lot number(s) for product(s) reviewed: The firm utilizes a "sell by" date for finished products. Beans and carrots have 18 days shelf-life and corn has 17 days. During the inspection, the firm was processing corn with this "sell by" code Mar 30 08. The lot codes break down as follows:
Mar= month of manufacturing
30= expiration date
08= the year of manufacturing (2008)

RECALL INFORMATION

	YES	NO
Does the firm have recall procedures?	☒	☐
If yes, name of recall contact person:		
Have there been any recalls since the last inspection?	☐	☒

COMPLAINT INFORMATION

	YES	NO
Has the firm received any consumer complaints in the last year?	☐	☒

CALIFORNIA ESTABLISHMENT INSPECTION REPORT FOR FOOD

If the firm received any critical complaints, describe the nature of the complaint and actions taken by the firm:

BUILDING / FACILITY DESCRIPTION:

Construction Material: ☐ **Brick** ☒ **Concrete** ☒ **Wood** ☐ **Steel** ☒ **Metal**
Number of Stories: 1
Square Footage: (b) (6)
Other occupants: None
Location: ☐ **Industrial Park** ☒ **Commercial/Residential** ☐ **Rural** ☐ **Other**
Specialized processing equipment used: None.

DISTRIBUTION

Number of Vehicles: (b)
Type(s) of vehicle(s) used: (b) (4)
Does the firm utilize:
(b) (4)

EXHIBITS AND ATTACHMENTS:

	YES	NO
Was a Notice of Violation (NOV) issued for objectionable conditions?	☒	☐

If a NOV was issued, what will the firm do to correct the objectionable conditions?
A 4-item Notice of Violation was issued and discussed with management during the inspection and at the close of inspection. Mr. Richard De Franco promised to repaint the wire top cover of the corn husking machine and repair the ceilings of the processing rooms within 10 days. Also, he will purchase and provide beard covers for male employees. Finally, he will ask (b) (6) /HACCP Coordinator, to verify HACCP critical control points monitoring records (refrigeration units and daily thermometer calibration) on a weekly basis as stated on the firm's produce HACCP plan. A response letter with corrective actions is forthcoming.

Note: If photographs were taken, please include them as exhibits. Include other items as appropriate.
Exhibit#1. Notice of Violation.
Exhibit#2. CDPH/FDB, Notice of Violation issued to the firm on 10/28/2005.
Exhibit#3. Product labels:
12 oz. Fresh Trimmed Beans.
12 oz. (b) (4) Green Beans & Carrots.
Exhibit#4. HACCP plans for refrigerated tomatoes, corn, and green beans.
Exhibit#5. Process flow for green beans.
Exhibit#6. Micro test results analyzed by (b) (4)
(b) (4) received on 1/24/2008.
a. SPC and total Coliforms – results: <1CFU/ml for hand washing tab water

CALIFORNIA ESTABLISHMENT INSPECTION REPORT FOR FOOD

and green bean water.

b. Coliforms, E. Coli, and Salmonella- results: Negative for finished products (corn, tomatoes, green bean, and green bean & carrots).

Exhibit#7. Chemical concentration logs for vegetable wash and equipment from 12/21/2007 to 3/13/2008.

Exhibit#8. Firm's response letter dated 324/08

SIGNATURE REVIEW

(b) (6) [redacted]

Investigator's Signature **Badge #:** 119

(b) (6) [redacted]

Investigator Printed Name **Title:** Senior Food & Drug Investigator

Report Date: 3/24/2008

(b) (6) [redacted]

Supervisor's Signature

Review Date: 3/26/08

Additional Comments: ____

Attached is the December 18, 2008 (FDA inspection);

Establishment Inspection Report	FEI:	**3004655865**
PARIMAR dba D. DE FRANCO & SONS	EI Start:	12/18/2008
LOS ANGELES, CA 90021-1620	EI End:	12/18/2008

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SUMMARY

This comprehensive inspection of a high-risk food manufacturer of raw, refrigerated produce such as tomatoes, green beans and sweet corn and (seasonal) repacker of shelled tree nuts such as walnuts, pecans and hazelnuts was conducted for the LOS-DO FY'09 work plan. This inspection was conducted in accordance with the CP 7303.803, Domestic Food Safety Program. An NLEA field exam was conducted as per CP 7321.005 and reported separately in FACTS. This inspection covered good manufacturing practices (GMPs).

This is the first inspection conducted at this firm by the FDA. The previous inspection conducted on 03/13/08 by the California Food and Drug Branch (CFDB) was classified VAI because of objectionable conditions. Objectionable conditions included: 1) rust and peeling paint on the wire top cover on the corn husker machine; 2) ceiling above bean processing and packing line had holes and aluminum ceiling material above corn husker machine was hanging loose and exposing insulation; 3) employees were not wearing beard covers; and 4) the firm failed to verify HACCP monitoring records on a (b) (4) basis. CFDB received a letter from the firm's management dated 3/24/08 stating that all objectionable conditions had been corrected. On 12/18/08, objectionable conditions #1, #2 and #4 were verified as corrected. However, objectionable condition #4 was not corrected because I observed employees with mustaches and beards in the processing areas without beard covers. These items were reported separately in the Compliance Achievement Reporting System (CARS) database.

Establishment Inspection Report	FEI:	**3004655865**
PARIMAR dba D. DE FRANCO & SONS	EI Start:	12/18/2008
LOS ANGELES, CA 90021-1620	EI End:	12/18/2008

On 12/18/08, Supervisory Consumer Safety Officer (SCSO) Vien Q. Le and I displayed our credentials and issued an FDA-482, Notice of Inspection, to Mr. Jerry S. DeFranco, who introduced himself as the Plant Manager and the most responsible person at the firm. Mr. Jerry S. DeFranco informed SCSO Le and me that he and his brothers are co-owners of the firm and that he is also the Vice President. Later, Mr. J. DeFranco introduced SCSO Le and me to his brother, Mr. Richard J. DeFranco, Secretary. SCSO Le and I displayed our credentials to Mr. Richard J. DeFranco. Initially, Mr. Jerry S. DeFranco escorted us during the walk-through of the firm and then instructed SCSO Le and me to conduct the inspection independently. As they carried out their daily responsibilities, including supervising firm employees, Mr. Jerry S. DeFranco and Mr. Richard J. DeFranco were both available (intermittently) throughout the entire inspection. At approximately 9:30 a.m., President Mr. Paul F. DeFranco arrived. SCSO Le and I displayed our credentials and I explained to him that an FDA-482, Notice of Inspection, had been issued to Vice President/Plant Manager, Mr. Jerry S. DeFranco, and that we were there to conduct an inspection. Mr. Paul F. DeFranco, President, accompanied SCSO Le and me throughout the remainder of the inspection and he, Mr. Jerry S. DeFranco and Mr. Richard J. DeFranco provided information that is contained within this report.

At the conclusion of the inspection, no FDA-483, Inspectional Observations, was issued. Several items were discussed with management including: 1) the women's bathroom door was left open and the trash can inside the women's bathroom did not have a lid; 2) male employees with mustaches and beards were observed working in processing areas without beard covers; 3) there was a personal item (what appeared to be a sweatshirt) sitting directly on finished product packaging material; 4) the rolling garage door inside the corn processing area was left open during production; 5) lack of metal detector used to detect metal or other foreign objects prior to product packaging/shipment; and 6) lack of backflow prevention devices on hoses at facility. All deficiencies noted were discussed with and promised to be voluntarily corrected by management.

A food firm registration booklet, a Food Protection Plan booklet (November 2007), an ALERT pamphlet and card, Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables (printed from the CFSAN website), and an information sheet about backflow prevention devices were provided to management.

According to Vice President, Mr. Jerry S. DeFranco, Vice President, raw produce waste (corn, beans, etc.) is collected (b) (4) and picked up by (b) (4) The raw produce waste is used as animal feed for the farm's cattle.

Currently, the firm uses an independent laboratory, (b) (4) (b) (4) to test the firm's water and food products. All microanalysis tests results have been negative.

Establishment Inspection Report	FEI:	**3004655865**
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A reconciliation exam was conducted and there were no discrepancies noted. There were no refusals and no samples collected during this inspection. No evidence of rodent or pest activity was observed.

A walk-through of the facility during the inspection revealed that the firm continues to manufacture refrigerated produce such as tomatoes, beans and sweet corn and repack and distribute shelled nuts. Firm employees were in different stages of production and packaging of sweet corn and beans; hand-packing and moving finished products into a walk-in cooler; and in the process of cleaning manufacturing areas and equipment.

ADMINISTRATIVE DATA

Inspected firm:	PARIMAR dba D. DE FRANCO & SONS
Location:	1000 LAWRENCE ST LOS ANGELES, CA 90021-1620
Phone:	213-627-8575
FAX:	
Mailing address:	1000 LAWRENCE ST LOS ANGELES, CA 90021-1620
Dates of inspection:	12/18/2008
Days in the facility:	1
Participants:	Tara L Stockton, Investigator

On 12/18/08, SCSO Le and I displayed our credentials and issued the FDA 482, Notice of Inspection, to Mr. Jerry S. DeFranco, Vice President/Plant Manager. Upon their arrival, SCSO Le and I displayed our credentials to Mr. Richard J. DeFranco and Mr. Paul F. DeFranco, Secretary and President, respectively.

(b)(3) [redacted]

During this inspection on 12/18/08, the firm was receiving, holding and shipping FDA regulated products. On this day, deficiencies were observed and were presented for discussion with management during the close-out meeting.

Business Hours:	*Office*:	6:00am-2:00pm, Monday-Friday.
	Production Hours:	(b)(4) [redacted]

HISTORY

Establishment Inspection Report	FEI:	**3004655865**
PARIMAR dba D. DE FRANCO & SONS	EI Start:	12/18/2008
LOS ANGELES, CA 90021-1620	EI End:	12/18/2008

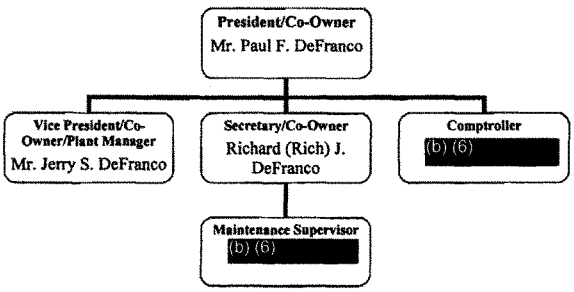
No previous inspections have been conducted at this firm by the FDA. Parimar dba D. DeFranco & Sons is a family-owned business founded in (b) (6) The firm was incorporated in the state of California. According to Vice President, Mr. Jerry S. DeFranco, The firm does not have any subsidiaries and is not affiliated with any other company.

The firm has been at its current address of 1000 Lawrence Street, Los Angeles, CA 90021 since the late (b) (6) The firm is a manufacturer of raw, refrigerated produce such as tomatoes, corn and beans and (seasonal) repacker and distributor of shelled nuts.

According to Vice President, Mr. Jerry S. DeFranco, the firm is also inspected by the CFDB and the Los Angeles County Health Department.

There have been no product recalls and no regulatory actions for this firm. There ar(b) (4) full-time employees at this facility.

The firm's management structure remains as follows:



Business Hours: *Office:* 6:00am-2:00pm, Monday-Friday.
Production Hours: (b) (4)

Gross annual sales are estimated at (b) (4) dollars.

A reconciliation exam was performed and there were no discrepancies noted. Parking is very limited at this firm.

Establishment Inspection Report	FEI:	**3004655865**
PARIMAR dba D. DE FRANCO & SONS	EI Start:	12/18/2008
LOS ANGELES, CA 90021-1620	EI End:	12/18/2008

Food security and registration requirements were discussed during this inspection and an FFR booklet was given to Mr. Paul F. DeFranco, President.

All correspondence should be sent to:
Mr. Paul F. DeFranco, President
D. DeFranco & Sons
1000 Lawrence Street
Los Angeles, CA 90021-1620

INTERSTATE COMMERCE
The firm holds, repacks and ships a variety of fresh vegetables and nuts including corn, beans, tomatoes, walnuts, pecans, and hazelnuts. All of the firm's products are sold wholesale. Mr. Jerry S. DeFranco was not certain of the estimated amount of products received from out-of-state; however, he stated that the firm's main supplier, (b) (4) is located in (b) (4) AZ. In addition, on 12/18/08, I observed four pallets of beans inside the firm's raw product walk-in cooler with labels stating that the beans were a "PRODUCT OF MEXICO" (**Exhibit #8**). Mr. J. DeFranco confirmed that the raw produce is from Mexico and is used during processing. The firm's other raw produce suppliers include but are not limited to (b) (4) (tomatoes) located in Nogales, AZ and (b) (4) (sweet corn) located in CA. Packaging supplies are provided by located in CA; located in (b) (4) CA; and located in CA.

Mr. Jerry S. DeFranco, Mr. Richard J. DeFranco and Mr. Paul F. DeFranco are food brokers for the firm and promote their own products. According to Mr. J. DeFranco, food items such as tomatoes, corn, and beans are sold wholesale to distributors located in the (b) (4) CA who may be distributing its products through interstate commerce. The firm also sells products to local markets. Products that move through interstate commerce are transported on contracted carriers. For example, on 12/18/08, I observed a truck driver sign for one pallet of shelled nuts which included several 50-lb bags and 1-lb boxes. The truck driver stated that he was delivering the items to a firm located in Wisconsin. Mr. Paul F. DeFranco provided photocopies of Purchase Order # (dated 12/16/08) and Invoice # (dated 12/17/08), showing shipment to (**Exhibit #13**).

Some of the firm's customers include (b) (4) and local retail markets. The firm is also a contract manufacturer for a private label account with (b) (4) s. The firm owns (b) (4) refrigerated trucks used to pick up and/or transport products locally.

JURISDICTION
Products manufactured or repacked by the firm are subject to the FD&C Act. The firm manufactures and/or repacks fresh, raw produce under the DeFranco & Sons brand name. Also the firm repacks and/or distributes products containing allergens such as peanuts and tree nuts (**Exhibit #4**). However, Mr. Jerry S. DeFranco, Vice President, stated that all nuts are shelled and not processed on

any equipment inside the firm. **Exhibits #16–#18** are retail labels for the FDA-regulated fresh produce products.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED
On 12/18/2008, Supervisory Investigator Le and I displayed our credentials and issued the FDA 482, Notice of Inspection, to Mr. Jerry S. DeFranco, Vice President/Plant Manager, who stated that he was the most responsible person at the firm at the time. Mr. DeFranco informed Investigator Le and me that his brothers, Mr. Paul F. DeFranco and Richard J. DeFranco are co-owners of the firm. The DeFranco brothers' grandfather started the family-owned business in 1916 and the business has been at its current location since the 1950s.

Key firm officials for Parimar dba D. DeFranco and Sons are as follows:

Paul F. DeFranco, President/Co-owner– Mr. DeFranco has been in the produce business for over 30 years. He stated that he is responsible for the day-to-day operations at the firm and oversees all operations including the receiving, storage, and shipment of the firm's products and administrative duties. He has the ultimate knowledge of and responsibility for all the products received and shipped from the firm. Mr. DeFranco has the authority to hire and fire employees and he makes the final decision to spend company funds for improvements as well as corrective action. Although there is a joint collaboration as co-owner with his brothers, Mr. DeFranco makes the final decision for all activities at the firm.

Jerry S. DeFranco, Vice President/Co-owner– Mr. DeFranco has been in the produce business for over 20 years. He is responsible for the day-to-day operations at the firm and oversees all operations including the receiving, storage, and shipment of the firm's products. In addition, Mr. DeFranco purchases and sells raw materials and is responsible for ordering maintenance supplies. He is *one* of *three* co-owners at the firm and has the authority to hire and fire personnel, spend company funds and make corrective actions/improvements.

Mr. Richard (Rich) J. DeFranco, Secretary/Co-owner – Mr. DeFranco has been in the produce business for over 30 years. He is *one* of *three* owners at the firm and has the authority to hire and fire personnel, spend company funds, and make corrective actions/improvements. Mr. DeFranco assists (b) (6) Comptroller, with bookkeeping and administrative duties. He is also responsible for researching information for the firm, purchasing supplies, and inventory control.

The firm's corporate structure is as follows:

- President/Co-owner—Mr. Paul F. DeFranco
- Vice President/Co-owner/Plant Manager—Mr. Jerry S. DeFranco
- Secretary/Co-owner—Mr. Richard J. DeFranco
- Maintenance Supervisor—Mr. (b) (6)

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➢ Comptroller—(b) (6)

FIRM'S TRAINING PROGRAM

President, Mr. Paul F. DeFranco is responsible for the firm's training program. He stated that employees receive training on hygiene and safety. Training is conducted by Mr. (b) (6) senior safety consultant, who works with the firm training its mostly Spanish-speaking employees. Also (b) (4) is a contractor responsible for OSHA training given to employees. Mr. P. DeFranco stated that because the firm has very little to no turnover and maintains the same employees (with >20 years experience), safety and hygiene refresher training is provided approximately every (b) (4) All training is conducted on-site and records are maintained at the firm. **Exhibit #14** is a photocopy of the training consultants' business cards.

MANUFACTURING/DESIGN OPERATIONS

This (b) (4) sq. ft. facility consists of the following designated areas:

- *Receiving Warehouse*: Raw materials (i.e., raw produce, nuts, etc.); one of (b) (4) loading docks is used for depositing vacuumed (corn husks) and other raw produce waste into a parked truck
- *Corn/Tomato Processing Room*: Corn husker & packaging machines
- *Bean Processing Room*: Bean trimming & packaging machines

  A storage area behind plastic strip curtains and adjacent to the bean processing machines is used to store old/outdated equipment
- *Cooler #1*: Raw produce
- *Cooler #2*: Finished products
- *Storage Areas*: Retail packaging (i.e., product labels, styrofoam trays, shipping/cardboard boxes, etc.); locked cabinets for chemical storage
- *Employee Break Room*: Area adjacent to corn processing room with no separating walls; includes storage area for employee aprons, personal items, etc.

The general product flow for *raw produce* at this firm is as follows:

Receiving → Storage → Processing and/or Packaging/Labeling → Storage/Distribution

Receiving

For each product that comes into the firm, a lot code is assigned and placed on the pallets prior to storage. All shipments received are checked and recorded on a receiving log sheet. Mr. Jerry S. DeFranco (Vice President), Mr. Paul F. DeFranco and Mr. Richard (Rich) J. DeFranco (Secretary) are responsible for checking shipments when they arrive. On 12/18/08, I observed the firm's receiving log data sheet which documented the following information: (b) (4) (b) (4) (b) (4) Mr. Jerry S. DeFranco stated that standard operating procedures for receiving raw produce are included in the firm's HACCP Plan.

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Storage

After a lot code is assigned, raw produce is stored inside the raw produce cooler until ready for processing and/or packaging.

Processing and/or Packaging/Labeling → Storage/Distribution

On 12/18/08, at approximately 8:20 a.m., the firm began processing DeFranco and Sons brand Super Sweet Corn (Item # (b) (4) on its corn husker machine. The corn husker machine is a fully-automated, floor-standing machine made of stainless steel. I observed the following:

First, employees remove pallets of corn from the raw produce cooler via a pallet jack and stage them in front of the corn husker machine in the processing room. Next, an employee opens a wooden crate or cardboard box of corn-on-the-cob (**Exhibit #1**) and empties the corn onto the corn husker machine conveyor belt. As the corn moves along the conveyor belt, employees manually inspect and (b) (4) corn before it goes onto the (b) (4) conveyor. Then, corn is conveyed to the mechanism which removes the husks and silks of corn-on-the-cob. Finally, corn is conveyed to the cutting mechanism which cuts both ends of the corn-on-the-cob. After the ends are cut, the corn is conveyed to an area where an employee manually places the cut corn into a cardboard box for storage. Corn is placed inside the cardboard box until it is filled. Then, the box is pushed into an enclosed, plastic area on the conveyor belt to await packaging. Employees manually (b) (4) from the box and place them onto a styrofoam tray. Next, employees inspect the corn before it is labeled/packaged. If the corn does not meet the firm's QC standards, it is discarded into a (b) (4) (b) (4) used for food waste (**Exhibit #7**). These food waste bins are picked up (b) (4) by a (b) (4) Finally, the styrofoam tray is conveyed through the packaging/labeling mechanism which wraps the tray of corn in a (b) (4) stretch film label. The label is stamped via an ink-jet coding system with a use-by date (provided by the customer). On this day of production, the use-by date for corn (and trimmed green beans) was "JAN 05 09" (interpreted as January 5, 2009). 12/16 oz. packages of corn are manually placed inside cardboard/shipping boxes by (b) (4) (**Exhibit #2**). Finished product is manually placed onto pallets and moved to the finished product cooler via a pallet jack operated by employees. Finished product remains inside the finished product cooler until ready for shipment to a distribution center and/or local market or picked up by the customer (b) (4) The finished product requires further cooking by the end-customer, either boiling or microwaving per label instructions.

The general product flow for (seasonal) nuts at this firm is as follows:

(b) (4)

Vice President, Mr. Jerry S. DeFranco, stated that shelled nuts are purchased seasonally between November and December. The nuts are purchased in bulk in (b) (4) bags and then re-distributed and/or repacked under the DeFranco brand name in 1-lb boxes. On 12/18/08, I observed (b) (4) bags of hazelnuts and mixed nuts in their original packaging (**Exhibit #4, Page 1**) stored inside

the corn/tomato processing area and 1-lb boxes of almonds, pecans, and walnuts in the DeFranco brand shipping/cardboard boxes stored inside the bean processing area.

The firm's daily/weekly production depends on product and/or customer demand.

MANUFACTURING CODES

Receiving

The firm operates using a pen and paper, manual tag inventory system which involves a tag that is attached to every product that comes into the firm. Each item is assigned a lot number.(b) (4) (b) (4) (b) (4) (b) (4) The firm is able to track each product and its supplier using the assigned lot number and corresponding year.

On 12/18/08, I observed handwritten *receiving* lot codes on raw produce boxes/pallets inside the firm (See **Exhibit #10, Page 1**). I observed the following products and lot codes:

Thrifty brand carrots	*Blue Lake brand beans*	*Divine Flavor brand tomatoes* (**Exhibit #5**)
"(b) (4) 12·18·08"	"(b) (4) 12·18·08"	"(b) (4) 12·15·08"

The four-digit number is assigned to each product via the firm's manual tag inventory system and the three-digit number represents the date products were received, December 18, 2008 and December 15, 2008, respectively.

Finished Product

On 12/18/08, I observed Fresh Trimmed Beans being processed by the firm. A lot code is applied to the top of each sealed, cello/plastic bag (12 oz.) via an ink jet coding system which read:

"PRODUCT MEXICO"
"SELL BY JAN 05 09"

According to President, Mr. Paul F. DeFranco, this manufacturing lot code is interpreted as the beans are a product of Mexico and they have an 18-day shelf-life.

CLEANING/SANITATION & PEST CONTROL

Cleaning/Sanitation

There ar(b) (4) employees on the firm's 'cleaning crew' responsible for washing and sanitizing all equipment, processing rooms, and all (other) areas inside the facility. Mr. Paul F. DeFranco,

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President, stated that cleaning/sanitation operations occur (b) (4), after (b) (4) and on (b) (4), (b) (4) employees conduct a deep-cleaning and sanitizing of equipment and areas inside the firm including the walls, floors, drains, etc. Mr. Paul F. DeFranco is responsible for checking cleaning and sanitizing procedures. In addition, a consultant contracted by the firm helps with SSOPs and its HACCP Plan. Large equipment such as the bean trimming and corn husker machines are cleaned and sanitized after each use. High pressure hoses are used to spray down the machines, floors and all other equipment (stainless steel fans, plastic bins, etc.) in processing areas.

Hand washing sinks with supplies were noted throughout the facility. A three-compartment sink is located next to the corn husker machine. It was not being used at the time of the inspection and Mr. Jerry S. DeFranco, Vice President, stated that the sink is not used during processing. He stated that the sink is used only as an additional hand washing sink for firm employees. Employees were observed wearing blue smocks, hair restraints, beard covers, gloves, and water-proof boots. These items are designated for food production areas. All smocks are hung in the same location on hooks next to the corn processing area (in employee break room). Employees are also required to wash/sanitize their hands prior to entering processing areas.

On 12/18/08, I observed firm employees sweeping corn husks (waste) into the corn husker machine vacuum during corn processing. The vacuum (b) (4) (b) (4) **(Exhibit #6)**.

The following chemicals are used inside the firm:

1) (b) (4) (b) (4) detergent used to clean processing equipment
2) (b) (4) -cleaning supplies used to clean bathrooms, processing areas, etc. These chemicals are stored inside a locked cabinet (in corn processing area).
3) (b) (4) -detergent used to clean floors
4) (b) (4) - antimicrobial water additive used during bean processing (**Exhibit #9**)

The firm's water source is (b) (4).

Pest Control Program

The firm contracts with (b) (6) for its monthly pest control needs. Mr. Paul F. DeFranco, President, stated that the pest control company services bait stations and sprays the exterior of the building. After each service, (b) (6) submits a comprehensive service report to the firm. All reports are given to him and he is responsible for addressing any pest control problems. I reviewed the pest control file for the last six months and there were no problems noted. I observed bait stations and electronic insect killers throughout the facility. There was no evidence of pest activity at the firm during the inspection.

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COMPLAINTS
Paul F. DeFranco, President, stated that the firm has never had any illness or injury complaints but does receive occasional complaints about product aesthetics (i.e., product labels facing the wrong direction on produce). He stated that he is responsible for handling complaints. A complaint file is maintained at the firm.

RECALL PROCEDURES
The firm does have a written recall procedure in place and Mr. Jerry S. DeFranco, Vice President, stated that the firm is capable of tracking products shipped. Mr. Paul F. DeFranco, President, is responsible for recall procedures. According to Mr. P. DeFranco, the firm has never had to conduct a formal recall of any of its products.

REFUSALS
There were no refusals.

GENERAL DISCUSSION WITH MANAGEMENT
At the end of the inspection, I conducted a close-out meeting with Mr. Paul F. DeFranco, President; Mr. Jerry S. DeFranco, Vice President; and Mr. Richard J. DeFranco, Secretary. Also SCSO Vien Le was present at the close-out meeting. Mr. J. DeFranco and Mr. R. DeFranco were in and out of the room during the discussion and contributed to the discussion on a limited basis. However, Mr. Paul F. DeFranco, the most responsible person at the firm and the person who has the ultimate authority to spend funds and make corrective actions, was available during the entire close-out meeting discussion. We verbally discussed the following:

1) The women's bathroom door was left open and the trash can inside the women's bathroom did not have a lid. Employee bathrooms are located approximately twenty-five feet away from the corn processing area and there are no walls separating the two areas.

Management Response: Mr. Paul F. DeFranco stated that he will re-train and re-educate the firm's two females to keep the door closed at all times and purchase a lid for the trash can inside the women's bathroom.

1) Male employees with mustaches and beards were working in processing areas without beard covers.

Management Response: Mr. Paul F. DeFranco stated that he will re-train and re-educate employees with beards and mustaches to use beard covers when working in processing areas. In addition, he will contact Mr. (b) (6) Senior Safety Consultant, to conduct health and safety training.

2) In the corn processing area, there was a personal item (what appeared to be a sweatshirt) sitting directly on finished product packaging material (**Exhibit #3**).

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Management Response: Mr. Paul F. DeFranco stated that he will re-train and re-educate employees to store personal items in the proper location. He stated that employees have an area in the break room where personal items such as jackets, smocks, etc. can be stored on hooks. In addition, he will contact Mr. (b) (6) Senior Safety Consultant, to conduct health and safety training.

4) The rolling garage door inside the corn processing area was left open. Manufacturing and the storage of raw produce and packaging/shipping boxes occur in this area.

Management Response: Mr. Paul F. DeFranco stated that the door is used by employees during breaks. However, he will re-educate employees to close the door after taking breaks and to keep the door closed at all (other) times.

5) I noted that there were no metal detectors or other devices inside the facility to detect metal or other foreign objects as in-process and finished product was put *into, onto* and *removed from* equipment and prior to employees hand-packing finished product into cardboard/ shipping boxes.

Management Response: Mr. Paul F. DeFranco stated that the firm has never used a metal detector; however he has talked to a representative about x-ray and metal detector machine prices and installment. The firm has not made a commitment to purchase any equipment at this time but will continue to look into the matter.

6) There was no backflow prevention device on hose(s) used inside the firm. I provided Mr. DeFranco with an information sheet depicting backflow prevention devices.

Management Response: Mr. Paul F. DeFranco stated that he was not sure what a backflow prevention device was and that he had talked to a plumber in the past about plumbing issues inside the firm. He stated that he will call a certified plumber to check for backflow prevention devices and discuss the information sheet provided with the plumber. He did not provide a time-frame for completion.

ADDITIONAL INFORMATION

According to Vice President, Mr. Jerry S. DeFranco, raw produce waste (corn, beans, etc.) is collected (b) (4) and picked up by (b) (6) a dairy farm located in (b) (6) CA. The raw produce waste is used as animal feed for the farm's cattle.

Currently, the firm uses an independent laboratory, (b) (6) (b) (6) CA, to test the firm's water and food products. Mr. P. DeFranco voluntarily provided a photocopy of the firm's laboratory representative's business card (**Exhibit #15**). I reviewed microanalysis tests results provided by the laboratory and all tests have been negative.

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A Nutrition Labeling and Education Act (NLEA) field exam was conducted for three (3) product labels. There were no discrepancies noted.

Digital photos taken at the firm have been captured directly onto a compact disc recordable (CD-R). The CD-R with *.*jpg file photographs was placed into an FDA-525-Sample Package Identification and officially sealed (**Exhibit #19**).

SAMPLES COLLECTED
There were no samples collected during this inspection.

VOLUNTARY CORRECTIONS
The previous inspection conducted on 03/13/08 by the California Food and Drug Branch (CFDB) was classified VAI because of objectionable conditions. Objectionable conditions included: 1) rust and peeling paint on the wire top cover on the corn husker machine (**Exhibit #11**); 2) ceiling above bean processing and packing line had holes and aluminum ceiling material above corn husker machine was hanging loose and exposing insulation (**Exhibit #12**); 3) employees were not wearing beard covers; and 4) the firm failed to verify HACCP monitoring records on a weekly basis. CFDB received a letter from the firm's management dated 3/24/08 stating that all objectionable conditions had been corrected. On 12/18/08, objectionable conditions #1, #2 and #4 were verified as corrected. However, objectionable condition #4 was not corrected because I observed male employees with mustaches and beards in the processing areas without beard covers. All items were reported separately in the Compliance Achievement Reporting System (CARS) database.

EXHIBITS COLLECTED
1. Digital photograph of corn used during production of the DeFranco and Sons brand sweet corn. *This raw produce is used in production and is documentation of interstate commerce.*
2. Digital photograph of hand-packed DeFranco and Sons brand corn in firm's cardboard/shipping box.
3. Digital photograph of personal item (what appeared to be a sweatshirt) sitting directly on finished product packaging material stored in the corn processing area.
4. Digital photographs of (b) (4) bags of shelled nuts stored inside the corn processing area.
5. Digital photograph of (b) (4) boxes of tomatoes stored inside the corn processing area. *This raw produce is grown and packed in Mexico, used in production and is documentation of interstate commerce.*
6. Digital photograph of waste truck used to collect corn husks and other raw produce waste generated during production.
7. Digital photograph of plastic drums (gallon) and bins used to collect raw produce waste. Raw produce waste (corn, beans, etc.) is collected (b) (4) and picked up by (b) (6) a dairy farm located in (b) (6) CA. The raw produce waste is used as animal feed for the farm's cattle.

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8. Photocopy of Load #805346 showing delivery of (b) (4) cases of (b) (4) (b) (4) to DeFranco and Sons. Upon delivery, the raw produce was assigned lot (b) (4). *The beans are a product of Mexico, used during production and are documentation of interstate commerce.*
9. Digital photograph of (b) (4) product label. This is an antimicrobial water additive used during bean processing.
10. Digital photographs of Julia (label) beans used during bean processing at the firm. A pallet tag shows the lot number placed on the raw produce in receiving. 10/12 oz. cello bags of finished product are hand-packed into cardboard/shipping boxes.
11. Digital photograph of corn husker machine showing rust and peeling paint on the wire top cover has been removed.
12. Digital photographs of ceiling above bean processing and packing line showing holes have been repaired.
13. Photocopies of P.O. # (b) (4) and P.O.# (b) (4) showing 50-lb bags and 1-lb boxes of nuts sold and shipped to (b) (4) *This is documentation of interstate commerce.*
14. Photocopies of business cards of consultants contracted by the firm to conduct health and safety training.
15. Photocopy of the firm's laboratory representative's business card from (b) (6) Inc.
16. Label for DeFranco and Sons brand Super Sweet Corn.
17. Label for DeFranco and Sons brand tomatoes.
18. Label for Fresh Trimmed Beans (private label account with Trader Joes).
19. FDA-525, CD-R disc containing digital photographs taken during establishment inspection.

ATTACHMENTS
FDA 482, Notices of Inspection, dated 12/18/08 and issued to Mr. Jerry S. DeFranco, Plant Manager.

Tara L. Stockton

Tara L Stockton, Investigator

Attached is the October 23, 2009 (FDA inspection);

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SUMMARY *(NJA)*

This comprehensive/allergen inspection of a high risk food manufacturer/repacker was conducted in accordance with Compliance Program 7303.803, Domestic Food Safety. Also, a BSE Inspection was conducted in accordance with 7371.009. 127 environmental swabs were collected in accordance with "Request for Inspections and Environmental Sampling for Salmonellae at Firms Producing Nuts and Nut Products" per DFPG #10-03 in accordance with ORA Concurrence #2009092802 and FACTS # 1101846. This inspection covered Good Manufacturing Practices and Allergens.

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The previous inspection was conducted by FDA in 2008 and classified VAI for GMP deficiencies; however, no FDA 483, Inspectional Observations, was issued. These following deficiencies were discussed with management: 1) the women's bathroom door was left open and the trash can inside the women's bathroom did not have a lid; 2) male employees with mustaches and beards were observed working in processing areas without beard covers; 3) there was a personal item (what appeared to be a sweatshirt) sitting directly on finished product packaging material; 4) the rolling garage door inside the corn processing area was left open during production; 5) lack of metal detector used to detect metal or other foreign objects prior to product packaging/shipment; and 6) lack of backflow prevention devices on hoses at facility. All deficiencies noted were discussed with and promised to be voluntarily corrected by management.

The current inspection covered the processing of sweet corn, green beans, tree nuts, and tomatoes. An FDA 483, Inspectional Observations, was issued for the following: 1) backsplash from a water pressure gun containing a mixture of sanitizer and water while cleaning the floor and corn husking machine getting on raw tomatoes before they were packaged; 2) a plastic gas can was observed in the main production room during the processing of sweet corn; 3) two employees were observed to be wearing hand watches while packaging raw tomatoes; 4) the continuation of having personal items, bottled drinks and a sweatshirt, in the processing area.

Also, the following deficiencies were discussed with management:

- a free metal razor was observed on the packaging side of the nut packing machine in the second production room
- condensation was observed dripping from a fan cooler machine on the ceiling to the floor near the green bean processing line
- visible nut remnants, dust, and tree nut products are left on both nut packing machines while not in use and cleaned only once a week

A sample was collected under sample # INV 519039 and contained 127 subs, including closed and open controls. The sample consisted of environmental swabs and will be tested for Salmonella.

The facility is registered. ALERT card and the Reportable Food Registry were discussed and given during the beginning of the inspection to Mr. Gerald S. DeFranco, Secretary. A reconciliation exam was conducted, no discrepancies were noted.

ADMINISTRATIVE DATA *(NJA)*

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Inspected firm:	PARIMAR dba D. DE FRANCO & SONS
Location:	1000 LAWRENCE ST LOS ANGELES, CA 90021-1620
Phone:	213-627-8575
FAX:	
Mailing address:	1000 LAWRENCE ST LOS ANGELES, CA 90021-1620
Dates of inspection:	10/19/2009, 10/20/2009, 10/23/2009
Days in the facility:	3
Participants:	Natalie J. Ayoub, Consumer Safety Officer Dyana K. Stone, Investigator Michael D. Kawalek, Microbiologist Angelina M. Albert, Microbiologist

On 10/19/09, CSO Dyana K. Stone and I, Natalie J. Ayoub, along with Microbiologists Angelina Albert and Michael Kawalek, displayed our credentials and issued a FDA 482, Notice of Inspection, to Gerald S. DeFranco, Plant Manager/Secretary/Co-Owner. The most responsible person at the firm, Paul F. DeFranco, President/Co-Owner, and the second most responsible person at the firm, Richard J. DeFranco, Vice President/Co-Owner, was not present at the time we issued the FDA 482.

Analysts Albert and Kawalek were not present on 10/20/09 and during the close-out on 10/23/09.

The sections of the report that Investigator Dyana K. Stone wrote will be identified by her initials DKS. The sections of the report that I, Natalie J. Ayoub, wrote will be identified by my initials NJA.

HISTORY *(DKS)*

Parimar dba D. DeFranco & Sons is a family-owned business founded in (b) (6) The firm was incorporated in the state of California in (b) as Parimar, Inc. According to Mr. Gerald S. DeFranco, the firm does not have any subsidiaries and is not affiliated with any other company.

The firm has been at its current address of 1000 Lawrence Street, Los Angeles, CA 90021 since the late (b) (6). The firm is a manufacturer of raw, refrigerated produce such as tomatoes, corn, and green beans. The firm is a seasonal repacker and distributor of in-shell nuts during the months of September to December.

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There have been no regulatory actions for this firm. According to Mr. Gerald S. DeFranco, the firm is also inspected by the CFDB and the Los Angeles County Health Department.

There are (b) full-time employees at this (b) (4) sq ft facility.

The hours of operation are as followed:

- *Office:* 6:00am-2:00pm, Monday-Friday.
- *Production Hours:* (b) (4)

ALERT card and the Reportable Food Registry were discussed and given during the beginning of the inspection to Mr. Gerald S. DeFranco, Secretary. A reconciliation exam was performed and there were no discrepancies noted.

All correspondence should be sent to:
Mr. Paul F. DeFranco, President
D. DeFranco & Sons
1000 Lawrence Street
Los Angeles, CA 90021-1620

INTERSTATE COMMERCE *(NJA)*

The firm ships % of their product in interstate commerce. The firm ships produce to the states of (b) (4) The firm ships tree nuts to (b) (4) within the United States of America. The firm sells % wholesale. A copy of the firm's invoice for tree nuts shipped to (b) (4) can be seen in Exhibit 1. Also, I observed DeFranco & Sons repacked Brazil Nuts labeled "PRODUCT OF BRAZIL" (Exhibit 2).

The firm's main customers are (b) (6)

Products are advertised (b) (4)

JURISDICTION *(NJA)*

The firm processes green beans and sweet corn. Also, the firm repacks tomatoes and shelled tree nuts; such as, hazelnuts, Brazil nuts, walnuts, and pecans. All nuts are labeled under the label Sunripe and everything else is labeled under DeFranco & Sons.

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Product list of products processed during the environmental swab collection can be seen in Exhibit 3.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED *(NJA)*

On 10/19/09, CSO Dyana K. Stone, Microbiologist Angelina Albert, Microbiologist Michael Kawalek, and I went to Parimar dba D. DeFranco & Sons. We showed our credentials and I issued an FDA-482 Notice of Inspection to Gerald S. DeFranco, Plant Manager/Secretary/Co-Owner, the most responsible person of the firm at the time this form was issued.

The key firm officials are as followed:

Paul F. DeFranco, President/Co-Owner: As the President of the company Mr. P. DeFranco holds the ultimate authority and responsibility at the firm. His main role and responsibility is to direct and overlook the plant. He has the authority to authorize expenditures, hire and fire employees, and change the business operations. Mr. P. DeFranco has the knowledge, duty, and the power to prevent, detect and correct objectionable conditions within the plant.

Richard J. DeFranco, Vice President/Co-Owner: He overlooks the facility and carries out any requests made by the President. He reports solely to Mr. P. DeFranco. He has the authority to authorize expenditures, hire and fire employees, and change the business operations. Mr. R. DeFranco has the knowledge, duty, and the power to prevent, detect and correct objectionable conditions within the plant.

Gerald (Jerry) S. DeFranco, Secretary/Plant Manager/Co-Owner: His roles and responsibilities include managing employees, sales, receiving, quality control, and overseeing production. He reports to the President and Vice President. He has the authority to authorize expenditures, hire and fire employees, and change the business operations. Mr. G. DeFranco has the knowledge, duty, and the power to prevent, detect and correct objectionable conditions within the plant. Mr. G. DeFranco was the primary source of the information contained in this report, except were noted. He accompanied me during the inspection.

The firm's management structure is as follows:

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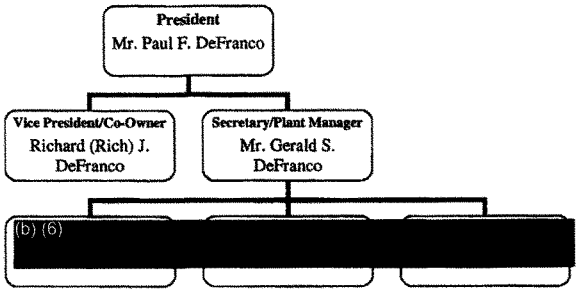

FIRM'S TRAINING PROGRAM *(NJA)*

All 3 DeFranco brothers instruct employees on their roles. The 3 Supervisors, Mr. (b) (6) Mr. (b) (6) and Mr. (b) (6) later instruct the employees on employee practices. According to Mr. Gerald DeFranco, an outside instructor, (b) (6) Senior Safety Consultant, from the company (b) (4) comes once every (b) (4) to instruct employees on food safety and cleanliness.

MANUFACTURING/DESIGN OPERATIONS *(NJA)*

The equipment and operations remain the same from the previous inspection.

The facility consists of the following designated areas:

- *Main Production Room* consists of 3 separate areas and contains chemical storage cabinets:
  1) Corn/Tomato Processing Area: contains corn husking machine that extends to packaging machines used for both corn and tomatoes
  2) Nut Packaging Area: contains a nut repackaging machine that drops the tree nuts into a plastic bag formed by the machine then seals the bag
  3) Employee Break Area: the area is adjacent to the packaging machine part of the corn husking machine. The area is not separated by walls.
- *Second Production Room* consists of 2 separate areas:
  1) Bean Processing Area: contains bean trimming machine, bean wash, and packaging machine
  2) Nut Packaging Area: contains a nut repackaging machine that mixes the tree nuts and then drops them into a plastic bag formed by the machine then seals the bag

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- *Shipping/Receiving/Staging Area* is located at the back of the firm and contains the shipping and receiving docks
- *Cooler #1*: Raw Produce before processed
- *Cooler #2*: Finished produce ready to be shipped
- *Pallet Storage Room*: located in between the entrance of the main production room and second production room.

A handmade map of the production areas of the facility can be seen in Exhibit 4.

The general product flow for *raw produce* at this firm is as follows:
Receiving → Storage → Processing and/or Packaging/Labeling → Storage/Distribution

Receiving: For each product that comes into the firm, a lot code is assigned and placed on the pallets prior to storage. All shipments received are checked and recorded on a receiving log sheet. Mr. Gerald DeFranco, Mr. Paul DeFranco, and Mr. Richard DeFranco are responsible for checking shipments when they arrive. On 10/20/09, I observed the firm's receiving log data sheet which documented the following information: (b) (4)
(b) (4)

Storage: After a lot code is assigned and sticker is placed on pallet, raw produce is stored inside the raw produce cooler until ready for processing or it goes straight to the processing room and production may begin.

Processing and/or Packaging/Labeling:
Processing for Sweet Corn
(b) (4)

Processing for Green Beans:
(b) (4)

Processing for Tomatoes
(b) (4)

Storage/Distribution: Finished product is manually placed onto pallets and moved to the finished product cooler via a (b) (4) operated by employees. Finished product remains inside the finished product cooler until ready for shipment to a distribution center or picked up by the customer.

The turnover rate, from receiving to shipping, for fresh produce is (b) (4)

The general product flow for *tree nuts*, during its seasonal production, is as followed:
Receiving → Storage → Repackaging → Storage/Distribution

Some tree nut products are not repackaged and are just redistributed.

Receiving and storage is the same process as raw produce, except nuts are stored throughout the facility such as the staging area, main production room near nut machine, and second production room along the wall.

Processing for Tree Nuts:
(b) (4)

Storage/Distribution: Finished product is manually placed onto pallets and moved to the staging area until ready for shipment to a distribution center or picked up by the customer.

The turnover rate, from receiving to shipping, for tree nuts varies from (b) (4)

SANITATION/PEST CONTROL *(NJA)*

Cleaning/Sanitation
Produce machines are cleaned and sanitized (b) (4) Tree nut machines are cleaned (b) (4). There are also dedicated employees that clean the area around the corn husking machine (b) (4) sweet corn.

The cleaning and sanitation of the corn husker machine was observed as follows:
(b) (4)

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(b) (4)

Sampling

The firm uses an outside company, (b) (4) Inc., to conduct environmental swabs for (b) (4) in the firm and collect samples to test them for (b) (4) (b) (4) The items that are sampled for (b) (4) are: (b) (4) (b) (4) (b) (4) The received date for the records I reviewed is 03/18/09 and 07/15/09. All samples were documented to be negative.

Pest Control Program

The firm contracts with (b) (4) for its monthly pest control needs. Mr. G. DeFranco, Plant Manager/Secretary, stated that the pest control company services bait stations and sprays the exterior of the building. After each service, (b) (4) submits a comprehensive service report to the firm. All reports are given to him and he is responsible for addressing any pest control problems. CSO Stone reviewed pest control records and did not observe any discrepancies.

MANUFACTURING CODES *(DKS)*

Receiving

The firm operates using a pen and paper, manual tag inventory system which involves a tag that is attached to every product that comes into the firm. Each item is assigned a lot number. (b) (4) (b) (4) (b) (4) (b) (4) The firm is able to track each product and its supplier using the assigned lot number and corresponding year.

Sunripe mixed nuts	*De Franco & Sons brand beans*	*De Franco & Sons brand tomatoes*
"Lot # (b) (4) 10-15-09"	"Lot # (b) (4) 10-15-09"	"Lot # (b) (4) 10-15-09"

The four-digit number is assigned to each product via the firm's manual tag inventory system and the three-digit number represents the date products were received, October 15, 2009.

Finished Product

On 10/20/08, CSO Ayoub and CSO Stone observed fresh trimmed green beans being processed by the firm. A lot code is applied to the top of each sealed, cello/plastic bag (12 oz.) via an (b) (4) coding system which read:

"PRODUCT OF USA"
"SELL BY NOV 07 09"

According to Mr. Gerald S. De Franco, this manufacturing lot code is interpreted as the green beans are a product of USA and they have an 18-day shelf-life. He also explained that the expiration date for tree nuts is marked one year from the packing date.

Coding for tomatoes, corn, and tree nuts are as follows:

Coding for tomatoes uses a pack date:
"PRODUCT OF USA"
"PACKED ON OCT 22 09"

Coding for corn uses a sell by date:
"SELL BY 11-10-2009"
"PRODUCT OF USA"

Coding for tree nuts uses a sell by date:
"SELL BY 10-31-2010"
"PRODUCT OF BRAZIL"

COMPLAINTS *(DKS)*

Mr. Gerald S. De Franco is in charge of customer complaints. According to Mr. Gerald S. De Franco, the firm has only one complaint since the year 2000 and no illnesses or injuries. The firm provides an email address on their product label for complaints and Mr. Gerald S. De Franco personally monitors any complaints and replies to any complaints via email. Also, complaints are documented and maintained by the firm.

RECALL PROCEDURES *(NJA)*

The firm conducted a mock recall on April 20, 2009. The firm is able to locate products based on the receiving log and shipping records. According to Mr. Paul DeFranco, the firm is capable of conducting a recall for products received at the firm then repacked and shipped out. According to Mr. Jerry DeFranco, the firm has never conducted a recall. I mentioned the Reportable Food Registry once again in case a recall should ever occur.

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OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE *(NJA)*

The FDA 483 was issued to Gerald S. DeFranco, Plant Manager/Secretary/Co-Owner, who is the most responsible person. Investigator Dyana K. Stone and I were present during the closing meeting. I read the introductory paragraph on the FDA-483 form. I explained these were my observations and that upon further review they could be found to be violations to FDA regulations. I also explained regulatory sanctions available to the agency should the firm fail to correct violations to FDA regulations.

Observations listed on form FDA 483

OBSERVATION 1

Failure to conduct cleaning and sanitizing operations for utensils and equipment in a manner that protects against contamination of food.

Specifically, on 10/20/09, employees were witnessed washing the floor and corn husker machine with a water pressure gun that contains a mixture of water and sanitizer. The condensate and backsplash from the water pressure gun being used on the floor splashed onto the raw tomatoes that were in the process of getting packaged.

Annotation:

Reference: 21 CFR 110.35(a)

Supporting Evidence and Relevance:

The employees were observed to be spraying the ground with the air pressure water guns near the corn husking section of the machine. The packaging line attached to the corn husking section is approximately 10 meters away. The area by the packaging line was observed to be misty. The mist caused condensation to form on the packaging line and was dripping on the tomato product and near the product. A picture could not be taken because of the mist.

Discussion with Management:

When I pointed out the observation to Mr. G. DeFranco, cleaning was stopped immediately and continued at the end of the shift after tomatoes were finished being packaged. At the close out meeting Mr. G. DeFranco informed me that management has decided to enforce cleaning to be

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conducted at the end of the day when no processing or packaging is taking place in order to avoid cross contamination.

OBSERVATION 2

Storage or use of toxic materials which are not required to maintain clean and sanitary conditions, are unnecessary for use in laboratory testing procedures, are unnecessary for plant and equipment maintenance, and are unnecessary for use in plant operations.

Specifically, on 10/19/09, a plastic gas can was observed in the main production room along the wall approximately 2 meters away of a pallet of packaged corn.

Annotation:

Reference: 21 CFR 110.35(b)(1)

Supporting Evidence and Relevance:

The firm has two locked chemical cabinets that the plastic gas can is usually stored in. The gas can was observed on the floor adjacent to packaged sweet corn (Exhibit 5) and about 10 meters away from where the sweet corn is packaged. The gas in the plastic gas can is utilized for the air pressure water guns that are used during cleaning and sanitation of the firm.

Discussion with Management:

I discussed food safety with Mr. G. DeFranco and referred to the ALERT pamphlet I supplied him with at the beginning of the inspection. Mr. G. DeFranco agreed that the observation is not good food safety practices and his employees have been educated on food safety. He also said that his employees are told to store the plastic gas can in the locked chemical cabinet and that he will remind the employees to continue the practice.

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OBSERVATION 3

Employees failed to remove unsecured jewelry or other objects which might fall into food and containers.

Specifically, on 10/20/09, two employees were observed to be wearing hand watches during the packaging of tomatoes. One employee was wearing gloves with the hand watch on while handling the raw tomatoes and placing them into plastic trays. The other employee wearing the hand watch was not wearing gloves while labeling the outside package of the packaged tomatoes.

Annotation:

Reference: 21 CFR 110.10(b)(4)

Supporting Evidence and Relevance:

Two employees were witnessed wearing hand watches while handling and packaging raw tomatoes. When the deficiency was pointed out, no corrective action was observed to be taken.

Discussion with Management:

Mr. Gerald DeFranco stated that he has spoken to his employees and reminded them to not wear jewelry.

OBSERVATION 4

Personal clothing and belongings were stored in an area where food is exposed.

Specifically, on 10/19/09, a bike was stored in the main production room adjacent to the storage area of boxes and bags of prepackaged Brazil nuts.

In addition, a sweater and a bottled drink were atop boxes of plastic trays used for tomatoes in the main production room. Also, two bottled drinks were observed in the nut packaging area in the second production room in a box below the hopper where raw nuts are poured into.

Annotation:

Reference: 21 CFR 110.10(b)(7)

Supporting Evidence and Relevance:

The observation of a sweater atop finished product packing material in the production room was also a discussion item for the last inspection that occurred on 12/18/08. Photographs of personal belongings and a bike in the production room can be seen in Exhibit 6. The two bottled drinks observed in the nut packaging area of the second production room were in a box directly under a hopper where tree nuts are poured in.

Discussion with Management:

Mr. Gerald DeFranco explained that the firm's trainer, as well as the owners, constantly reminds the employees to keep personal belongings out of the production area. Mr. Gerald DeFranco stated that management will keep an eye out for personal belongings in the production room and continue to instruct the employees.

REFUSALS *(NJA)*

There were no refusals.

GENERAL DISCUSSION WITH MANAGEMENT *(NJA)*

The firm conducts cleaning and sanitation on the nut packing machines on (b) (4) (b) (4) (b) (4) (b) (4) On 10/19/09 and 10/20/09, we did not observe any production of tree nuts; however, the machines had visible nut remnants, dust, and tree nut products still on the machine (Exhibit 7). When asking Mr. G. DeFranco and Mr. P. DeFranco how often the nut machines are cleaned, Mr. P. DeFranco informed me that they are cleaned (b) (4) I pointed out the conditions of the firm and informed them that possible cross contamination may occur on the product despite the fact that the product is shelled. Also, the nut machines may attract pests since the

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raw product is left on the machines and cleaned (b) (4) During the close out meeting, Mr. G. DeFranco informed me and CSO Stone that management has made the decision to clean the nut machines (b) (4)

On 10/19/09, while collecting environmental swabs by the bean processing line, condensation was observed dripping from fan cooling equipment box on the ceiling approximately 1 meter away from the processing line (Exhibit 8). The condensation was dripping on the floor and not on any food products or food contact surfaces. I pointed out the condensation to Mr. G. DeFranco and informed him that condensation may cause cross contamination to food products. He informed me that a mechanic has already been called in prior to my arrival and that the fan cooling box will be fixed. On 10/20/09, no condensation was observed dripping from the fan cooling box and it appeared to be fixed.

While collecting environmental swabs on 10/19/09, a piece of unstable concrete was observed in the main production room by the doorway to the bean packing area (Exhibit 9). When pressure is applied to the top of the concrete, water emerges from beneath it.

ADDITIONAL INFORMATION *(NJA)*

According to Mr. Gerald DeFranco, raw produce waste, corn and green beans, is collected via private carriers set up by Mr. G. DeFranco or a broker. The raw produce waste is used as cattle feed. A BSE questionnaire was completed.

SAMPLES COLLECTED *(NJA)*

Environmental swabs were collected for Salmonella sample analysis under sample # INV 519039. 127 environmental swabs were collected, including controls, in the Main Production Room and Second Production Room of the facility. The Collection Report may be viewed in Attachment 2.

VOLUNTARY CORRECTIONS *(NJA)*

On 10/19/09 and 10/20/09, a free razor blade was observed on the packaging side of the nut packing machine in the second production room (Exhibit 10). The packaging area is 2 meters away from bagged tree nuts and adjacent to the section of the machine that bags the tree nuts. I pointed out the free razor blade to Mr. G. DeFranco and he removed the razor blade immediately.

EXHIBITS COLLECTED

1. Invoices of mixed nuts shipped to (b) (4)

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2. Brazil nuts label reading Made in Brazil
3. Product list of products processed and packed on 10/19/09
4. Hand made map of production area showing environmental swab locations
5. Picture of plastic gas can in main production room
6. Picture of personal belongings in processing area
7. Picture of nut remnants, dust, and tree nut products still on the nut packing machine
8. Picture of condensation puddle from condensation dripping on fan equipment box on ceiling
9. Picture of unstable concrete floor in main production room by the entrance to the bean room
10. Picture of free razor in packaging area of nut machine in second production room
11. White and clear officially sealed envelope containing CD-R of pictures taken during the inspection

ATTACHMENTS

1. FDA 463a, Affidavit, signed by Gerald S. DeFranco, Plant Manager/Secretary/Co-Owner, on 10/23/09
2. FDA 464, Collection Report, for sample # INV 519039 of environmental swabs collected on 10/19/09
3. FDA 482, Notice of Inspection, issued to Gerald S. DeFranco, Co-Owner, on 10/19/09
4. FDA 483, Inspectional Observations, issued to Gerald S. DeFranco, Plant Manager/Secretary/Co-Owner, on 10/23/09
5. FDA 484, Sample Receipt, issued to Gerald S. DeFranco, Plant Manager/Secretary/Co-Owner, on 10/23/09

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Natalie J. Ayoub, Consumer Safety Officer

Dyana K. Stone, Investigator

Angelina Albert, Microbiologist

Michael D. Kawalek, Microbiologist

Attached is the memorandum of the DeFranco Investigation March 3, 2011.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Los Angeles District
Pacific Region
19701 Fairchild
Irvine, CA 92612

Telephone: 949-608-2900
FAX: 949-608-2912

Date: March 03, 2011

To: Tamala Bogan, SCSO, LOS-DO

From: Celena Ngo, CSO, LOS-DO

Subject: Request for distributor trace back investigation at D. Defranco & Sons regarding filberts and mixed nuts sold to (b) (4) and (b) (4) from 10/01/10 to 02/28/11.

Firm: Parimar Inc. dba D. Defranco & Sons
1000 Lawrence St.
Los Angeles, CA 90021
FEI: 3004655865

This was a trace back investigation of filberts/hazelnuts possibly link to E. coli O157:H7 1102WIEXH-1 illness cluster in MI, MN, and WI. This investigation was requested by Office of Emergency Operations (EOE) to obtain documentation/information on the source of the filberts/hazelnuts (lot # 28001403 and 28343601) and mixed nuts (lot # 28192004) sold by Defranco & Sons to (b) (4) and (b) (4) from 10/01/10 to 02/28/11.

Endorsement

From: Tamala Bogan, SCSO
Los Angeles District Office

This joint operation with CFDB and FDA was conducted in response to an Office of Emergency Operations (OEO) request for trace back investigation at Defranco & Sons. Filberts/hazelnuts and mixed nuts distributed by the firm were linked to E. coli O157:H7 1102WIEXH-1 illness cluster in MI, MN, and WI.

Based on the epidemiological evidence the firm initiated a recall.

O: LOS-DO Central Files
Cc: Steven Porter, Emergency Response Coordinator

2) Bill of lading, Invoice # 1617, dated 9/14/2010 from (b) (4) covering the purchase of (b) (4) lbs of Giant In-shell Hazelnuts and (b) (4) lbs of Jumbo In-shell Hazelnuts that was delivered to Defranco & Sons on 09/17/10 via (b) (4) (b) (4) Truck License: (b) (6) and Trailer License: (b) (6) (b) USDA grading specifications for this shipment was also attached to the bill of lading. Exhibit 3

3) Bill of lading, Invoice # 1643, dated 10/11/2010 from (b) (4) covering the purchase of (b) (4) (50lb) bags of large in-shell hazelnuts with a total weight of (b) (4) lbs. that was delivered to Defranco & Sons on 10/18/10 via (b) (4) (b) (4) Truck License: (b) (6) and Trailer License: (b) (6) under seal # 9328512. USDA grading specifications for this shipment was also attached to the bill of lading. Exhibit 4

4) Bill of lading, Invoice # 1671, dated 10/27/2010 from (b) (4) covering the purchase of (b) (4) of large in-shell hazelnuts that was delivered to Defranco & Sons on 11/02/10. USDA grading specifications for this shipment was also attached to the bill of lading. Exhibit 5

5) Bill of Lading, Invoice # 1683, dated 11/02/2010 from (b) (4) covering the purchase of (b) (4) of large in-shell hazelnuts that was delivered to Defranco & Sons on 11/24/10 via (b) (4) Truck License: (b) (6) and Trailer License: (b) (6) under seal # 9328558. Exhibit 6

On 02/28/10, I requested a copy of the firm's receiving invoice (Invoice No. 595178) for 1 shipment of hazelnuts received by the firm from (b) (4) Mr. Defranco informed me that he would call (b) (4) because he could not find this invoice in the firm's files. He promised to fax it to me by 03/01/11.

Exhibit 7 is a copy of the firm's receiving invoices and bills of lading that covered 1 shipment of hazelnuts sold to Defranco & Sons from (b) (4)

1) Invoice # 595178, dated 11/22/2010 from (b) (4) covering the purchase of (50lb) bags of large in-shell hazelnuts that was picked up by Defranco & Sons on 11/22/2010.

According to Mr. Defranco, the firm assigned a (b) (4) four-digit lot number for each product that comes into the firm. The lot number was written on an orange pallet tag and placed on the pallet with a receiving date. The lot code and receiving date were also recorded on a receiving log and receiving invoice upon receiving. However, on numerous occasions, the written lot # on receiving invoices did not correspond to what was written on the receiving log.

Mr. Defranco also provided computer printouts of the firm's shipping data that document all customers received mixed nuts and filberts from September 1, 2010 through February 25, 2011. (Exhibit 14)

During the walkthrough of the facility, we observed two rodent traps were stored on a pallet of Crain Ranch California walnuts, lot # 1460 and at least 20 bags of Crain Ranch California walnuts, lot # 1460 had apparent rodent gnawed marks on them (Exhibit 15). We did not observe any apparent mouse excreta pellets on the bags or in the warehouse. A comprehensive inspection was conducted by CFDB on 03/03/11 and a Notice of Violation (NOV) was issued to the firm.

Different kinds of nuts were observed stored in the firm's refrigerated warehouse:

[redacted] pallets of Crain Ranch California Walnut, lot # 1460, receiving date: 12/09/10
(b) (4) pallets of Defranco Mixed nuts
[redacted] pallets of Crain Ranch California Jumbo Walnuts, lot # 1426, receiving date 11/24/10
(b) (4) pallets of Blue Diamond Growers Almonds, lot # 1429, receiving date 11/26/10
[redacted] pallets of North Valley Nut Almonds, lot # 1365
[redacted] pallets of Crain Ranch California Walnut, lot # 1425, receiving date 11/24/10
(b) (4) bags of Defranco Brazil nuts

According to Mr. Defranco, each pallet had (b) (4) (50lb) bags of nuts.

On 03/02/11 environmental samples were aseptically collected from Defranco & Sons by Investigator Zugsmith and Ngo who were assisted by Investigator Grant. We collected 50 swabs in the (50lb bag) packing room and 10 swabs in the nut storage areas as well as 10 - 50lb bags from [redacted] pallets of mixed nuts. The environmental and product samples were shipped to the CDPH-FDB Richmond Lab for E.coli analysis.

On 03/02/11, FDB and FDA discussed the epidemiology and traceback results with Mr. Richard DeFranco and he agreed to recall all hazelnuts and mixed nuts shipped between 11/2/10 and 12/22/10.

On 03/04/11, I returned to Defranco & Sons to obtain Attachment B information. Product labels for the following recalled products were provided by Mr. Jerry Defranco, Co-Owner and Salesman:

Sunripe Large Hazelnuts (1 lb)
Sunripe mixed nuts (2 lbs)
Season's Greetings mixed nuts (4 lbs)
Sunripe mixed nuts (50 lbs)
Photos of labels were attached as Exhibit 16

Attachment

FDA-482, Notice of Inspection, dated 02/25/11 and issued to Mr. Richard Defranco, Owner and Secretary (3 pages)
Email dated 02/25/11 providing traceback information.
Attachment B information (3 pages)

Exhibits:

1) Copy of the firm's receiving transaction details that show the firm's nut suppliers (4 pages)
2) Bill of lading, Invoice # 1582, dated 7/29/2010 from (b) (4) (4 pages)
3) Bill of lading, Invoice # 1617, dated 9/14/2010 from (b) (4) (3 pages)
4) Bill of lading, Invoice # 1643, dated 10/11/2010 from (b) (4) (4 pages)
5) Bill of lading, Invoice # 1671, dated 10/27/2010 from (b) (4) (5 pages)
6) Bill of lading, Invoice # 1683, dated 11/02/2010 from (b) (4) (1 page)
7) Invoice # 595178, dated 11/22/2010 from (b) (4) (1 page)
8) Computer printouts of the firm's shipping data containing all products sold to (b) (4) (b) (4) and (b) (4) from Feb 1, 2010 to Feb 25, 2011. (4 pages)
9) Shipping invoices and Bills of Lading for all nut products shipped to (b) (4) from 10/01/10 to 02/28/11. (11 pages)
10) Shipping invoices and Bills of Lading for all nut products shipped to (b) (4) (b) (4) from 10/01/10 to 02/28/11. (19 pages)
11) Invoice No. 165800, dated 11/22/2010, P.O No. 280014, Ship date 11/22/2010 from Defranco & Sons. (1 page)
12) Invoice No. 166170, dated 12/15/2010, P.O No. 283436, Ship date 12/15/2010 from Defranco & Sons. (1 page)
13) Invoice No. 166019, dated 12/06/2010, P.O No. 281920, Ship date 12/06/2010 from Defranco & Sons. (1 page)
14) Computer printouts of the firm's shipping data that document all customers received mixed nuts and filberts from September 1, 2010 through February 25, 2011. (8 pages)
15) Photos of two rodent traps stored directly on top of a pallet of walnuts and gnawed marks on bags of Crain Ranch California walnuts. (3 pages)
16) Photos of labels of recalled products. (4 pages)

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION	1. DISTRICT OFFICE ADDRESS & PHONE NO.

TO	2. NAME AND TITLE OF INDIVIDUAL	3. DATE
	4. FIRM NAME	5. HOUR a.m.
	6. NUMBER AND STREET	p.m.
	7. CITY AND STATE & ZIP CODE	8. PHONE NO. & AREA CODE

Notice of Inspection is hereby given pursuant to Section 704(a)(1) of the Federal Food, Drug, and Cosmetics Act [21 U.S.C. 374(a)][1] and/or Part F or G, Title III of the Public Health Service Act [42 U.S.C. 262-264][2]

As a small business that is subject to FDA regulation, you have the right to seek assistance form the U.S. Small Business Administration (SBA). This assistance includes a mechanism to address the enforcement actions of Federal agencies. SBA has a National Ombudsman's Office that receives comments form small businesses about Federal agency enforcement actions. If you wish to comment on the enforcement actions of FDA, CALL (888) 734-3247. The website address is www.sba.gov/ombudsman.

FDA has an Office of the Ombudsman that can directly assist small business with complaints or disputes about actions of the FDA. That office can be reached by calling (301) 796-8530 or by email at ombuds@oc.fda.gov.

For industry information, go to www.fda.gov/oc/industry.

9. SIGNATURE(S) *(Food and Drug Administration Employee(s))*	10. TYPE OR PRINT NAME(S) AND TITLE(S) *(FDA Employee(s))*

[1] Applicable portions of Section 704 and other Sections of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374] are quoted below:

Sec. 704(a)(1) For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (A) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, tobacco products, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, tobacco products, or cosmetics in interstate commerce; and (B) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. In the case of any person (excluding farms and restaurants) who manufactures, processes, packs, transports, distributes, holds, or imports foods, the inspection shall extend to all records and other information described in section 414 when the Secretary has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, subject to the limitations established in section 414(d). In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs, nonprescription drugs intended for human use, restricted devices, or tobacco products are manufactured, processed, packed, or held, inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs, nonprescription drugs intended for human use, restricted devices, or tobacco products which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this Act. No inspection authorized by the preceding sentence or by paragraph (3) shall extend to financial data, sales data other than shipment data, pricing data, personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to this Act), and research data

(Continued on Reverse)

of any virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product aforesaid for sale, barter, or exchange in the District of Columbia, or to be sent, carried, or brought from any State or possession into any other State or possession or into any foreign country, or from any foreign country into any State or possession."

Part F – * * * * * *Control of Radiation.

Sec. 360 A (a) "If the Secretary finds for good cause that the methods, tests, or programs related to electronic product radiation safety in a particular factory, warehouse, or establishment in which electronic products are manufactured or held, may not be adequate or reliable, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are thereafter authorized (1) to enter, at reasonable times any area in such factory, warehouse, or establishment in which the manufacturer's tests (or testing programs) required by section 358(h) are carried out, and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, the facilities and procedures within such area which are related to electronic product radiation safety. Each such inspection shall be commenced and completed with reasonable promptness. In addition to other grounds upon which good cause may be found for purposes of this subsection, good cause will be considered to exist in any case where the manufacturer has introduced into commerce any electronic product which does not comply with an applicable standard prescribed under this subpart and with respect to which no exemption from the notification requirements has been granted by the Secretary under section 359(a)(2) or 359(e)."

(b) "Every manufacturer of electronic products shall establish and maintain such records (including testing records), make such reports, and provide such information, as the Secretary may reasonably require to enable him to determine whether such manufacturer has acted or is acting in compliance with this subpart and standards prescribed pursuant to this subpart and shall, upon request of an officer or employee duly designated by the Secretary, permit such officer or employee to inspect appropriate books, papers, records, and documents relevant to determining whether such manufacturer has acted or is acting in compliance with standards prescribed pursuant to section 359(a)."

* * * * * *

(f) "The Secretary may by regulation (1) require dealers and distributors of electronic products, to which there are applicable standards prescribed under this subpart and the retail prices of which is not less than $50, to furnish manufacturers of such products such information as may be necessary to identify and locate, for purposes of section 359, the first purchasers of such products for purposes other than resale, and (2) require manufacturers to preserve such information Any regulation establishing a requirement pursuant to clause (1) of the preceding sentence shall (A) authorize such dealers and distributors to elect, in lieu of immediately furnishing such information to the manufacturer to hold and preserve such information until advised by the manufacturer or Secretary that such information is needed by the manufacturer for purposes of section 359, and (B) provide that the dealer or distributor shall, upon making such election, give prompt notice of such election (together with information identifying the notifier and the product) to the manufacturer and shall, when advised by the manufacturer or Secretary, of the need therefore for the purposes of Section 359, immediately furnish the manufacturer with the required information. If a dealer or distributor discontinues the dealing in or distribution of electronic products, he shall turn the information over to the manufacturer. Any manufacturer receiving information pursuant to this subsection concerning first purchasers of products for purposes other than resale shall treat it as confidential and may use it only if necessary for the purpose of notifying persons pursuant to section 359(a)."

* * * * * *

Sec. 360 B.(a) It shall be unlawful--

(1) * * *

(2) * * *

(3) "for any person to fail or to refuse to establish or maintain records required by this subpart or to permit access by the Secretary or any of his duly authorized representatives to, or the copying of, such records, or to permit entry or inspection, as required or pursuant to section 360A."

* * * * * *

Part G - Quarantine and Inspection

Sec. 361(a) "The Surgeon General, with the approval of the Secretary, is authorized to make and enforce such regulations as in his judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession. For purposes of carrying out and enforcing such regulations, the Surgeon General may provide for such inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings, and other measures, as in his judgment may be necessary."

Ngo, Celena

From: Porter, Steven
Sent: Friday, February 25, 2011 11:49 AM
To: Maxwell, Monica; Bogan, Tamala; Ngo, Celena
Subject: FW:
Attachments: WI MI MN Traceback.xlsx; (b) (4) shipments to customers 110110_122310.xlsx

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From: Barnes, Amber (CDPH-PS-DFDRS-FDB) [mailto:Amber.Barnes@cdph.ca.gov]
Sent: Friday, February 25, 2011 11:47 AM
To: Zugsmith, Nicole (CDPH-DFDRS); Grant, Christina (CDPH-DFDRS)
Cc: Reick, Jane (CDPH-FDB); StateRFR-Kennelly, Patrick; Hernandez, Michael (CDPH-DFDRS); Weathers, Jeanne-Marie (CDPH-FDB); Miller, Mary Kate (CDPH-FDB); Porter, Steven
Subject:

Christina and Nicole:

Attached is the traceback diagram and an Excel spreadsheet some info I have about the lots that were shipped form (b) (4) to the retail stores where people purchased the mixed nuts and hazelnuts.

Below is a summary of what I've put together from e-mails:

E. coli O157:H7 1102WIEXH-1 cluster
Likely food vehicle: In-shell Hazelnuts

Common distributor in 5 of the 6 U.S. cases:

Defranco and Sons (New England Tomato Company)
1000 Lawrence St.
Los Angeles, CA 90021
1-800-992-3992, 213-627-9837 fax

Cases had onsets in late Dec.
Isolation dates for E. coli: 12/27-1/29:

3 WI (2 ate mixed nuts): Lot unknown
(1ate hazelnuts): Lot 28001403 and/or 28343601
1 MI (1 ate hazelnuts): Lot 28001403
2 MN (2 ate mixed nuts): Lot 28192004
2 Canada: Lot unknown

Visit firm before 1pm today, 2/25/11

Questions for Defranco and Sons:
Who is their hazelnut and mixed nut supplier/grower?
How do they (Defranco) handle the nuts from receiving to packaging? [ie. hulling, cleaning, processing (drying, steam, gas, roasting), kill step?, segregating raw and unraw]
How are the nuts harvested?
Decode the lot numbers.
How to connect the lot numbers to the invoices?

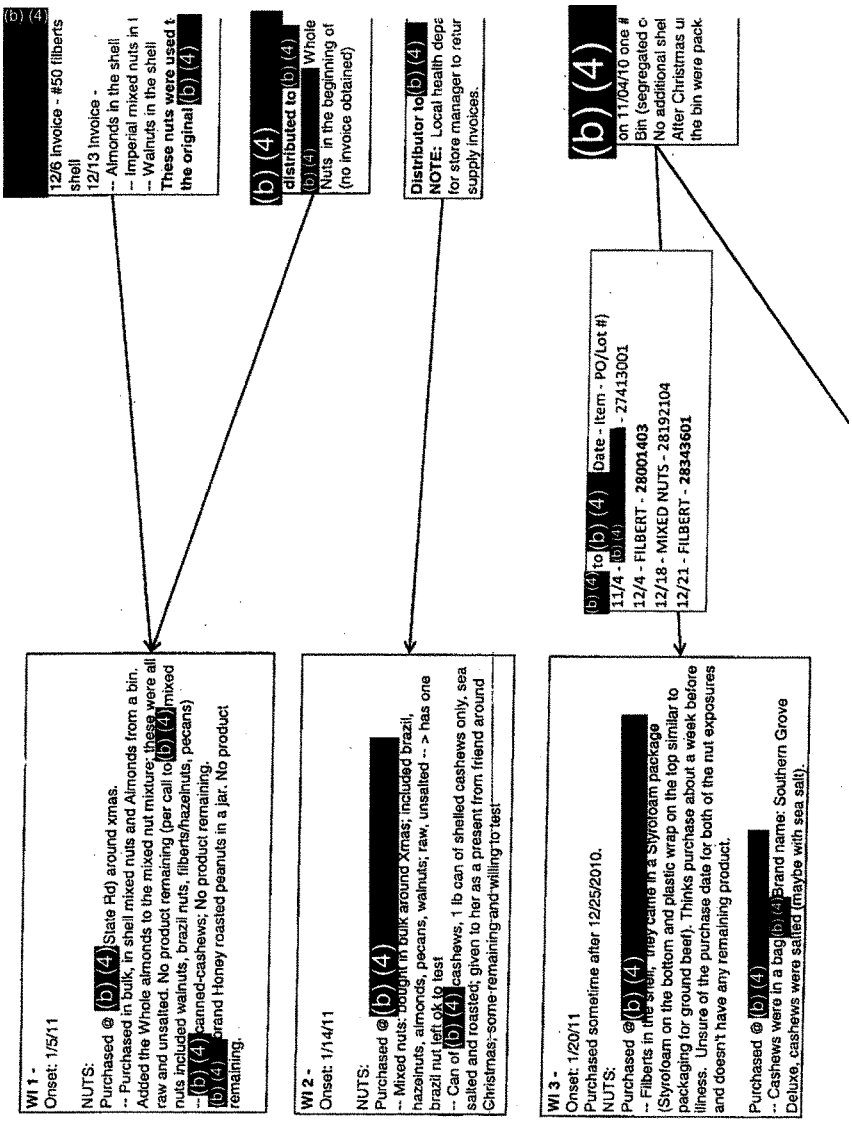
Documents to collect:
SOP's
SSOP's
Shipping invoices and Bills of Lading for all nut products shipped to (b) (4) (b) (4) and (b) (4) from 10/1/10 to 2/28/11
Receiving invoices and Bills of Lading for product received by Defranco and Sons and subsequently shipped to (b) (4) and (b) (4) (b) (4) between 10/1/10 and 2/27/11 of the products with common lot numbers
Any Retained samples (entire bag—do not split) from these products/lots:

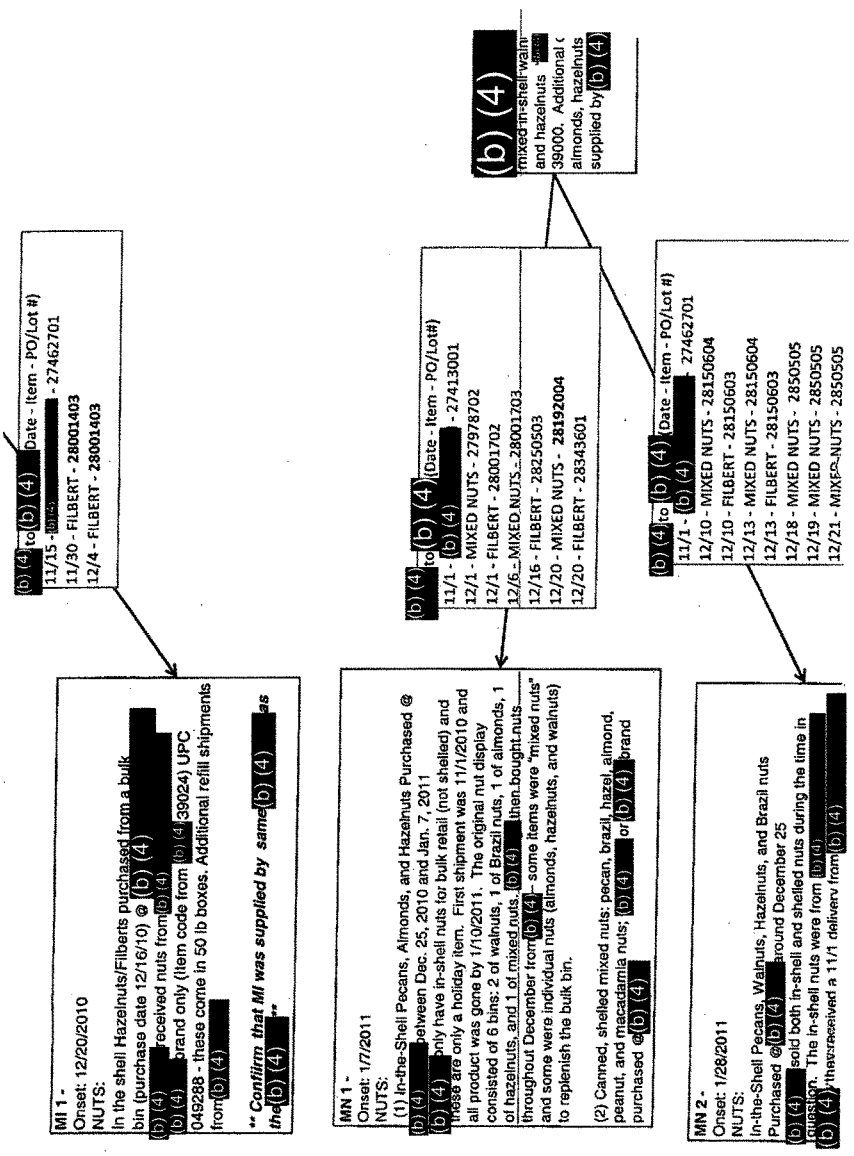
Filberts: **28001403 & 28343601**
28001702, 28250503, 28343601, 2815063

Mixed Nuts: **28192004**
28192104, 27978702, 28001703, 28150604, 28250505

Common lots are in color and bold

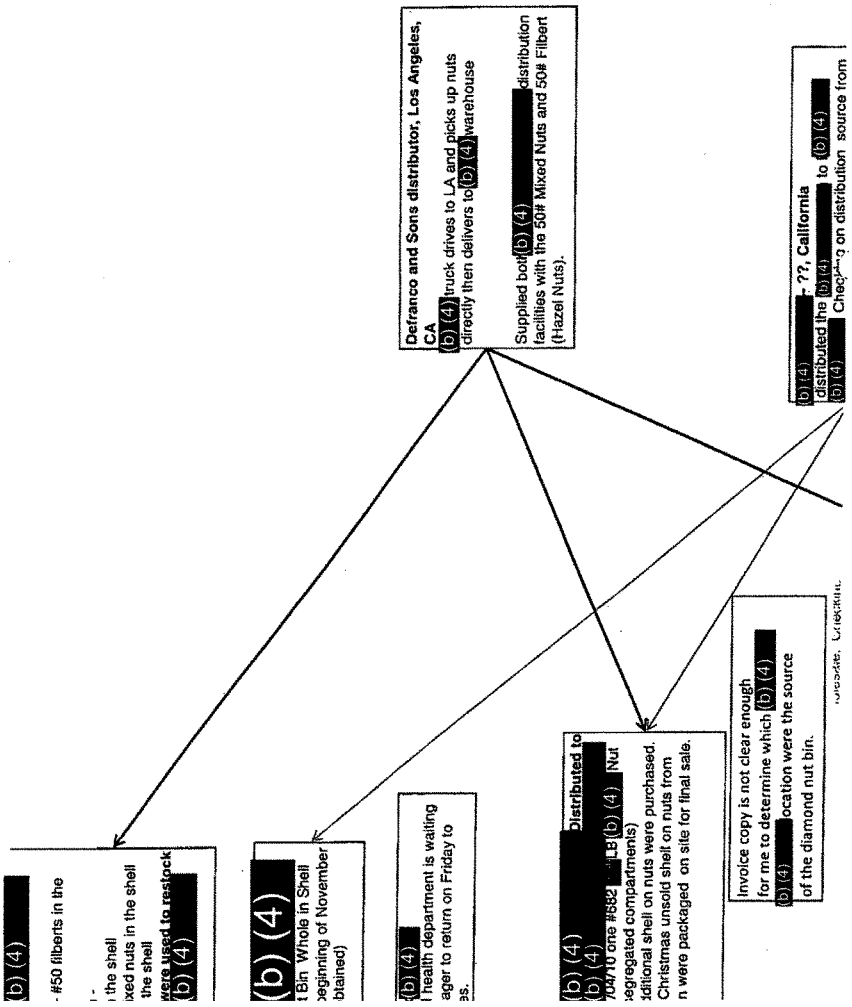
Amber Barnes
Investigator
California Department of Public Health
Emergency Response Unit
(916) 324-0991 phone
(916) 440-5455 fax

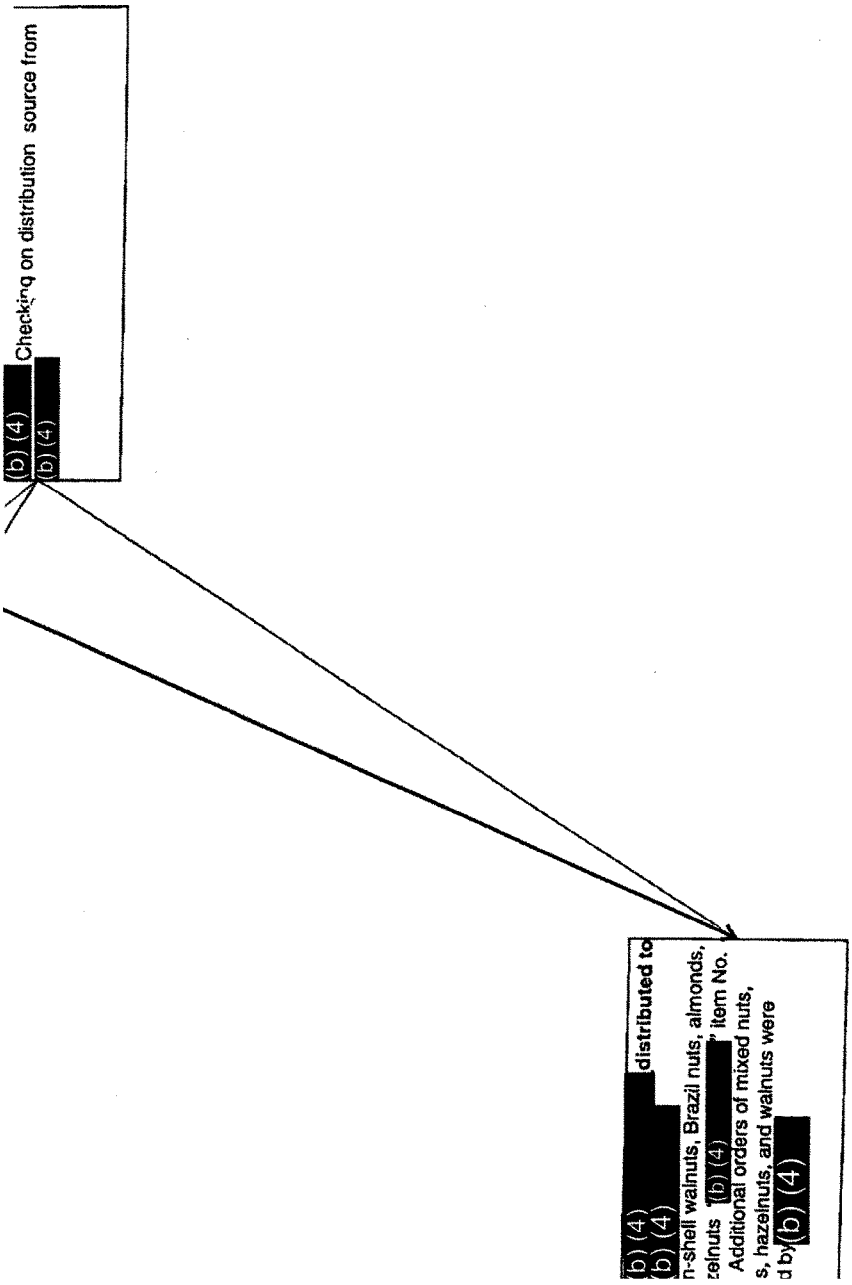

(b) (4)
12/6 invoice - #50 filberts shell
12/13 invoice -
-- Almonds in the shell
-- Imperial mixed nuts in
-- Walnuts in the shell
These nuts were used t
the original (b) (4)
(b) (4)
distributed to (b) (4)
(b) (4) Whole Nuts in the beginning of
(no invoice obtained)
Distributor to (b) (4)
NOTE: Local health depa
for store manager to retur
supply invoices.
(b) (4)
on 11/04/10 one #
Bin (segregated c
No additional shel
After Christmas u
the bin were pack
WI 1 -
Onset: 1/5/11
NUTS:
Purchased @ (b) (4) State Rd) around xmas.
-- Purchased in bulk, in shell mixed nuts and Almonds from a bin.
Added the Whole almonds to the mixed nut mixture; these were all
raw and unsalted. No product remaining (per call to (b) (4) mixed
nuts included walnuts, brazil nuts, filberts/hazelnuts, pecans)
-- (b) (4) canned-cashews; No product remaining.
(b) (4) brand Honey roasted peanuts in a jar. No product
remaining.
WI 2 -
Onset: 1/14/11
NUTS:
Purchased @ (b) (4)
-- Mixed nuts; bought in bulk around Xmas; included brazil,
hazelnuts, almonds, pecans, walnuts; raw, unsalted -- > has one
brazil nut left ok to test
-- Can of (b) (4) cashews, 1 lb can of shelled cashews only, sea
salted and roasted; given to her as a present from friend around
Christmas; some remaining and willing to test
WI 3 -
Onset: 1/20/11
Purchased sometime after 12/25/2010.
NUTS:
Purchased @ (b) (4)
-- Filberts in the shell, they came in a Styrofoam package
(Styrofoam on the bottom and plastic wrap on the top similar to
packaging for ground beef). Thinks purchase about a week before
illness. Unsure of the purchase date for both of the nut exposures
and doesn't have any remaining product.
Purchased @ (b) (4)
-- Cashews were in a bag (b) (4) Brand name: Southern Grove
Deluxe, cashews were salted (maybe with sea salt).
(b) (4) to (b) (4) Date - Item - PO/Lot #)
11/4 - (b) (4) - 27413001
12/4 - FILBERT - 28001403
12/18 - MIXED NUTS - 28192104
12/21 - FILBERT - 28343601


(b) (4) to (b) (4) Date - Item - PO/Lot #)
11/15 - [redacted] - 27462701
11/30 - FILBERT - 28001403
12/4 - FILBERT - 28001403
MI 1 -
Onset: 12/20/2010
NUTS:
In the shell Hazelnuts/Filberts purchased from a bulk
bin (purchase date 12/16/10) @ (b) (4)
(b) (4) received nuts from (b) (4)
(b) (4) brand only (item code from (b) (4) 39024) UPC
049288 - these come in 50 lb boxes. Additional refill shipments
from (b) (4)
** Confirm that MI was supplied by same (b) (4) as
the (b) (4) **
(b) (4) to (b) (4) (Date - Item - PO/Lot#)
11/1 - (b) (4) - 27413001
12/1 - MIXED NUTS - 27978702
12/1 - FILBERT - 28001702
12/6 - MIXED NUTS - 28001703
12/16 - FILBERT - 28250503
12/20 - MIXED NUTS - 28192004
12/20 - FILBERT - 28343601
(b) (4)
mixed in-shell walnuts and hazelnuts [redacted] 39000. Additional [redacted] almonds, hazelnuts supplied by (b) (4)
MN 1 -
Onset: 1/7/2011
NUTS:
(1) In-the-Shell Pecans, Almonds, and Hazelnuts Purchased @
(b) (4) between Dec. 25, 2010 and Jan. 7, 2011
(b) (4) only have in-shell nuts for bulk retail (not shelled) and
these are only a holiday item. First shipment was 11/1/2010 and
all product was gone by 1/10/2011. The original nut display
consisted of 6 bins: 2 of walnuts, 1 of Brazil nuts, 1 of almonds, 1
of hazelnuts, and 1 of mixed nuts. (b) (4) then bought nuts
throughout December from (b) (4) - some items were "mixed nuts"
and some were individual nuts (almonds, hazelnuts, and walnuts)
to replenish the bulk bin.
(2) Canned, shelled mixed nuts: pecan, brazil, hazel, almond,
peanut, and macadamia nuts; (b) (4) or (b) (4) brand
purchased @ (b) (4)
(b) (4) to (b) (4) (Date - Item - PO/Lot #)
11/1 - (b) (4) - 27462701
12/10 - MIXED NUTS - 28150604
12/10 - FILBERT - 28150603
12/13 - MIXED NUTS - 28150604
12/13 - FILBERT - 28150603
12/18 - MIXED NUTS - 2850505
12/19 - MIXED NUTS - 2850505
12/21 - MIXED NUTS - 2850505
MN 2 -
Onset: 1/26/2011
NUTS:
In-the-Shell Pecans, Walnuts, Hazelnuts, and Brazil nuts
Purchased @ (b) (4) around December 25
(b) (4) sold both in-shell and shelled nuts during the time in
question. The in-shell nuts were from (b) (4)
(b) (4) they received a 11/1 delivery from (b) (4)

(b) (4) : they received a 11/1 delivery from (b) (4)
(b) (4) of (b) (4) lbs. of (b) (4) , item No. 3 0 (the same as (b) (4) Additional nuts were purchased throughout December to supplement and replenish the bin.

12/21 - MIXED NUTS - 2850505
12/21 - FIL - **28343601**
12/22 - MIXED NUTS - **28192004**
12/22 - FILBERT - **28343601**
12/23 - MIXED NUTS - 28250505
12/23 - FILBERT - **28343601**


Defranco and Sons distributor, Los Angeles, CA
(b) (4) truck drives to LA and picks up nuts directly then delivers to (b) (4) warehouse
Supplied both (b) (4) distribution facilities with the 50# Mixed Nuts and 50# Filbert (Hazel Nuts).
(b) (4)
- #50 filberts in the
the shell
ixed nuts in the shell
the shell
were used to restock
(b) (4)
(b) (4)
t Bin Whole in Shell
beginning of November
blained)
(b) (4)
health department is waiting
ager to return on Friday to
es.
(b) (4)
(b) (4)
704/10 one #882
LB (b) (4) Nut
egregated compartments)
ditional shell on nuts were purchased.
Christmas unsold shell on nuts from
n were packaged on site for final sale.
Invoice copy is not clear enough
for me to determine which (b) (4)
(b) (4) ocation were the source
of the diamond nut bin.
(b) (4)
distributed the (b) (4) to (b) (4)
(b) (4) Checking on distribution source from


(b) (4)
(b) (4)
Checking on distribution source from
(b) (4)
(b) (4)
distributed to
n-shell walnuts, Brazil nuts, almonds,
zelnuts (b) (4) item No.
Additional orders of mixed nuts,
s, hazelnuts, and walnuts were
d by (b) (4)

INFORMATION/DOCUMENTS NEEDED BY FDA FOR RECALLS OF FOOD PRODUCTS

1. PRODUCT

A. Brand name and container size of each product.

Brand	Size	Product	Sell By Date	UPC
Sunripe	1 lb	Large Hazelnuts	6/30/11	070533000167
Sunripe	1 lb	Mixed nuts	6/30/11	070533000143
Sunripe	2 lbs	Mixed nuts	6/30/11	070533001003
None	4 lbs	Mixed Nuts	6/30/11	070533101024
Sunripe	50 lbs	Mixed Nuts	None	
George Packing	50 lbs	Hazelnuts	Only the products distributed by DeFranco and Sons between 11/2/10 to 12/22/10.	
Firestone Farms	50 lbs	Hazelnuts		
Northwest Hazelnuts	50 lbs	Hazelnuts		

B. Two copies of label for each product recalled.

C. Number of units packed per shipping carton/case.

1lb hazelnuts, large hazelnuts, and mixed nuts: [redacted] (1lb) bags/ box
2lbs mixed nuts: [redacted] (2lb) bags/ box
4lbs mixed nuts: [redacted] (4lb) bags/box

D. Digital photo of the principle panel of the retail package.

See Exhibit 16

2. CODE **(See Section 1A)**

3A. RECALLING FIRM

D. Defranco & Sons
1000 Lawrence St., Los Angeles, CA 90021

3B. MANUFACTURER

D. Defranco & Sons, 1000 Lawrence St., Los Angeles, CA 90021

[redacted]

09/01/2010 to 02/25/2011 were attached.(Exhibit 14)

8. RECALL STRATEGY

Ms. (b) (6) stated that she is still working on the recall letter. Mr. Jerry Defranco stated that the recall notification letter will be sent out to the firm's customers within a week via email or fax. Mr. Jerry Defranco added that the recall letter would include instructions on what customers should do with the recalled product. The firm would follow up with non-responding customers by phone. Details of recall plan will be sent to Larry Howell, LOS-DO Recall Coordinator, on 03/07/11.

9. FIRM OFFICIAL

Richard Defranco, Co-Owner and Secretary
Paul Defranco, Co-owner
Jerry Defranco, Co-owner and salesman
(b) (6) Bookeeper

2:52 PM
02/25/11
Accrual Basis

D DE FRANCO & SONS
Transaction Detail By Account
September 1, 2010 through February 25, 2011

Type	Date	Num	Name	Memo
B-COGS-NUTS				
COGS-FILBERTS				
Bill	10/1/2010	(b) (4)	(b) (4)	(b) (4)
Bill	10/1/2010			
Bill	10/12/2010			
Bill	10/18/2010			
Bill	10/18/2010			
Bill	11/2/2010			
Bill	11/2/2010			
Bill	11/22/2010			
Bill	11/24/2010			
Bill	1/1/2011			
General Journal	1/1/2011			
General Journal	1/1/2011			
Total COGS-FILBERTS				
Total B-COGS-NUTS				
TOTAL				

2:53 PM
02/25/11
Accrual Basis

D DE FRANCO & SONS
Transaction Detail By Account
September 2, 2010 through February 25, 2011

Type	Date	Num	Name	Memo
B-COGS-NUTS				
COGS-PECANS				
Bill	9/29/2010	(b) (4)	(b) (4)	(b) (4)
Bill	10/1/2010			
Bill	10/1/2010			
Bill	10/6/2010			
Bill	11/12/2010			
Bill	11/18/2010			
Bill	11/19/2010			
Bill	12/2/2010			
Bill	12/14/2010			
General Journal	1/1/2011			
General Journal	1/1/2011			
Total COGS-PECANS				
Total B-COGS-NUTS				
TOTAL				

2:49 PM
02/25/11
Accrual Basis

D DE FRANCO & SONS
Transaction Detail By Account
February 1, 2010 through February 25, 2011

Type	Date	Num	Name	Memo
B-COGS-NUTS				
COGS-ALMONDS				
Bill	8/2/2010	(b) (4)	(b) (4)	(b) (4)
Bill	9/16/2010			
Bill	9/17/2010			
Bill	10/1/2010			
Bill	10/1/2010			
Bill	10/4/2010			
Bill	10/6/2010			
Bill	10/10/2010			
Bill	10/11/2010			
Bill	10/12/2010			
Bill	10/21/2010			
Bill	10/21/2010			
Bill	11/9/2010			
Bill	11/9/2010			
Bill	11/26/2010			
Bill	11/26/2010			
General Journal	1/1/2011			
General Journal	1/1/2011			
Total COGS-ALMONDS				
Total B-COGS-NUTS				
TOTAL				

2:51 PM
02/25/11
Accrual Basis

D DE FRANCO & SONS
Transaction Detail By Account
September 1, 2010 through February 25, 2011

Type	Date	Num	Name	Memo
B-COGS-NUTS				
COGS-JUMBO HARTLEY WALNUT				
Bill	9/29/2010	(b) (4)	(b) (4)	(b) (4)
Bill	10/1/2010			
Bill	10/5/2010			
Bill	10/5/2010			
Bill	10/12/2010			
Bill	10/12/2010			
Bill	10/18/2010			
Bill	10/18/2010			
Bill	10/19/2010			
Bill	10/20/2010			
Bill	10/21/2010			
Bill	10/22/2010			
Bill	10/22/2010			
Bill	11/1/2010			
Bill	11/1/2010			
Bill	11/11/2010			
Bill	11/11/2010			
Bill	11/15/2010			
Bill	11/16/2010			
Bill	11/24/2010			
Bill	11/24/2010			
Bill	12/9/2010			
Bill	1/1/2011			
General Journal	1/1/2011			
General Journal	1/1/2011			
Total COGS-JUMBO HARTLEY WALNUT				
Total B-COGS-NUTS				
TOTAL				

(b) (4)

Invoice

Date	Invoice #
7/29/2010	1582

Bill To	Ship To
De Franco & Sons 1000 Lawrence Street Los Angeles, CA 90021	1000 Lawrence Street Los Angeles, CA 90021 USA

P.O. Number	Terms	Rep	Ship	Via	F.O.B.	S.O. No.
	(b) (4)		7/29/2010	PickUp	(b) (4)	1386

Quantity	Item Code	Description	Price Each	USDA Inspection	Amount
(b) (4)	Large	Large Inshell Hazelnuts 50lb bags large barcelona inshell	(b) (4)	a-015419	(b) (4)

F.O.B

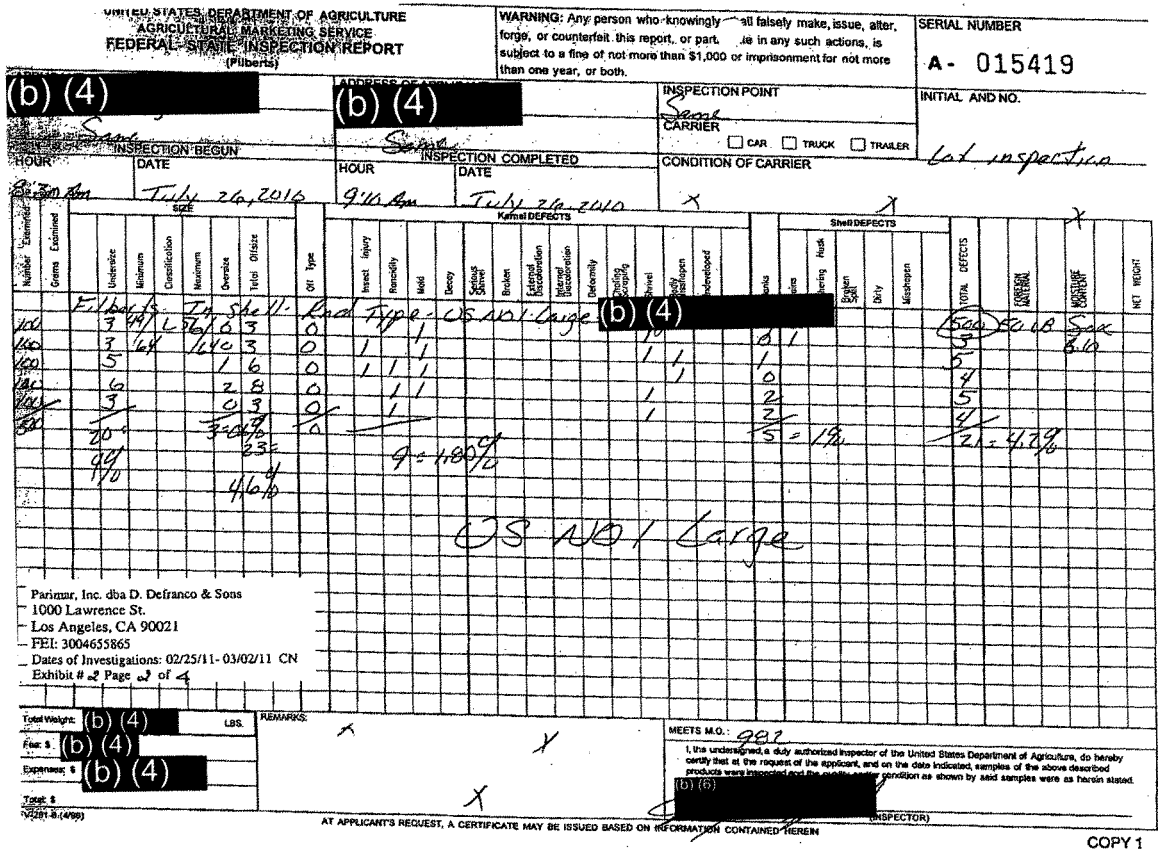
Los Angeles

63,50

Parimar, Inc. dba D. Defranco & Sons
1000 Lawrence St.
Los Angeles, CA 90021
FEI: 3004655865
Dates of Investigations: 02/25/11- 03/02/11 CN
Exhibit # 2 Page 1 of 4

Packing is now Kosher Certified.

Total USD (b) (4)



UNITED STATES DEPARTMENT OF AGRICULTURE
AGRICULTURAL MARKETING SERVICE
FEDERAL-STATE INSPECTION REPORT
(Filberts)

WARNING: Any person who knowingly shall falsely make, issue, alter, forge, or counterfeit this report, or participate in any such actions, is subject to a fine of not more than $1,000 or imprisonment for not more than one year, or both.

SERIAL NUMBER: A- 015419

(b) (4)

Sent

INSPECTION BEGUN — HOUR: 8:30 Am — DATE: July 26, 2016

(b) (4)

Sent

INSPECTION COMPLETED — HOUR: 9:45 Am — DATE: July 26, 2016

INSPECTION POINT: Sent
CARRIER: ☐ CAR ☐ TRUCK ☐ TRAILER
CONDITION OF CARRIER: X

INITIAL AND NO.: Last inspection

Number	Examined	Grams	Undersize	Minimum	Classification	Maximum	Oversize	Total Offsize	Off Type	Insect Injury	Rancidity	Mold	Decay	Serious Stained	Broken	Extraneous Substance	Internal Discoloration	Deformity	Shelling Stock	Shrivel	Badly Misshapen	Undeveloped	Total Kernel DEFECTS	Blanks	Splits	Shriveling	Husk	Broken Shell	Dirty	Misshapen	Total Shell DEFECTS	TOTAL DEFECTS	FOREIGN MATERIAL	MOISTURE CONTENT	NET WEIGHT
100		3	44	156		03			0		1													01										
100		3	64	140		03			0	1		1									1	1		10										
100		5		16					0	1	1	1										1		10										
100		6		28					0		1	1												02										
100		3		03					0			1										1		02										
500		20		23					0															05										
		40																																
		100		46																														

9 = 4.80%

05 AND 1 Large

Parimar, Inc. dba D. Defranco & Sons
1000 Lawrence St.
Los Angeles, CA 90021
FEI: 3004655865
Dates of Investigations: 02/25/11- 03/02/11 CN
Exhibit # 2 Page 3 of 4

Total Weight: (b) (4) LBS.
Fee: $ (b) (4)
Expenses: $ (b) (4)
Total: $

REMARKS: X X X

MEETS M.O.: 982

I, the undersigned, a duly authorized inspector of the United States Department of Agriculture, do hereby certify that at the request of the applicant, and on the date indicated, samples of the above described products were inspected and the quality and/or condition as shown by said samples were as herein stated.

(b) (6)
(INSPECTOR)

AT APPLICANT'S REQUEST, A CERTIFICATE MAY BE ISSUED BASED ON INFORMATION CONTAINED HEREIN

FV291-8 (4/99)

COPY 1

(b) (4)

Phone # (b) (4)

Bill of Lading

Date	Invoice #
7/29/2010	1582

Ship To
1000 Lawrence Street Los Angeles, CA 90021 USA

P.O. No.	Ship	Via	FOB	Project
	7/29/2010	PickUp	(b) (4)	

Quantity	Item Code	Description	USDA Inspection
(b) (4)	Large	Large Inshell Hazelnuts [redacted] 50lb bags large barcelona inshell	a-015419

Truck Co (b) (4)
Truck Lic. (b) (6)
Trailer Lic [redacted] CA
Seal:

CARRIER NAME (Sign and Date) accepts the property described above in good order.
(b) (6)

(b) (4)

Phone # (b) (4)

Bill of Lading

Date	Invoice #
7/29/2010	1582

Ship To
1000 Lawrence Street
Los Angeles, CA 90021
USA

State of California Dept. of Food and Agriculture
JUL 30 2010
Hombrook Inspection Station

P.O. No.	Ship	Via	FOB	Project
	7/29/2010	PickUp	(b) (4)	

Quantity	Item Code	Description	USDA Inspection
(b) (4)	Large	Large Inshell Hazelnuts (b) (4) 50lb bags largy barcelona inshell	a-015419

Richard 8-2-10

Lot # 8018

Truck Co (b) (4)
Truck Lic. (b) (6) CAL.
Trailer Lic CA
Seal:

CARRIER NAME (Sign and Date) accepts the property described above in good order.
(b) (6)

Parimar, Inc. dba D. Defranco & Sons
1000 Lawrence St.
Los Angeles, CA 90021
FEI: 3004655865
Dates of Investigations: 02/25/11- 03/02/11 CN

(b) (4)

Invoice

Date	Invoice #
9/14/2010	1617

Bill To	Ship To
De Franco & Sons 1000 Lawrence Street Los Angeles, CA 90021	1000 Lawrence Street Los Angeles, CA 90021 USA

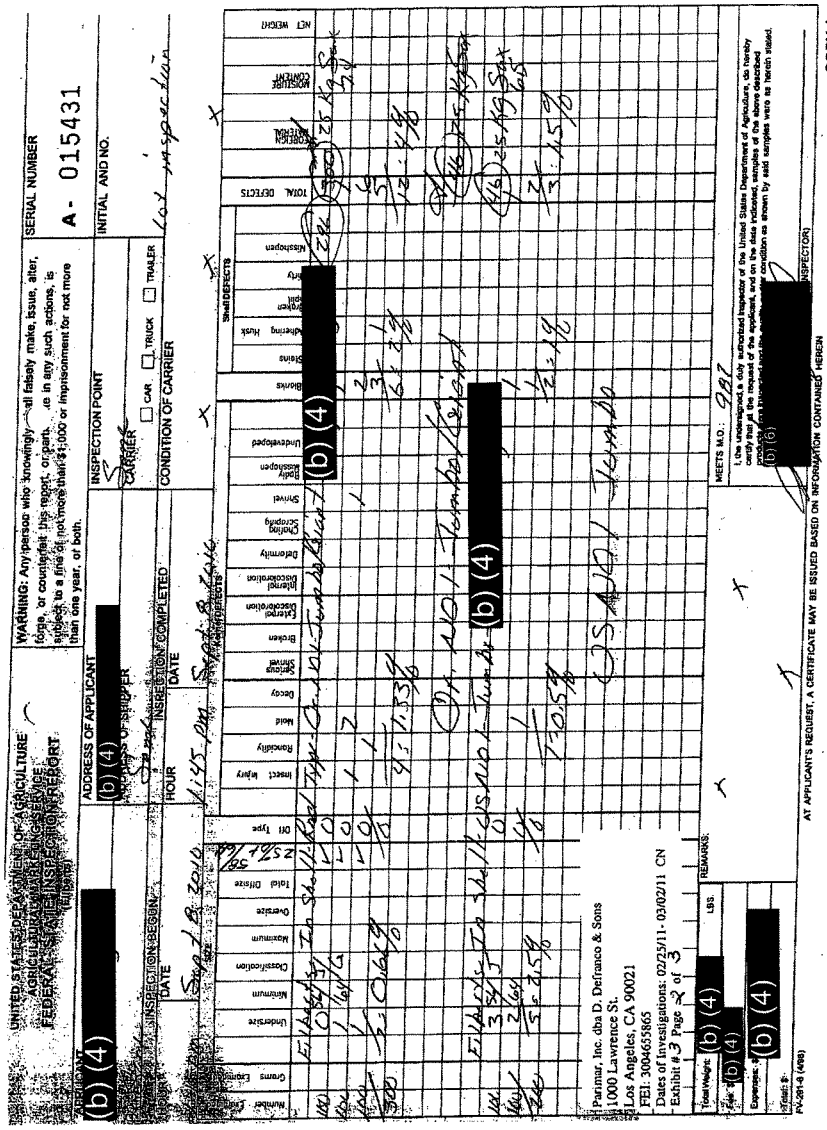
P.O. Number	Terms	Rep	Ship	Via	F.O.B.	S.O. No.
	(b) (4)		9/14/2010	PickUp	(b) (4)	1401

Quantity	Item Code	Description	Price Each	USDA Inspection	Amount
(b) (4)	Jumbo/Giant	Jumbo/Giant Inshell Hazelnuts	(b) (4)	A-015431	(b) (4)
(b) (4)	Jumbo	Jumbo Inshell Hazelnuts	(b) (4)	A-015431	(b) (4)

Parimar, Inc. dba D. Defranco & Sons
1000 Lawrence St.
Los Angeles, CA 90021
FEI: 3004655865
Dates of Investigations: 02/25/11- 03/02/11 CN
Exhibit # 3 Page 1 of 3

: Packing is now Kosher Certified.

Total USD (b) (4)


UNITED STATES DEPARTMENT OF AGRICULTURE
AGRICULTURAL MARKETING SERVICE
FEDERAL-STATE INSPECTION SERVICE
WARNING: Any person who knowingly shall falsely make, issue, alter, forge, or counterfeit this report, or part... ate in any such actions, is subject to a fine of not more than $1,000 or imprisonment for not more than one year, or both.
SERIAL NUMBER
A- 015431
APPLICANT
(b) (4)
ADDRESS OF APPLICANT
(b) (4)
INSPECTION POINT
CARRIER
INITIAL AND NO.
CAR TRUCK TRAILER
INSPECTION BEGUN
DATE
Sept 8, 2010
HOUR
1:45 pm
INSPECTION COMPLETED
DATE
Sept 8, 2010
CONDITION OF CARRIER
Lot inspection
Parimar, Inc. dba D. Defranco & Sons
1000 Lawrence St.
Los Angeles, CA 90021
FEI: 3004655865
Dates of Investigations: 02/25/11- 03/02/11 CN
Exhibit #3 Page 2 of 3
(b) (4)
LBS.
REMARKS:
MEETS M.O.:
AT APPLICANT'S REQUEST, A CERTIFICATE MAY BE ISSUED BASED ON INFORMATION CONTAINED HEREIN
(INSPECTOR)
COPY 1

(b) (4)

Bill of Lading

Date	Invoice #
9/14/2010	1617

Ship To
1000 Lawrence Street Los Angeles, CA 90021 USA

P.O. No.	Ship	Via	FOB	Project
	9/14/2010	PickUp	(b) (4)	

Quantity	Item Code	Description	USDA Inspection
(b) (4)	Jumbo/Giant	Jumbo/Giant Inshell Hazelnuts	A 015431
(b) (4)	Jumbo	Jumbo Inshell Hazelnuts	A 015431

9-17-10

CFL (b) (6)

Truck

Trailer

LOTE #9093

...IER NAME (Sign and Date) accepts the property described above in good order.

(b) (6)

Parimar, Inc. dba D. Defranco & Sons
1000 Lawrence St.
Los Angeles, CA 90021
FEI: 3004655865
Dates of Investigations: 02/25/11- 03/02/11 CN
Exhibit # 3 Page 3 of 3

(b) (4)

Invoice

Date	Invoice #
10/11/2010	1643

Bill To	Ship To
De Franco & Sons 1000 Lawrence Street Los Angeles, CA 90021	1000 Lawrence Street Los Angeles, CA 90021 USA

P.O. Number	Terms	Rep	Ship	Via	F.O.B.	S.O. No.
(	(b) (4)		10/11/2010	Truck	(b) (4)	1410

Quantity	Item Code	Description	Price Each	USDA Inspection	Amount
(b) (4)	Large	Large Inshell Hazelnuts (b) (4) 50lb bags on wooden pallets	(b) (4)	2016086	(b) (4)

only

(b) (4)

(b) (4)

(b) (4)

Parimar, Inc. dba D. Defranco & Sons
1000 Lawrence St.
Los Angeles, CA 90021
FEI: 3004655865
Dates of Investigations: 02/25/11- 03/02/11 CN
Exhibit # 4 Page 1 of 4

orge Packing is now Kosher Certified.

Total USD (b) (4)

(b) (4)

Bill of Lading

Date	Invoice #
10/11/2010	1643

Ship To
1000 Lawrence Street Los Angeles, CA 90021 USA

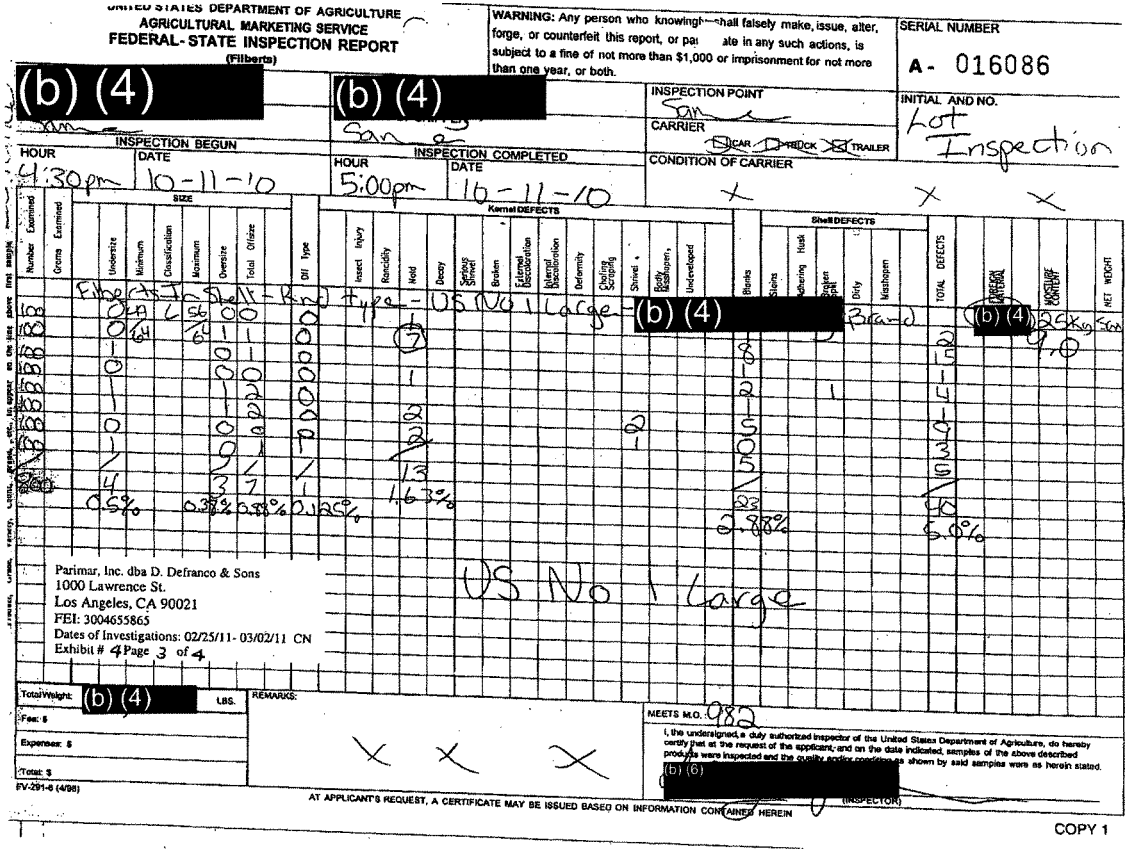
P.O. No.	Ship	Via	FOB	Project
	10/11/2010	Truck	(b) (4)	

Quantity	Item Code	Description	USDA Inspection
(b) (4)	Large	Large Inshell Hazelnuts Truck Co: Truck Lic (b) (6) Trailer Lic: Seal:	a-016086

ARRIER NAME (Sign and Date) accepts the property described above in good order.

(b) (6)

Parimar, Inc. dba D. Defranco & Sons
1000 Lawrence St.
Los Angeles, CA 90021
FEI: 3004655865
Dates of Investigations: 02/25/11- 03/02/11 CN
Exhibit # 4 Page 2 of 4



UNITED STATES DEPARTMENT OF AGRICULTURE
AGRICULTURAL MARKETING SERVICE
FEDERAL-STATE INSPECTION REPORT
(Filberts)

WARNING: Any person who knowingly shall falsely make, issue, alter, forge, or counterfeit this report, or participate in any such actions, is subject to a fine of not more than $1,000 or imprisonment for not more than one year, or both.

SERIAL NUMBER: A- 016086

(b) (4)

(b) (4)

INITIAL AND NO.: Lot Inspection

INSPECTION POINT: San

CARRIER: CAR TRUCK TRAILER

CONDITION OF CARRIER: X X X

INSPECTION BEGUN — HOUR: 4:30pm DATE: 10-11-10

INSPECTION COMPLETED — HOUR: 5:00pm DATE: 10-11-10

SIZE: Number Examined; Grams Examined; Undersize; Minimum; Classification; Maximum; Oversize; Total; Off Type

Kernel DEFECTS: Insect Injury; Rancidity; Mold; Decay; Serious Stained; Broken; External Discoloration; Internal Discoloration; Deformity; Cloying Scraping; Shrivel +; Body Misshapen, Undeveloped

Shell DEFECTS: Blanks; Stains; Adhering Husk; Broken Shell; Dirty; Misshapen

TOTAL DEFECTS; FOREIGN MATERIAL; MOISTURE CONTENT; NET WGHT

Shell - Run of Type - US No 1 Large

(b) (4) Brand

Parimar, Inc. dba D. Defranco & Sons
1000 Lawrence St.
Los Angeles, CA 90021
FEI: 3004655865
Dates of Investigations: 02/25/11- 03/02/11 CN
Exhibit # 4 Page 3 of 4

US No 1 Large

Total Weight: (b) (4) LBS.

REMARKS: X X X

Fee: $

Expenses: $

Total: $

MEETS M.O.: 982

I, the undersigned, a duly authorized inspector of the United States Department of Agriculture, do hereby certify that at the request of the applicant, and on the date indicated, samples of the above described products were inspected and the quality and/or conditions as shown by said samples were as herein stated.

(b) (6)

(INSPECTOR)

FV-291-6 (4/98)

AT APPLICANT'S REQUEST, A CERTIFICATE MAY BE ISSUED BASED ON INFORMATION CONTAINED HEREIN

COPY 1

(b) (4)

Bill of Lading

Date	Invoice #
10/11/2010	1643

Ship To
1000 Lawrence Street Los Angeles, CA 90021 USA

P.O. No.	Ship	Via	FOB	Project
	10/11/2010	Truck	(b) (4)	

Quantity	Item Code	Description	USDA Inspection
(b) (4)	Large	Large Inshell Hazelnuts	a-016086

(b) (4)

LOTE #1289

Truck Co:
Truck Lic
Trailer Lic:
Seal: 9328512

(b) (4)

(b) (4) SX

State of California
Dept. of Food and Agriculture

OCT 1 6 2010

Handbook Inspection Station

Feliz cumpleaños

RRIER NAME (Sign and Date) accepts the property described above in good order.
(b) (6)

Parimar, Inc. dba D. Defranco & Sons
1000 Lawrence St.
Los Angeles, CA 90021
FEI: 3004655865
Dates of Investigations: 02/25/11- 03/02/11 CN
Exhibit # 4 Page 4 of 4

(b) (4)

Invoice

Date	Invoice #
10/27/2010	1671

Bill To	Ship To
De Franco & Sons 1000 Lawrence Street Los Angeles, CA 90021	1000 Lawrence Street Los Angeles, CA 90021 USA

P.O. Number	Terms	Rep	Ship	Via	F.O.B.	S.O. No.
(	(b) (4)		10/27/2010	Ocean Vessel	(b) (4) Plant	1429

Quantity	Item Code	Description	Price Each	USDA Inspection	Amount
(b) (4)	Large	Large Inshell Hazelnuts Load (b) (4)	1.62	A-016662	(b) (4)

(b) (4) SY

(b) (4) Bag

(b) (4)

Parimar, Inc. dba D. Defranco & Sons
1000 Lawrence St.
Los Angeles, CA 90021
FEI: 3004655865
Dates of Investigations: 02/25/11- 03/02/11 CN
Exhibit # 5 Page 1 of 5

a pleasure working with you!

Total USD (b) (4)

(b) (4)

Bill of Lading

Date	Invoice #
10/27/2010	1671

Ship To
1000 Lawrence Street Los Angeles, CA 90021 USA

P.O. No.	Ship	Via	FOB	Project
	10/27/2010	Ocean Vessel	(b) (4)	

Quantity	Item Code	Description	USDA Inspection
(b) (4)	Large	Large Inshell Hazelnuts (b) (4) F.O.B	A-016662

Truck: (b) (4)
Truck Lic:
Trailer Lic:

State of California
Dept. of Food and Agriculture

NOV 0 1 2010

Hornbrook Inspection Station

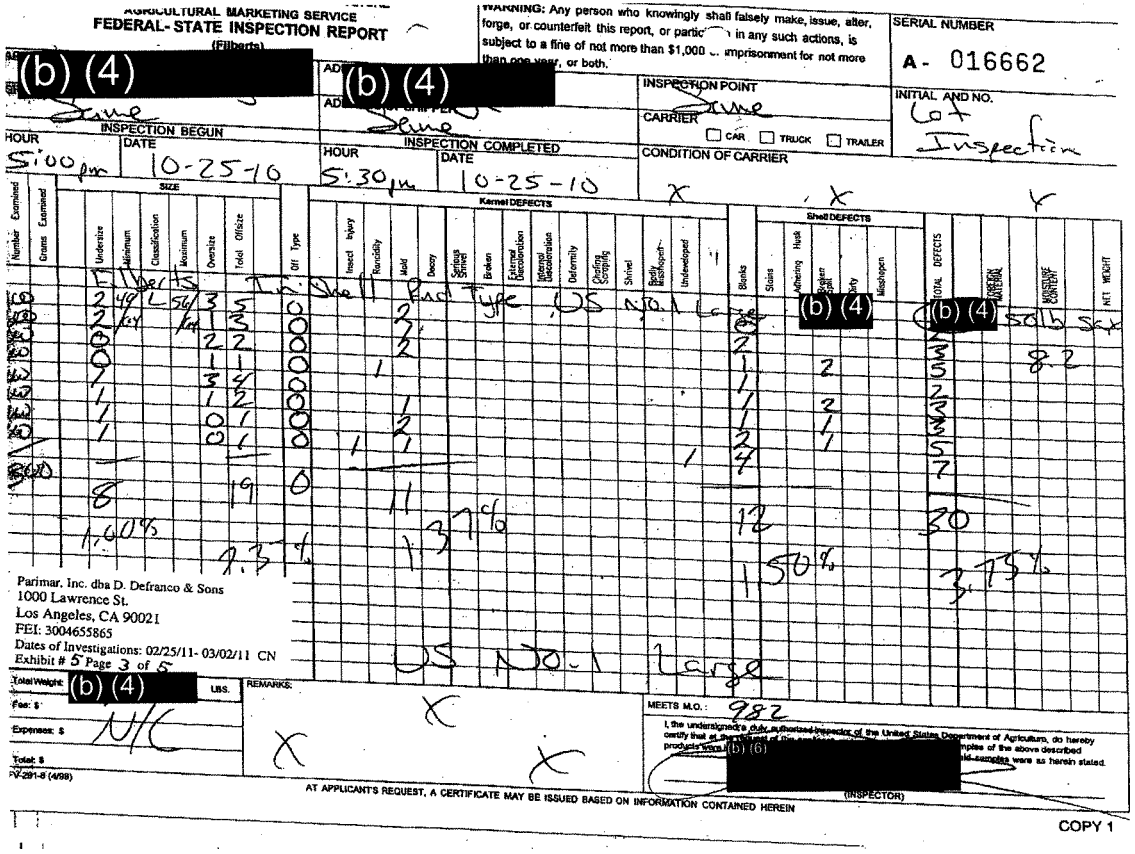
11-2-10

LOT # 1342

ER NAME (Sign and Date) accepts the property described above in good order.

(b) (6)

Parimar, Inc. dba D. Defranco & Sons
1000 Lawrence St.
Los Angeles, CA 90021
FEI: 3004655865
Dates of Investigations: 02/25/11- 03/02/11 CN
Exhibit # 5 Page 2 of 5



AGRICULTURAL MARKETING SERVICE
FEDERAL-STATE INSPECTION REPORT
(Filberts)

WARNING: Any person who knowingly shall falsely make, issue, alter, forge, or counterfeit this report, or partic[illegible] in any such actions, is subject to a fine of not more than $1,000 [illegible] imprisonment for not more than one year, or both.

SERIAL NUMBER: A- 016662

(b) (4) [redacted]

Same

INSPECTION BEGUN: HOUR 5:00 pm DATE 10-25-10

(b) (4) [redacted]

Same

INSPECTION COMPLETED: HOUR 5:30 pm DATE 10-25-10

INSPECTION POINT: Same

CARRIER: ☐ CAR ☐ TRUCK ☐ TRAILER

CONDITION OF CARRIER: X

INITIAL AND NO.: Lot Inspection

X

X

SIZE: Number Examined; Grams Examined; Undersize; Minimum; Classification; Maximum; Oversize; Total Offsize; Off Type

Kernel DEFECTS: Insect Injury; Rancidity; Mold; Decay; Serious Shrivel; Broken; External Discoloration; Internal Discoloration; Deformity; Checking Scorching; Shrivel; Body Mashopen; Undeveloped; Blanks

Shell DEFECTS: Stains; Adhering Husk; Broken Shell; Dirty; Mashopen

TOTAL DEFECTS; MATERIAL OTHER; MOISTURE CONTENT; NET WEIGHT

Parimar, Inc. dba D. Defranco & Sons
1000 Lawrence St.
Los Angeles, CA 90021
FEI: 3004655865
Dates of Investigations: 02/25/11- 03/02/11 CN
Exhibit # 5 Page 3 of 5

Total Weight: (b) (4) [redacted] LBS.

Fee: $

Expenses: $

Total: $

N/C

REMARKS:

X

X

MEETS M.O.: 982

I, the undersigned duly authorized Inspector of the United States Department of Agriculture, do hereby certify that at the request of the applicant I inspected a sample of the above described products and that the results of the said samples were as herein stated.

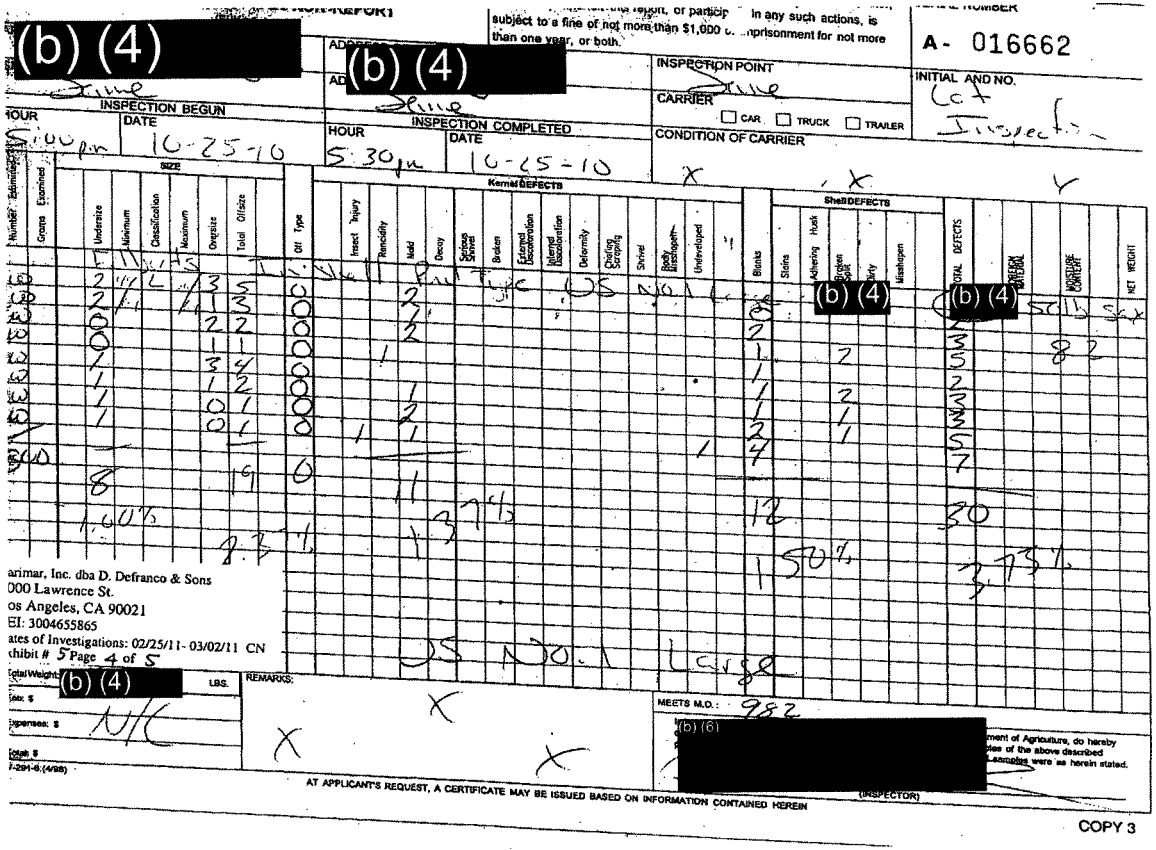
(b) (6) [redacted]

(INSPECTOR)

AV-291-8 (4/98)

AT APPLICANT'S REQUEST, A CERTIFICATE MAY BE ISSUED BASED ON INFORMATION CONTAINED HEREIN

COPY 1



(b) (4)

(b) (4)

subject to a fine of not more than $1,000 ... imprisonment for not more than one year, or both.

A- 016662

INITIAL AND NO.

INSPECTION POINT

CARRIER ☐ CAR ☐ TRUCK ☐ TRAILER

CONDITION OF CARRIER

INSPECTION BEGUN HOUR 5:00 p.m. DATE 10-25-10

INSPECTION COMPLETED HOUR 5:30 p.m. DATE 10-25-10

SIZE

KernelDEFECTS

ShellDEFECTS

(b) (4)

(b) (4)

arimar, Inc. dba D. Defranco & Sons
000 Lawrence St.
os Angeles, CA 90021
EI: 3004655865
ates of Investigations: 02/25/11- 03/02/11 CN
chibit # 5 Page 4 of 5

(b) (4) LBS.

REMARKS:

MEETS M.D.: 982

(b) (6)

(INSPECTOR)

AT APPLICANT'S REQUEST, A CERTIFICATE MAY BE ISSUED BASED ON INFORMATION CONTAINED HEREIN

COPY 3

(b) (4)

CERTIFICATE OF FUMIGATION

DATE OF FUMIGATION: **10/25/2010**

This is to certify that on this date we have fumigated:

BOOKING NO.: **Import Permit#P-2007-03940**

COMMODITY: **Hazelnuts**

GAS: (b) (4)

LOCATED AT: (b) (4)

TEMPERATURE: **72 Degrees F.** EXPOSURE TIME: **24 Hours**

Fumigation performed by (b) (4)

FOR THE ACCOUNT OF: (b) (4)

Final Reading: less than 5PPM

(b) (6)

Parimar, Inc. dba D. Defranco & Sons
1000 Lawrence St.
Los Angeles, CA 90021
FEI: 3004655865
Dates of Investigations: 02/25/11- 03/02/11 CN

(b) (4)

Bill of Lading

Date	Invoice #
11/2/2010	1683

Ship To
1000 Lawrence Street Los Angeles, CA 90021 USA

P.O. No.	Ship	Via	FOB	Project
	11/2/2010	Truck	(b) (4)	

Quantity	Item Code	Description	USDA Inspection
~~44,000~~ (b) (4)	Large	Large Inshell Hazelnuts TRUCK CO: (b) (4) TRUCK LIC: TRAILER LI Seal # 9328558 (b) (4) Pallets Donald DeFranco (b) (4) Bags 11/24/10	LOT # 1425

(b) (4)

IER NAME (Sign and Date) accepts the property described above in good order.

(b) (6)

Parimar, Inc. dba D. Defranco & Sons
1000 Lawrence St.
Los Angeles, CA 90021
PEI: 3004655865
Dates of Investigations: 02/25/11- 03/02/11 CN

(b) (4)

INVOICE

Invoice : Original
Page 1 of 1

Invoice No : 595178
Invoice Date : 11/22/2010
Order No : 632010-0
Order Date : 11/22/2010
Cust PO No :

Date Shipped : 11/22/2010
Carrier : (b) (4)
Freight :
FOB : (b) (4)

Sold To : DDE01
D DE FRANCO & SONS
1000 LAWRENCE ST
LOS ANGELES, CA 90021

Ship To :
D DE FRANCO & SONS
1000 LAWRENCE ST
LOS ANGELES, CA 90021

Contact : (b) (4)
Terms :
Tax : EXEMPT

	Item No / Description	Ordered	Shipped	UOM	Unit Price	Ext Amount
1	430-010 FILBERTS IN SHELL LARGE 50 LB	(b) (4)	(b) (4)	EA	(b) (4)	(b) (4)

(b) (6)

Parimar, Inc. dba D. Defranco & Sons
1000 Lawrence St.
Los Angeles, CA 90021
FEI: 3004655865
Dates of Investigations: 02/25/11- 03/02/11 CN
Exhibit # 7 Page 1 of 1

Remit To : (b) (4)

Qty Shipped: (b) (4)

Comments :

If any of the above items are labeled organic, they have been organically grown and processed in accordance with the USDA National Organic Standards

Subtotal : (b) (4)
Tax :
Freight :
Invoice Total : (b) (4)
Total Payments :
Amount Due :

2:29 PM
02/25/11
Accrual Basis

D DE FRANCO & SONS
Sales by Customer Detail
February 1, 2010 through February 25, 2011

Type	Date	Num	Memo	Name	Qty
(b) (4)					
Invoice	5/3/2010	(b) (4)	(b) (4)	(b) (4)	(b) (4)
Invoice	6/14/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	9/17/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	10/18/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	10/18/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	10/18/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	10/18/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	10/18/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	10/18/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	10/18/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	10/18/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	10/18/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	10/18/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	10/18/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	10/18/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	10/18/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	10/18/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	10/18/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	10/18/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	10/18/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	10/18/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	10/18/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	10/18/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	10/18/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	10/18/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	10/18/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	10/18/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	10/18/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	11/3/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	11/3/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	11/3/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	11/11/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	11/11/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	11/11/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	11/11/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	11/11/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	11/11/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	11/11/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	11/11/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	11/11/2010	[redacted]	[redacted]	b) (4)	[redacted]
Invoice	11/11/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	11/12/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	11/12/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	11/12/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	11/12/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	11/12/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	11/18/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	11/18/2010	(b) (4)	[redacted]	[redacted]	[redacted]
Invoice	11/19/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	11/19/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	11/19/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	11/19/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	11/19/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	11/19/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	11/19/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	11/19/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	11/19/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	11/19/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	11/22/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	11/22/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	11/22/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	11/22/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	11/22/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	11/22/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	11/22/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	11/22/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	11/22/2010	[redacted]	[redacted]	[redacted]	[redacted]

Parimar, Inc. dba D. Defranco & Sons
1000 Lawrence St.
Los Angeles, CA 90021
FEI: 3004655865
Dates of Investigations: 02/25/11 - 03/02/11 CN
Exhibit # 8 Page 1 of 4

2:29 PM

02/25/11

Accrual Basis

D DE FRANCO & SONS
Sales by Customer Detail
February 1, 2010 through February 25, 2011

Type	Date	Num	Memo	Name	Qty
Invoice	11/22/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	11/22/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	11/22/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	11/22/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	11/22/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	11/22/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	11/29/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	12/2/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	12/2/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	12/2/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	12/2/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	12/2/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	12/2/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	12/2/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	12/6/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	12/6/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	12/6/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	12/6/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	12/6/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	12/6/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	12/6/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	12/6/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	12/6/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	12/6/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	12/6/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	12/6/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	12/6/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	12/6/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	12/6/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	12/6/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	12/6/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	12/6/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	12/9/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	12/9/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	12/9/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	12/9/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	12/9/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	12/9/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	12/15/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	12/15/2010	[redacted]	[redacted]	[redacted]	[redacted]
Invoice	2/3/2011	[redacted]	[redacted]	[redacted]	[redacted]

Total RUSS DAVIS WHOLESALE, INC.

TOTAL

Parimar, Inc. dba D. Defranco & Sons
1000 Lawrence St.
Los Angeles, CA 90021
FEI: 3004655865
Dates of Investigations: 02/25/11 - 03/02/11 CN
Exhibit # 8 Page 9 of 4

2:30 PM
02/25/11
Accrual Basis

D DE FRANCO & SONS
Sales by Customer Detail
February 1, 2010 through February 25, 2011

Type	Date	Num	Memo	Name	Qty
(b) (4)					
Invoice	10/20/2010				
Invoice	10/20/2010				
Invoice	10/20/2010				
Invoice	10/20/2010				
Invoice	10/20/2010				
Invoice	10/20/2010				
Invoice	10/20/2010				
Invoice	10/20/2010				
Invoice	10/20/2010				
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Invoice	11/10/2010				
Invoice	11/17/2010				
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Invoice	11/17/2010				
Invoice	11/17/2010				
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Invoice	11/17/2010				
Invoice	11/17/2010				

(b) (4)

(b) (4)

(b) (4)

(b) (4)

Parimar, Inc. dba D. Defranco & Sons
1000 Lawrence St.
Los Angeles, CA 90021
FEI: 300465865
Dates of Investigations: 02/25/11- 03/02/11 CN
Exhibit # 8 Page 3 of 4

2:30 PM
02/25/11
Accrual Basis

D DE FRANCO & SONS
Sales by Customer Detail
February 1, 2010 through February 25, 2011

Type	Date	Num	Memo	Name	Qty
Invoice	11/17/2010	(b) (4)	(b) (4)		(b) (4)
Invoice	11/17/2010				
Invoice	11/17/2010				
Invoice	11/17/2010				
Invoice	11/24/2010				
Invoice	11/24/2010				
Invoice	11/24/2010				
Invoice	11/24/2010				
Invoice	11/24/2010				
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Invoice	11/24/2010				
Invoice	11/24/2010				
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Invoice	11/24/2010				
Invoice	12/1/2010				
Invoice	12/1/2010				
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Invoice	12/15/2010				
Invoice	12/22/2010				
Invoice	12/22/2010				
Invoice	12/22/2010				
Invoice	12/22/2010				
Invoice	12/22/2010				
Total THE POTATO KING CO					
TOTAL					

1000 LAWRENCE ST.
LOS ANGELES, CA 90021-1620
TEL. (213) 627-8575 • FAX (213) 627-9837
E-mail: Defrancomp@aol.com

INVOICE

DATE	INVOICE NO
10/20/2010	165310

BILL TO

(b) (4)

SHIP TO

(b) (4)

Product of	P.O. No.	TERMS	DUE DATE	REP	SHIP DATE
USA	28292	(b) (4)	10/20/2010		10/20/2010

CODE	SHIPPED	DESCRIPTION	QTY	U.P.	AMOUNT
400-465M	(b) (4)	11 LB MEDJOOL DATES	(b) (4)	(b) (4)	(b) (4)
400-324		24/1 LB MIXED NUTS			
400-336		24/1LB BRAZILS			
400-338		24/1LB FILBERTS			
400-440		24/1LB WALNUTS			
400-335		24/1LB ALMONDS			
400-331		24/1 LB PECANS			
00-423		50 LB IMPERIAL MIXED NUTS			
400-334		50 LB BRAZILS			
400-326		50 LB FILBERTS			
400-111		50 LB JUMBO WALNUT			
400-327		50 LB ALMONDS			
400-346		50 LB NATURAL PECANS			
00-461		DISPLAY NUT BINS			
ALLETS		PALLETS			
		(b) (6)			

ank you for your business.

TOTAL [redacted]

NEW TOTAL (b) (4)

Perishable Agricultural Commodities Listed on this invoice are sold subject to the
utory trust authorized by section 5(c) of the perishable agricultural commodities act,
0 (7 U.S.C. 499 e(c)). The seller of these commodities retains a trust claim over these
modities. All inventories of food or other products derived from these commodities, and
receivables or proceeds from the sale of these commodities until full payment is
ived.

. ACCOUNTS PAYABLE WEEKLY - NO DISCOUNTS - FREIGHT COLLECT

DRIVER is responsible for all merchandise unless invoiced otherwise.

Parimar, Inc. dba D. Defranco & Sons
1000 Lawrence St.
Los Angeles, CA 90021
FEI: 3004655865
Dates of Investigations: 02/25/11- 03/02/11 CN

1000 LAWRENCE ST.
LOS ANGELES, CA 90021-1620
TEL. (213) 627-8575 • FAX (213) 627-9837
E-mail: Defrancomp@aol.com

INVOICE

DATE	INVOICE NO
10/26/2010	165397

BILL TO

(b) (4)

SHIP TO

(b) (4)

Product of	P.O. No.	TERMS	DUE DATE	REP	SHIP DATE
USA	28392	(b) (4)	10/26/2010		10/26/2010

CODE	SHIPPED	DESCRIPTION	QTY	U.P.	AMOUNT
400-327	(b) (4)	50 LB ALMONDS	(b) (4)	(b) (4)	(b) (4)
00-423		50 LB IMPERIAL MIXED NUTS			
400-334		50 LB BRAZILS			
400-326		50 LB FILBERTS			
400-111		50 LB JUMBO WALNUT			
400-346		50 LB NATURAL PECANS			
400-465M		11 LB MEDJOOL DATES			
400-324		24/1 LB MIXED NUTS			
400-336		24/1LB BRAZILS			
400-338		24/1LB FILBERTS			
400-440		24/1LB WALNUTS			
400-335		24/1LB ALMONDS			
400-331		24/1 LB PECANS			
00-461		DISPLAY NUT BINS			
ALLETS		PALLETS			

(b) (6)

(b) (4)

Thank you for your business.

TOTAL (b) (4)

The Perishable Agricultural Commodities Listed on this invoice are sold subject to the Statutory trust authorized by section 5(c) of the perishable agricultural commodities act, 1930 (7 U.S.C. 499 e(c)). The seller of these commodities retains a trust claim over these commodities. All inventories of food of other products derived from these commodities, and any receivables or proceeds from the sale of these commodities until full payment is received.

ALL ACCOUNTS PAYABLE WEEKLY - NO DISCOUNTS - FREIGHT COLLECT

THE DRIVER is responsible for all merchandise when invoice is signed

Parimar, Inc. dba D. Defranco & Sons
1000 Lawrence St.
Los Angeles, CA 90021
FEI: 3004655865
Dates of Investigations: 02/25/11- 03/02/11 CN
Exhibit # 9 Page 2 of 11

1000 LAWRENCE ST.
LOS ANGELES, CA 90021-1620
TEL. (213) 627-8575 • FAX (213) 627-9837
E-mail: Defrancomp@aol.com

INVOICE

DATE	INVOICE NO
10/27/2010	165404

BILL TO

(b) (4)

SHIP TO

(b) (4)

Product of	P.O. No.	TERMS	DUE DATE	REP	SHIP DATE
USA	28392	(b) (4)	10/27/2010		10/27/2010

CODE	SHIPPED	DESCRIPTION	QTY	U.P.	AMOUNT
400-111 400-327 400-326 400-334	(b) (4)	50 LB JUMBO WALNUT 50 LB ALMONDS 50 LB FILBERTS 50 LB BRAZILS	(b) (4)	(b) (4)	(b) (4)

(b) (6)

(b) (4)

ank you for your business.

TOTAL (b) (4)

e Perishable Agricultural Commodities Listed on this invoice are sold subject to the
tutory trust authorized by section 5(c) of the perishable agricultural commodities act,
0 (7 U.S.C. 499 e(c)). The seller of these commodities retains a trust claim over these
modities. All inventories of food of other products derived from these commodities, and
receivables or proceeds from the sale of these commodities until full payment is
ived.

ACCOUNTS PAYABLE WEEKLY - NO DISCOUNTS - FREIGHT COLLECT

3 DRIVER is responsible for all merchandise when invoice is signed

Parimar, Inc. dba D. Defranco & Sons
1000 Lawrence St.
Los Angeles, CA 90021
FEI: 3004655865
Dates of Investigations: 02/25/11- 03/02/11 CN
Exhibit # 9 Page 2 of 11

1000 LAWRENCE ST.
LOS ANGELES, CA 90021-1620
TEL. (213) 627-8575 • FAX (213) 627-9837
E-mail: Defrancomp@aol.com

INVOICE

DATE	INVOICE NO
11/3/2010	165517

BILL TO

(b) (4)

SHIP TO

(b) (4)

Product of	P.O. No.	TERMS	DUE DATE	REP	SHIP DATE
USA	28511	(b) (4)	11/3/2010		11/3/2010

CODE	SHIPPED	DESCRIPTION	QTY	U.P.	AMOUNT
400-465M	(b) (4)	11 LB MEDJOOL DATES	(b) (4)	(b) (4)	(b) (4)
400-324		24/1 LB MIXED NUTS			
400-336		24/1LB BRAZILS			
400-338		24/1LB FILBERTS			
400-331		24/1 LB PECANS			
00-423		50 LB IMPERIAL MIXED NUTS			
400-334		50 LB BRAZILS			
400-326		50 LB FILBERTS			
400-111		50 LB JUMBO WALNUT			
400-346		50 LB NATURAL PECANS			
400-327		50 LB ALMONDS			
400-461		DISPLAY NUT BINS			
PALLETS		PALLETS			

(b) (4) (b) (6) TOTAL (b) (4)

The Perishable Agricultural Commodities Listed on this invoice are sold subject to the Statutory trust authorized by section 5(c) of the perishable agricultural commodities act, 1930 (7 U.S.C. 499 e(c)). The seller of these commodities retains a trust claim over these commodities. All inventories of food of other products derived from these commodities, and any receivables or proceeds from the sale of these commodities until full payment is received.

ALL ACCOUNTS PAYABLE WEEKLY - NO DISCOUNTS - FREIGHT COLLECT

THE DRIVER is responsible for all merchandise when invoice is signed

Parimar, Inc. dba D. Defranco & Sons
1000 Lawrence St.
Los Angeles, CA 90021
FEI: 3004655865
Dates of Investigations: 02/25/11- 03/02/11 CN

1000 LAWRENCE ST.
LOS ANGELES, CA 90021-1620
TEL. (213) 627-8575 • FAX (213) 627-9837
E-mail: Defrancomp@aol.com

INVOICE

DATE	INVOICE NO
11/10/2010	165623

BILL TO

(b) (4)

SHIP TO

(b) (4)

Product of	P.O. No.	TERMS	DUE DATE	REP	SHIP DATE
USA	28600	(b) (4)	11/10/2010		11/10/2010

CODE	SHIPPED	DESCRIPTION	QTY	U.P.	AMOUNT
400-465M	(b) (4)	11 LB MEDJOOL DATES	(b) (4)	(b) (4)	(b) (4)
400-440		24/1LB WALNUTS			
400-331		24/1 LB PECANS			
00-423		50 LB IMPERIAL MIXED NUTS			
400-334		50 LB BRAZILS			
400-326		50 LB FILBERTS			
400-111		50 LB JUMBO WALNUT			
400-327		50 LB ALMONDS			
400-346		50 LB NATURAL PECANS			
400-461		DISPLAY NUT BINS			
PALLETS		PALLETS			

Parimar, Inc. dba D. Defranco & Sons
1000 Lawrence St.
Los Angeles, CA 90021
FEI: 3004655865
Dates of Investigations: 02/25/11- 03/02/11 CN
Exhibit # 9 Page 5 of 11

ank you for your business.

TOTAL (b) (4)

Perishable Agricultural Commodities Listed on this invoice are sold subject to the utory trust authorized by section 5(c) of the perishable agricultural commodities act, 0 (7 U.S.C. 499 e(c)). The seller of these commodities retains a trust claim over these modities. All inventories of food of other products derived from these commodities, and receivables or proceeds from the sale of these commodities until full payment is ived.

(b) (6)

11-10-10.

ACCOUNTS PAYABLE WEEKLY - NO DISCOUNTS - FREIGHT COLLECT

DRIVER is responsible for all merchandise when invoice is signed

1000 LAWRENCE ST.
LOS ANGELES, CA 90021-1620
TEL. (213) 627-8575 • FAX (213) 627-9837
E-mail: Defrancomp@aol.com

INVOICE

DATE	INVOICE NO
11/17/2010	165734

BILL TO

(b) (4)

SHIP TO

(b) (4)

Product of	P.O. No.	TERMS	DUE DATE	REP	SHIP DATE
USA	28714	(b) (4)	11/17/2010		11/17/2010

CODE	SHIPPED	DESCRIPTION	QTY	U.P.	AMOUNT
400-465M	(b) (4)	11 LB MEDJOOL DATES	(b) (4)	(b) (4)	(b) (4)
400-324		24/1 LB MIXED NUTS			
400-440		24/1LB WALNUTS			
400-331		24/1 LB PECANS			
400-335		24/1LB ALMONDS			
00-423		50 LB IMPERIAL MIXED NUTS			
400-334		50 LB BRAZILS			
400-326		50 LB FILBERTS			
400-111		50 LB JUMBO WALNUT			
400-327		50 LB ALMONDS			
400-346		50 LB NATURAL PECANS			
PALLETS		PALLETS			
				TOTAL	(b) (4)

(b) (4)

(b) (6)

The Perishable Agricultural Commodities Listed on this invoice are sold subject to the Statutory trust authorized by section 5(c) of the perishable agricultural commodities act, 1930 (7 U.S.C. 499 e(c)). The seller of these commodities retains a trust claim over these commodities. All inventories of food of other products derived from these commodities, and any receivables or proceeds from the sale of these commodities until full payment is received.

ALL ACCOUNTS PAYABLE WEEKLY - NO DISCOUNTS - FREIGHT COLLECT

THE DRIVER is responsible for all merchandise when invoice is signed

Parimar, Inc. dba D. Defranco & Sons
1000 Lawrence St.
Los Angeles, CA 90021
FEI: 3004655865
Dates of Investigations: 02/25/11- 03/02/11 CN

1000 LAWRENCE ST.
LOS ANGELES, CA 90021-1620
TEL. (213) 627-8575 • FAX (213) 627-9837
E-mail: Defrancomp@aol.com

INVOICE

DATE	INVOICE NO
11/24/2010	165861

BILL TO

(b) (4)

SHIP TO

(b) (4)

Product of	P.O. No.	TERMS	DUE DATE	REP	SHIP DATE
USA	28839	(b) (4)	11/24/2010		11/24/2010

CODE	SHIPPED	DESCRIPTION	QTY	U.P.	AMOUNT
400-465M	(b) (4)	11 LB MEDJOOL DATES	(b) (4)	(b) (4)	(b) (4)
400-465		24/10 oz CUP PITTED DATES			
400-324		24/1 LB MIXED NUTS			
00-423		50 LB IMPERIAL MIXED NUTS			
400-334		50 LB BRAZILS			
400-326		50 LB FILBERTS			
400-111		50 LB JUMBO WALNUT			
400-327		50 LB ALMONDS			
400-346		50 LB NATURAL PECANS			
400-461		DISPLAY NUT BINS			
PALLETS		PALLETS			

(b) (6)

nk you for your business.

TOTAL (b) (4)

Perishable Agricultural Commodities Listed on this invoice are sold subject to the utory trust authorized by section 5(c) of the perishable agricultural commodities act,) (7 U.S.C. 499 e(c)). The seller of these commodities retains a trust claim over these modities. All inventories of food of other products derived from these commodities, and receivables or proceeds from the sale of these commodities until full payment is ved.

ACCOUNTS PAYABLE WEEKLY - NO DISCOUNTS - FREIGHT COLLECT

DRIVER is responsible for all merchandise when invoice is signed

Parimar, Inc. dba D. Defranco & Sons
1000 Lawrence St.
Los Angeles, CA 90021
FEI: 3004655865
Dates of Investigations: 02/25/11- 03/02/11 CN

1000 LAWRENCE ST.
LOS ANGELES, CA 90021-1620
TEL. (213) 627-8575 • FAX (213) 627-9837
E-mail: Defrancomp@aol.com

INVOICE

DATE	INVOICE NO
12/1/2010	165956

BILL TO
(b) (4)

SHIP TO
(b) (4)

Product of	P.O. No.	TERMS	DUE DATE	REP	SHIP DATE
USA-BRAZIL	28918	(b) (4)	12/1/2010		12/1/2010

CODE	SHIPPED	DESCRIPTION	QTY	U.P.	AMOUNT
400-324	(b) (4)	24/1 LB MIXED NUTS	(b) (4)	(b) (4)	(b) (4)
00-423		50 LB IMPERIAL MIXED NUTS			
400-334		50 LB BRAZILS			
400-326		50 LB FILBERTS			
400-111		50 LB JUMBO WALNUT			
400-327		50 LB ALMONDS			
400-346		50 LB NATURAL PECANS			
PALLETS		PALLETS			

(b) (4) (b) (6) TOTAL (b) (4)

The Perishable Agricultural Commodities Listed on this invoice are sold subject to the Statutory trust authorized by section 5(c) of the perishable agricultural commodities act, 1930 (7 U.S.C. 499 e(c)). The seller of these commodities retains a trust claim over these commodities. All inventories of food of other products derived from these commodities, and any receivables or proceeds from the sale of these commodities until full payment is received.

ALL ACCOUNTS PAYABLE WEEKLY - NO DISCOUNTS - FREIGHT COLLECT

THE DRIVER is responsible for all merchandise when invoice is signed

Parimar, Inc. dba D. Defranco & Sons
1000 Lawrence St.
Los Angeles, CA 90021
FEI: 3004655865
Dates of Investigations: 02/25/11- 03/02/11 CN
Exhibit # 4 Page 8 of 11

INVOICE

DATE	INVOICE NO
12/8/2010	166060

1000 LAWRENCE ST.
LOS ANGELES, CA 90021-1620
TEL (213) 627-8575 • FAX (213) 627-9837
E-mail: Defrancomp@aol.com

BILL TO

(b) (4)

SHIP TO

(b) (4)

Product of	P.O. No.	TERMS	DUE DATE	REP	SHIP DATE
usa	29031	(b) (4)	12/8/2010		12/8/2010

CODE	SHIPPED	DESCRIPTION	QTY	U.P.	AMOUNT
400-465M	(b) (4)	11 LB MEDJOOL DATES	(b) (4)	(b) (4)	(b) (4)
400-324		24/1 LB MIXED NUTS			
400-338		24/1LB FILBERTS			
400-440		24/1LB WALNUTS			
00-423		50 LB IMPERIAL MIXED NUTS			
400-334		50 LB BRAZILS			
400-326		50 LB FILBERTS			
400-111		50 LB JUMBO WALNUT			
400-327		50 LB ALMONDS			
PALLETS		PALLETS			

(b) (4)
(b) (6)

ank you for your business. **TOTAL** (b) (4)

: Perishable Agricultural Commodities Listed on this invoice are sold subject to the utory trust authorized by section 5(c) of the perishable agricultural commodities act, 0 (7 U.S.C. 499 e(c)). The seller of these commodities retains a trust claim over these modities. All inventories of food of other products derived from these commodities, and receivables or proceeds from the sale of these commodities until full payment is ived.

. ACCOUNTS PAYABLE WEEKLY - NO DISCOUNTS - FREIGHT COLLECT

DRIVER is responsible for all merchandise when invoice is signed

Parimar, Inc. dba D. Defranco & Sons
1000 Lawrence St.
Los Angeles, CA 90021
FEI: 3004655865
Dates of Investigations: 02/25/11- 03/02/11 CN

1000 LAWRENCE ST.
LOS ANGELES, CA 90021-1620
TEL. (213) 627-8575 • FAX (213) 627-9837
E-mail: Defrancomp@aol.com

INVOICE

DATE	INVOICE NO
12/15/2010	166163

BILL TO
(b) (4)

SHIP TO
(b) (4)

Product of	P.O. No.	TERMS	DUE DATE	REP	SHIP DATE
USA	29137	(b) (4)	12/15/2010		12/15/2010

CODE	SHIPPED	DESCRIPTION	QTY	U.P.	AMOUNT
400-465M	(b) (4)	11 LB MEDJOOL DATES	(b) (4)	(b) (4)	(b) (4)
00-423		50 LB IMPERIAL MIXED NUTS			
400-334		50 LB BRAZILS			
400-326		50 LB FILBERTS			
400-111		50 LB JUMBO WALNUT			
400-327		50 LB ALMONDS			
400-346		50 LB NATURAL PECANS			
PALLETS		PALLETS			

(b) (6)

Thank you for yo

TOTAL (b) (4)

The Perishable Agricultural Commodities Listed on this invoice are sold subject to the Statutory trust authorized by section 5(c) of the perishable agricultural commodities act, 1930 (7 U.S.C. 499 e(c)). The seller of these commodities retains a trust claim over these commodities. All inventories of food of other products derived from these commodities, and any receivables or proceeds from the sale of these commodities until full payment is received.

ALL ACCOUNTS PAYABLE WEEKLY - NO DISCOUNTS - FREIGHT COLLECT

THE DRIVER is responsible for all merchandise when invoice is signed

Parimar, Inc. dba D. Defranco & Sons
1000 Lawrence St.
Los Angeles, CA 90021
FEI: 3004655865
Dates of Investigations: 02/25/11- 03/02/11 CN
Exhibit # 9 Page 10 of 11

INVOICE

DATE	INVOICE NO
12/22/2010	166265

1000 LAWRENCE ST.
LOS ANGELES, CA 90021-1620
TEL. (213) 627-8575 • FAX (213) 627-9837
E-mail: Defrancomp@aol.com

BILL TO

(b) (4)

SHIP TO

(b) (4)

Product of	P.O. No.	TERMS	DUE DATE	REP	SHIP DATE
USA	29242	(b) (4)	12/22/2010		12/22/2010

CODE	SHIPPED	DESCRIPTION	QTY	U.P.	AMOUNT
00-423	(b) (4)	50 LB IMPERIAL MIXED NUTS	(b) (4)	(b) (4)	(b) (4)
400-334		50 LB BRAZILS			
400-326		50 LB FILBERTS			
400-111		50 LB JUMBO WALNUT			
400-327		50 LB ALMONDS			
PALLETS		PALLETS			

ank you for your business.
(b) (6)

TOTAL (b) (4)

; Perishable Agricultural Commodities Listed on this invoice are sold subject to the utory trust authorized by section 5(c) of the perishable agricultural commodities act, 0 (7 U.S.C. 499 e(c)). The seller of these commodities retains a trust claim over these modities. All inventories of food of other products derived from these commodities, and receivables or proceeds from the sale of these commodities until full payment is ived.

. ACCOUNTS PAYABLE WEEKLY - NO DISCOUNTS - FREIGHT COLLECT

: DRIVER is responsible for all merchandise when invoice is signed

Parimar, Inc. dba D. Defranco & Sons
1000 Lawrence St.
Los Angeles, CA 90021
FEI: 3004655865
Dates of Investigations: 02/25/11- 03/02/11 CN
Exhibit # 6 Page 11 of 11

1000 LAWRENCE ST.
LOS ANGELES, CA 90021-1620
TEL. (213) 627-8575 • FAX (213) 627-9837
E-mail: Defrancomp@aol.com

INVOICE

DATE	INVOICE NO
10/18/2010	165285

BILL TO

(b) (4)

SHIP TO

(b) (4)

Product of	P.O. No.	TERMS	DUE DATE	REP	SHIP DATE
USA	275196	(b) (4)	11/17/2010		10/18/2010

CODE	SHIPPED	DESCRIPTION	QTY	U.P.	AMOUNT
400-327 00-423 400-334 400-111 400-326 PALLETS	(b) (4)	50 LB ALMONDS 50 LB IMPERIAL MIXED NUTS 50 LB BRAZILS 50 LB JUMBO WALNUT 50 LB FILBERTS PALLETS	(b) (4)	(b) (4)	(b) (4)
		(b) (4)			
		(b) (4)			
		(b) (6)			

Thank you for your business.

TOTAL (b) (4)

The Perishable Agricultural Commodities Listed on this invoice are sold subject to the Statutory trust authorized by section 5(c) of the perishable agricultural commodities act, 930 (7 U.S.C. 499 e(c)). The seller of these commodities retains a trust claim over these ommodities. All inventories of food of other products derived from these commodities, and ay receivables or proceeds from the sale of these commodities until full payment is eceived.

LL ACCOUNTS PAYABLE WEEKLY - NO DISCOUNTS - FREIGHT COLLECT

IE DRIVER is responsible for all merchandise when invoice is signed

Parimar, Inc. dba D. Defranco & Sons
1000 Lawrence St.
Los Angeles, CA 90021
FEI: 3004655865
Dates of Investigations: 02/25/11- 03/02/11 CN

1000 LAWRENCE ST.
LOS ANGELES, CA 90021-1620
TEL. (213) 627-8575 • FAX (213) 627-9837
E-mail: Defrancomp@aol.com

INVOICE

DATE	INVOICE NO
10/18/2010	165286

BILL TO

(b) (4)

SHIP TO

(b) (4)

Product of	P.O. No.	TERMS	DUE DATE	REP	SHIP DATE
USA	275197	(b) (4)	11/17/2010		10/18/2010

CODE	SHIPPED	DESCRIPTION	QTY	U.P.	AMOUNT
400-327	(b) (4)	50 LB ALMONDS	(b) (4)	(b) (4)	(b) (4)
400-423		50 LB IMPERIAL MIXED NUTS			
400-334		50 LB BRAZILS			
400-111		50 LB JUMBO WALNUT			
400-326		50 LB FILBERTS			
PALLETS		PALLETS			
		(b) (4)			
		(b) (4)			
		(b) (6)			

k you for your business. TOTAL (b) (4)

erishable Agricultural Commodities Listed on this invoice are sold subject to the ıry trust authorized by section 5(c) of the perishable agricultural commodities act, 7 U.S.C. 499 e(c)). The seller of these commodities retains a trust claim over these ɔdities. All inventories of food of other products derived from these commodities, and eivables or proceeds from the sale of these commodities until full payment is d.

CCOUNTS PAYABLE WEEKLY - NO DISCOUNTS - FREIGHT COLLECT

RIVER is responsible for all merchandise when invoice is signed

Parimar, Inc. dba D. Defranco & Sons
1000 Lawrence St.
Los Angeles, CA 90021
FEI: 3004655865
Dates of Investigations: 02/25/11- 03/02/11 CN

INVOICE

DATE	INVOICE NO
10/18/2010	165287

1000 LAWRENCE ST.
LOS ANGELES, CA 90021-1620
TEL. (213) 627-8575 • FAX (213) 627-9837
E-mail: Defrancomp@aol.com

BILL TO

(b) (4)

SHIP TO

(b) (4)

Product of	P.O. No.	TERMS	DUE DATE	REP	SHIP DATE
USA	275204	(b) (4)	11/17/2010		10/18/2010

CODE	SHIPPED	DESCRIPTION	QTY	U.P.	AMOUNT
400-327	(b) (4)	50 LB ALMONDS	(b) (4)	(b) (4)	(b) (4)
00-423		50 LB IMPERIAL MIXED NUTS			
400-334		50 LB BRAZILS			
400-111		50 LB JUMBO WALNUT			
400-326		50 LB FILBERTS			
PALLETS		PALLETS			
		(b) (4)			
		(b) (6)			
Thank you for your business.			TOTAL		(b) (4)

The Perishable Agricultural Commodities Listed on this invoice are sold subject to the statutory trust authorized by section 5(c) of the perishable agricultural commodities act, 930 (7 U.S.C. 499 e(c)). The seller of these commodities retains a trust claim over these commodities. All inventories of food of other products derived from these commodities, and any receivables or proceeds from the sale of these commodities until full payment is received.

ALL ACCOUNTS PAYABLE WEEKLY - NO DISCOUNTS - FREIGHT COLLECT

THE DRIVER is responsible for all merchandise when invoice is signed

Parimar, Inc. dba D. Defranco & Sons
1000 Lawrence St.
Los Angeles, CA 90021
FEI: 3004655865
Dates of Investigations: 02/25/11- 03/02/11 CN
Exhibit # ID Page 3 of 19

1000 LAWRENCE ST.
LOS ANGELES, CA 90021-1620
TEL. (213) 627-8575 • FAX (213) 627-9837
E-mail: Defrancomp@aol.com

INVOICE

DATE	INVOICE NO
10/18/2010	165289

BILL TO

(b) (4)

SHIP TO

(b) (4)

Product of	P.O. No.	TERMS	DUE DATE	REP	SHIP DATE
USA	275211	(b) (4)	11/17/2010		10/18/2010

CODE	SHIPPED	DESCRIPTION	QTY	U.P.	AMOUNT
00-423 400-326 400-327 400-334 400-111 PALLETS	(b) (4)	50 LB IMPERIAL MIXED NUTS 50 LB FILBERTS 50 LB ALMONDS 50 LB BRAZILS 50 LB JUMBO WALNUT PALLETS	(b) (4)	(b) (4)	(b) (4)
		(b) (4)			
		(b) (6)			

you for your business.

TOTAL (b) (4)

rishable Agricultural Commodities Listed on this invoice are sold subject to the
ry trust authorized by section 5(c) of the perishable agricultural commodities act,
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'COUNTS PAYABLE WEEKLY - NO DISCOUNTS - FREIGHT COLLECT

IVER is responsible for all merchandise when invoice is signed

Parimar, Inc. dba D. Defranco & Sons
1000 Lawrence St.
Los Angeles, CA 90021
FEI: 3004655865
Dates of Investigations: 02/25/11- 03/02/11 CN
Exhibit # in Page 4 of 16

INVOICE

DATE	INVOICE NO
11/3/2010	165508

1000 LAWRENCE ST.
LOS ANGELES, CA 90021-1620
TEL. (213) 627-8575 • FAX (213) 627-9837
E-mail: Defrancomp@aol.com

BILL TO
(b) (4)

SHIP TO
(b) (4)

Product of	P.O. No.	TERMS	DUE DATE	REP	SHIP DATE
USA	277344	(b) (4)	12/3/2010		11/3/2010

CODE	SHIPPED	DESCRIPTION	QTY	U.P.	AMOUNT
00-423 400-346 PALLETS	(b) (4)	50 LB IMPERIAL MIXED NUTS 50 LB NATURAL PECANS PALLETS	(b) (4)	(b) (4)	(b) (4)

Thank you for your busine (b) (6)

TOTAL (b) (4)

The Perishable Agricultural Commodities Listed on this invoice are sold subject to the statutory trust authorized by section 5(c) of the perishable agricultural commodities act, 1930 (7 U.S.C. 499 e(c)). The seller of these commodities retains a trust claim over these commodities. All inventories of food of other products derived from these commodities, and any receivables or proceeds from the sale of these commodities until full payment is received.

ALL ACCOUNTS PAYABLE WEEKLY - NO DISCOUNTS - FREIGHT COLLECT

Parimar, Inc. dba D. Defranco & Sons
1000 Lawrence St.
Los Angeles, CA 90021
FEI: 3004655865
Dates of Investigations: 02/25/11- 03/02/11 CN
Exhibit #10 Page 5 of 10

INVOICE

DATE	INVOICE NO
11/11/2010	165655

1000 LAWRENCE ST.
LOS ANGELES, CA 90021-1620
TEL. (213) 627-8575 • FAX (213) 627-9837
E-mail: Defrancomp@aol.com

BILL TO

(b) (4)

SHIP TO

(b) (4)

Product of	P.O. No.	TERMS	DUE DATE	REP	SHIP DATE
USA	278750	(b) (4)	12/11/2010		11/11/2010

CODE	SHIPPED	DESCRIPTION	QTY	U.P.	AMOUNT
400-327	(b) (4)	50 LB ALMONDS	(b) (4)	(b) (4)	(b) (4)
400-326		50 LB FILBERTS			
00-423		50 LB IMPERIAL MIXED NUTS			
400-346		50 LB NATURAL PECANS			
400-111		50 LB JUMBO WALNUT			
PALLETS		PALLETS			
		(b) (4)			

Parimar, Inc. dba D. Defranco & Sons
1000 Lawrence St.
Los Angeles, CA 90021
FEI: 3004655865
Dates of Investigations: 02/25/11- 03/02/11 CN
Exhibit #10 Page 6 of 19

k you for your business. (b) (6)

TOTAL (b) (4)

(b) (4)

erishable Agricultural Commodities Listed on this invoice are sold subject to the ary trust authorized by section 5(c) of the perishable agricultural commodities act, 7 U.S.C. 499 e(c)). The seller of these commodities retains a trust claim over these odities. All inventories of food of other products derived from these commodities, and eivables or proceeds from the sale of these commodities until full payment is d.

CCOUNTS PAYABLE WEEKLY - NO DISCOUNTS - FREIGHT COLLECT

UYER is responsible for all merchandise when invoice is signed

(b) (6)

INVOICE

DATE	INVOICE NO
11/11/2010	165656

1000 LAWRENCE ST.
LOS ANGELES, CA 90021-1620
TEL. (213) 627-8575 • FAX (213) 627-9837
E-mail: Defrancomp@aol.com

BILL TO

(b) (4)

SHIP TO

(b) (4)

Product of	P.O. No.	TERMS	DUE DATE	REP	SHIP DATE
USA	278752	Net 30	12/11/2010		11/11/2010

CODE	SHIPPED	DESCRIPTION	QTY	U.P.	AMOUNT
400-327 400-326 400-111 PALLETS	(b) (4)	50 LB ALMONDS 50 LB FILBERTS 50 LB JUMBO WALNUT PALLETS (b) (4)	(b) (4)	(b) (4)	(b) (4)

Parimar, Inc. dba D. Defranco & Sons
1000 Lawrence St.
Los Angeles, CA 90021
FEI: 3004655865
Dates of Investigations: 02/25/11- 03/02/11 CN
Exhibit # 10 Page 7 of 19

Thank you for your business. (b) (6)

TOTAL (b) (4)

(b) (4)

(b) (6)

he Perishable Agricultural Commodities Listed on this invoice are sold subject to the statutory trust authorized by section 5(c) of the perishable agricultural commodities act, 930 (7 U.S.C. 499 e(c)). The seller of these commodities retains a trust claim over these commodities. All inventories of food of other products derived from these commodities, and any receivables or proceeds from the sale of these commodities until full payment is received.

ALL ACCOUNTS PAYABLE WEEKLY - NO DISCOUNTS - FREIGHT COLLECT

& DRIVER is responsible for all merchandise when invoice is signed

INVOICE

DATE	INVOICE NO
11/12/2010	165674

1000 LAWRENCE ST.
LOS ANGELES, CA 90021-1620
TEL. (213) 627-8575 • FAX (213) 627-9837
E-mail: Defrancomp@aol.com

BILL TO

(b) (4)

SHIP TO

(b) (4)

Product of	P.O. No.	TERMS	DUE DATE	REP	SHIP DATE
USA	278849	(b) (4)	12/12/2010		11/12/2010

CODE	SHIPPED	DESCRIPTION	QTY	U.P.	AMOUNT
400-327 400-326 00-423 400-111 PALLETS	(b) (4)	50 LB ALMONDS 50 LB FILBERTS 50 LB IMPERIAL MIXED NUTS 50 LB JUMBO WALNUT PALLETS (b) (4)	(b) (4)	(b) (4)	(b) (4)

Parimar, Inc. dba D. Defranco & Sons
1000 Lawrence St.
Los Angeles, CA 90021
FEI: 3004655865
Dates of Investigations: 02/25/11- 03/02/11 CN
Exhibit #10 Page 9 of 14

: you for your business. (b) (6)

TOTAL (b) (4)

(b) (4)

(b) (4)

(b) (4)

rishable Agricultural Commodities Listed on this invoice are sold subject to the ry trust authorized by section 5(c) of the perishable agricultural commodities act, 7 U.S.C. 499 e(c)). The seller of these commodities retains a trust claim over these dities. All inventories of food of other products derived from these commodities, and ivables or proceeds from the sale of these commodities until full payment is l.

COUNTS PAYABLE WEEKLY - NO DISCOUNTS - FREIGHT COLLECT

IVER is responsible for all merchandise when invoice is signed

INVOICE

DATE	INVOICE NO
11/18/2010	165769

1000 LAWRENCE ST.
LOS ANGELES, CA 90021-1620
TEL. (213) 627-8575 • FAX (213) 627-9837
E-mail: Defrancomp@aol.com

BILL TO

(b) (4)

SHIP TO

(b) (4)

Product of	P.O. No.	TERMS	DUE DATE	REP	SHIP DATE
USA	279787	(b) (4)	12/18/2010		11/18/2010

CODE	SHIPPED	DESCRIPTION	QTY	U.P.	AMOUNT
00-423	(b) (4)	50 LB IMPERIAL MIXED NUTS	(b) (4)	(b) (4)	(b) (4)
	(b) (4)	(b) (4) PALLET CHARGE (b) (4)			
	(b) (6)				

Thank you for your business

TOTAL (b) (4)

he Perishable Agricultural Commodities Listed on this invoice are sold subject to the atutory trust authorized by section 5(c) of the perishable agricultural commodities act, 30 (7 U.S.C. 499 e(c)). The seller of these commodities retains a trust claim over these mmodities. All inventories of food of other products derived from these commodities, and y receivables or proceeds from the sale of these commodities until full payment is eived.

L ACCOUNTS PAYABLE WEEKLY - NO DISCOUNTS - FREIGHT COLLECT

3 DRIVER is responsible for all merchandise when invoice is signed

Parimar, Inc. dba D. Defranco & Sons
1000 Lawrence St.
Los Angeles, CA 90021
FEI: 3004655865
Dates of Investigations: 02/25/11- 03/02/11 CN
Exhibit #10 Page 9 of 19

INVOICE

DATE	INVOICE NO
11/19/2010	165765

1000 LAWRENCE ST.
LOS ANGELES, CA 90021-1620
TEL. (213) 627-8575 • FAX (213) 627-9837
E-mail: Defrancomp@aol.com

BILL TO

(b) (4)

SHIP TO

(b) (4)

Product of	P.O. No.	TERMS	DUE DATE	REP	SHIP DATE
USA	279786	(b) (4)	12/19/2010		11/19/2010

CODE	SHIPPED	DESCRIPTION	QTY	U.P.	AMOUNT
400-327	(b) (4)	50 LB ALMONDS	(b) (4)	(b) (4)	(b) (4)
400-326		50 LB FILBERTS			
00-423		50 LB IMPERIAL MIXED NUTS			
400-111		50 LB JUMBO WALNUT			
		(b) (4)			
		(b) (4) PALLET CHARGE		(b) (4)	
	(b) (6)				

you for your business.

TOTAL (b) (4)

rishable Agricultural Commodities Listed on this invoice are sold subject to the
ry trust authorized by section 5(c) of the perishable agricultural commodities act,
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l.

COUNTS PAYABLE WEEKLY - NO DISCOUNTS - FREIGHT COLLECT

IVER is responsible for all merchandise when invoice is signed

Parimar, Inc. dba D. Defranco & Sons
1000 Lawrence St.
Los Angeles, CA 90021
FEI: 3004655865
Dates of Investigations: 02/25/11- 03/02/11 CN

INVOICE

DATE	INVOICE NO
11/19/2010	165766

1000 LAWRENCE ST.
LOS ANGELES, CA 90021-1620
TEL. (213) 627-8575 • FAX (213) 627-9837
E-mail: Defrancomp@aol.com

BILL TO

(b) (4)

SHIP TO

(b) (4)

Product of	P.O. No.	TERMS	DUE DATE	REP	SHIP DATE
USA	279787	(b) (4)	12/19/2010		11/19/2010

CODE	SHIPPED	DESCRIPTION	QTY	U.P.	AMOUNT
400-334 00-423 400-111 400-346	(b) (4)	50 LB BRAZILS 50 LB IMPERIAL MIXED NUTS 50 LB JUMBO WALNUT 50 LB NATURAL PECANS (b) (4) (b) (4) PALLET CHARGE	(b) (4)	(b) (4) (b) (4)	(b) (4)

(b) (6)

Thank you for your business.

TOTAL (b) (4)

he Perishable Agricultural Commodities Listed on this invoice are sold subject to the atutory trust authorized by section 5(c) of the perishable agricultural commodities act, 30 (7 U.S.C. 499 e(c)). The seller of these commodities retains a trust claim over these mmodities. All inventories of food of other products derived from these commodities, and y receivables or proceeds from the sale of these commodities until full payment is eived.

L ACCOUNTS PAYABLE WEEKLY - NO DISCOUNTS - FREIGHT COLLECT

Parimar, Inc. dba D. Defranco & Sons
1000 Lawrence St.
Los Angeles, CA 90021
FEI: 3004655865
Dates of Investigations: 02/25/11- 03/02/11 CN
Exhibit # 10 Page [illegible]

1000 LAWRENCE ST.
LOS ANGELES, CA 90021-1620
TEL. (213) 627-8575 • FAX (213) 627-9837
E-mail: Defrancomp@aol.com

INVOICE

DATE	INVOICE NO
11/22/2010	165799

BILL TO

(b) (4)

SHIP TO

(b) (4)

Product of	P.O. No.	TERMS	DUE DATE	REP	SHIP DATE
USA	280017	(b) (4)	12/22/2010		11/22/2010

CODE	SHIPPED	DESCRIPTION	QTY	U.P.	AMOUNT
400-334	(b) (4)	50 LB BRAZILS	(b) (4)	(b) (4)	(b) (4)
400-326		50 LB FILBERTS			
00-423		50 LB IMPERIAL MIXED NUTS			
400-[illegible]		50 LB JUMBO WALNUT			
PALLETS		PALLETS			
		(b) (4)			

SHIPPERS LOAD & COUNT
THE FOLLOWING SIGNATURE ACKNOWLEDGES RECEIPT OF PRODUCT ONLY. WORLD VARIETY PRODUCE INC. IS NOT LIABLE FOR ACCURACY OF COUNT OR QUALITY, WHICH IS THE RESPONSIBILITY OF SHIPPER.
NUMBER OF PALLETS RECEIVED _____
(b) (4)
11-22-10
(b) (6)

you for your business. TOTAL (b) (4)

rishable Agricultural Commodities Listed on this invoice are sold subject to the ry trust authorized by section 5(c) of the perishable agricultural commodities act, U.S.C. 499 e(c)). The seller of these commodities retains a trust claim over these dities. All inventories of food of other products derived from these commodities, and ivables or proceeds from the sale of these commodities until full payment is

COUNTS PAYABLE WEEKLY - NO DISCOUNTS - FREIGHT COLLECT

Parimar, Inc. dba D. Defranco & Sons
1000 Lawrence St.
Los Angeles, CA 90021
FEI: 3004655865
Dates of Investigations: 02/25/11- 03/02/11 CN
Exhibit # 10 Page 12 of 19

1000 LAWRENCE ST.
LOS ANGELES, CA 90021-1620
TEL. (213) 627-8575 • FAX (213) 627-9837
E-mail: Defrancomp@aol.com

INVOICE

DATE	INVOICE NO
11/22/2010	165823

BILL TO

(b) (4)

SHIP TO

(b) (4)

Product of	P.O. No.	TERMS	DUE DATE	REP	SHIP DATE
USA	280238	(b) (4)	12/22/2010		11/22/2010

CODE	SHIPPED	DESCRIPTION	QTY	U.P.	AMOUNT
00-423	(b) (4)	50 LB IMPERIAL MIXED NUTS	(b) (4)	(b) (4)	(b) (4)
400-327		50 LB ALMONDS			
400-326		50 LB FILBERTS			
PALLETS		PALLETS			

hank you for your business. (b) (6)

TOTAL (b) (4)

ıe Perishable Agricultural Commodities Listed on this invoice are sold subject to the
atutory trust authorized by section 5(c) of the perishable agricultural commodities act,
30 (7 U.S.C. 499 e(c)). The seller of these commodities retains a trust claim over these
mmodities. All inventories of food of other products derived from these commodities, and
r receivables or proceeds from the sale of these commodities until full payment is
eived.

L ACCOUNTS PAYABLE WEEKLY - NO DISCOUNTS - FREIGHT COLLECT

Parimar, Inc. dba D. Defranco & Sons
1000 Lawrence St.
Los Angeles, CA 90021
FEI: 3004655865
Dates of Investigations: 02/25/11- 03/02/11 CN

INVOICE

DATE	INVOICE NO
11/29/2010	165917

1000 LAWRENCE ST.
LOS ANGELES, CA 90021-1620
TEL. (213) 627-8575 • FAX (213) 627-9837
E-mail: Defrancomp@aol.com

BILL TO

(b) (4)

SHIP TO

(b) (4)

Product of	P.O. No.	TERMS	DUE DATE	REP	SHIP DATE
USA	281038	(b) (4)	12/29/2010		11/29/2010

CODE	SHIPPED	DESCRIPTION	QTY	U.P.	AMOUNT
400-346	(b) (4)	50 LB NATURAL PECANS (b) (4) DELIVER TO WORLD VARIETY DOCK		(b) (4)	(b) (4)

SHIPPERS LOAD & COUNT
THE FOLLOWING SIGNATURE ACKNOWLEDGES RECEIPT OF PRODUCT ONLY. WORLD VARIETY PRODUCE INC. IS NOT LIABLE FOR ACCURACY OF COUNT OR QUALITY, WHICH IS THE RESPONSIBILITY OF SHIPPER.
NUMBER OF PALLETS RECEIVED_____

(b) (4) (b) (4) 11-29-10

you for your business.

TOTAL (b) (4)

rishable Agricultural Commodities Listed on this invoice are sold subject to the ry trust authorized by section 5(c) of the perishable agricultural commodities act, U.S.C. 499 e(c)). The seller of these commodities retains a trust claim over these dities. All inventories of food of other products derived from these commodities, and ivables or proceeds from the sale of these commodities until full payment is l.

COUNTS PAYABLE WEEKLY - NO DISCOUNTS - FREIGHT COLLECT

IVER is responsible for all merchandise when invoice is signed

Parimar, Inc. dba D. Defranco & Sons
1000 Lawrence St.
Los Angeles, CA 90021
FEI: 3004655865
Dates of Investigations: 02/25/11- 03/02/11 CN
Exhibit # 10 Page 14 of 19

INVOICE

DATE	INVOICE NO
12/2/2010	165969

1000 LAWRENCE ST.
LOS ANGELES, CA 90021-1620
TEL. (213) 627-8575 • FAX (213) 627-9837
E-mail: Defrancomp@aol.com

BILL TO

(b) (4)

SHIP TO

(b) (4)

Product of	P.O. No.	TERMS	DUE DATE	REP	SHIP DATE
USA/BRAZIL	281506	(b) (4)	1/1/2011		12/2/2010

CODE	SHIPPED	DESCRIPTION	QTY	U.P.	AMOUNT
400-327 400-334 400-111 400-326 00-423 400-457 PALLETS	(b) (4)	50 LB ALMONDS 50 LB BRAZILS 50 LB JUMBO WALNUT 50 LB FILBERTS 50 LB IMPERIAL MIXED NUTS 10/4 LB MIXED NUTS (GARY NEU) PALLETS (b) (4)	(b) (4)	(b) (4)	(b) (4)

Thank you for your business. (b) (6)

TOTAL (b) (4)

The Perishable Agricultural Commodities Listed on this invoice are sold subject to the statutory trust authorized by section 5(c) of the perishable agricultural commodities act, 930 (7 U.S.C. 499 e(c)). The seller of these commodities retains a trust claim over these ommodities. All inventories of food of other products derived from these commodities, and ay receivables or proceeds from the sale of these commodities until full payment is ceived.

LL ACCOUNTS PAYABLE WEEKLY - NO DISCOUNTS - FREIGHT COLLECT

ID DUE is responsible for all merchandise when invoice is signed

Parimar, Inc. dba D. Defranco & Sons
1000 Lawrence St.
Los Angeles, CA 90021
FEI: 3004655865
Dates of Investigations: 02/25/11- 03/02/11 CN

INVOICE

DATE	INVOICE NO
12/6/2010	166020

1000 LAWRENCE ST.
LOS ANGELES, CA 90021-1620
TEL. (213) 627-8575 • FAX (213) 627-9837
E-mail: Defrancomp@aol.com

BILL TO

(b) (4)

SHIP TO

(b) (4)

Product of	P.O. No.	TERMS	DUE DATE	REP	SHIP DATE
USA	281933	(b) (4)	1/5/2011		12/6/2010

CODE	SHIPPED	DESCRIPTION	QTY	U.P.	AMOUNT
400-327	(b) (4)	50 LB ALMONDS		(b) (4)	(b) (4)
00-423		50 LB IMPERIAL MIXED NUTS			
400-334		50 LB BRAZILS			
400-111		50 LB JUMBO WALNUT			
400-326		50 LB FILBERTS			
PALLETS		PALLETS			
		(b) (4)			

c you for your busin (b) (6)

TOTAL (b) (4)

rishable Agricultural Commodities Listed on this invoice are sold subject to the ry trust authorized by section 5(c) of the perishable agricultural commodities act, 7 U.S.C. 499 e(c)). The seller of these commodities retains a trust claim over these odities. All inventories of food of other products derived from these commodities, and eivables or proceeds from the sale of these commodities until full payment is d.

SCOUNTS PAYABLE WEEKLY - NO DISCOUNTS - FREIGHT COLLECT

Parimar, Inc. dba D. Defranco & Sons
1000 Lawrence St.
Los Angeles, CA 90021
FEI: 3004655865
Dates of Investigations: 02/25/11- 03/02/11 CN
Exhibit # 10 Page 16 of 18

INVOICE

DATE	INVOICE NO
12/6/2010	166021

1000 LAWRENCE ST.
LOS ANGELES, CA 90021-1620
TEL. (213) 627-8575 • FAX (213) 627-9837
E-mail: Defrancomp@aol.com

BILL TO

(b) (4)

SHIP TO

(b) (4)

Product of	P.O. No.	TERMS	DUE DATE	REP	SHIP DATE
USA	281921	(b) (4)	1/5/2011		12/6/2010

CODE	SHIPPED	DESCRIPTION	QTY	U.P.	AMOUNT
400-327 400-334 400-326 00-423 400-111 PALLETS	(b) (4)	50 LB ALMONDS 50 LB BRAZILS 50 LB FILBERTS 50 LB IMPERIAL MIXED NUTS 50 LB JUMBO WALNUT PALLETS (b) (4)	(b) (4)	(b) (4)	(b) (4)

Thank you for your busines (b) (6)

TOTAL (b) (4)

he Perishable Agricultural Commodities Listed on this invoice are sold subject to the atutory trust authorized by section 5(c) of the perishable agricultural commodities act, 30 (7 U.S.C. 499 e(c)). The seller of these commodities retains a trust claim over these mmodities. All inventories of food of other products derived from these commodities, and y receivables or proceeds from the sale of these commodities until full payment is eived.

ALL ACCOUNTS PAYABLE WEEKLY - NO DISCOUNTS - FREIGHT COLLECT

Parimar, Inc. dba D. Defranco & Sons
1000 Lawrence St.
Los Angeles, CA 90021
FEI: 3004655865
Dates of Investigations: 02/25/11- 03/02/11 CN
Exhibit # 10 Page 17 of 19

INVOICE

DATE	INVOICE NO
12/9/2010	166085

1000 LAWRENCE ST.
LOS ANGELES, CA 90021-1620
TEL. (213) 627-8575 • FAX (213) 627-9837
E-mail: Defrancomp@aol.com

BILL TO

(b) (4)

SHIP TO

(b) (4)

Product of	P.O. No.	TERMS	DUE DATE	REP	SHIP DATE
USA	282505	(b) (4)	1/8/2011		12/9/2010

CODE	SHIPPED	DESCRIPTION	QTY	U.P.	AMOUNT
400-327 400-334 400-326 400-111 00-423 PALLETS	(b) (4)	50 LB ALMONDS 50 LB BRAZILS 50 LB FILBERTS 50 LB JUMBO WALNUT 50 LB IMPERIAL MIXED NUTS PALLETS (b) (4)	(b) (4)	(b) (4)	(b) (4)

(b) (6)

k you for your business.

TOTAL (b) (4)

erishable Agricultural Commodities Listed on this invoice are sold subject to the
ıry trust authorized by section 5(c) of the perishable agricultural commodities act,
7 U.S.C. 499 e(c)). The seller of these commodities retains a trust claim over these
ɔdities. All inventories of food of other products derived from these commodities, and
ɛivables or proceeds from the sale of these commodities until full payment is
d.

CCOUNTS PAYABLE WEEKLY - NO DISCOUNTS - FREIGHT COLLECT

Parimar, Inc. dba D. Defranco & Sons
1000 Lawrence St.
Los Angeles, CA 90021
FEI: 3004655865
Dates of Investigations: 02/25/11- 03/02/11 CN
Exhibit # 10Page 1 of 10

INVOICE

DATE	INVOICE NO
2/3/2011	166712

1000 LAWRENCE ST.
LOS ANGELES, CA 90021-1620
TEL. (213) 627-8575 • FAX (213) 627-9837
E-mail: Defrancomp@aol.com

BILL TO

(b) (4)

SHIP TO

(b) (4)

Product of	P.O. No.	TERMS	DUE DATE	REP	SHIP DATE
USA	289612	(b) (4)	3/5/2011		2/3/2011

CODE	SHIPPED	DESCRIPTION	QTY	U.P.	AMOUNT
00-423	(b) (4)	50 LB IMPERIAL MIXED NUTS DELIVER TO: (b) (4) (b) (6)	(b) (4)	(b) (4)	(b) (4)
Thank you for your business.			TOTAL		(b) (4)

The Perishable Agricultural Commodities Listed on this invoice are sold subject to the Statutory trust authorized by section 5(c) of the perishable agricultural commodities act, 1930 (7 U.S.C. 499 e(c)). The seller of these commodities retains a trust claim over these commodities. All inventories of food of other products derived from these commodities, and any receivables or proceeds from the sale of these commodities until full payment is received.

ALL ACCOUNTS PAYABLE WEEKLY - NO DISCOUNTS - FREIGHT COLLECT

THE DRIVER is responsible for all merchandise when invoice is signed

Parimar, Inc. dba D. Defranco & Sons
1000 Lawrence St.
Los Angeles, CA 90021
FEI: 3004655865
Dates of Investigations: 02/25/11- 03/02/11 CN
Exhibit # 10 Page 19 of 19

INVOICE

DATE	INVOICE NO
11/22/2010	165800

1000 LAWRENCE ST.
LOS ANGELES, CA 90021-1620
TEL. (213) 627-8575 • FAX (213) 627-9837
E-mail: Defrancomp@aol.com

BILL TO

(b) (4)

SHIP TO

(b) (4)

Product of	P.O. No.	TERMS	DUE DATE	REP	SHIP DATE
USA	280014	(b) (4)	12/22/2010		11/22/2010

CODE	SHIPPED	DESCRIPTION	QTY	U.P.	AMOUNT
400-327	(b) (4)	50 LB ALMONDS	(b) (4)	(b) (4)	(b) (4)
400-334		50 LB BRAZILS			
400-326		50 LB FILBERTS			
00-423		50 LB IMPERIAL MIXED NUTS			
400-111		50 LB JUMBO WALNUT			
PALLETS		PALLETS			

MERRILL

SHIPPERS LOAD & COUNT
THE FOLLOWING SIGNATURE ACKNOWLEDGES RECEIPT OF PRODUCT ONLY. WORLD VARIETY PRODUCE INC. IS NOT LIABLE FOR ACCURACY OF COUNT OR QUALITY, WHICH IS THE RESPONSIBILITY OF SHIPPER.
NUMBER OF PALLETS RECEIVED_____

(b) (4)

(b) (6)

11-22-10

: you for your business.

TOTAL (b) (4)

rishable Agricultural Commodities Listed on this invoice are sold subject to the ry trust authorized by section 5(c) of the perishable agricultural commodities act, U.S.C. 499 e(c)). The seller of these commodities retains a trust claim over these dities. All inventories of food of other products derived from these commodities, and eivables or proceeds from the sale of these commodities until full payment is l.

CCOUNTS PAYABLE WEEKLY - NO DISCOUNTS - FREIGHT COLLECT

Parimar, Inc. dba D. Defranco & Sons
1000 Lawrence St.
Los Angeles, CA 90021
FEI: 3004655865
Dates of Investigations: 02/25/11- 03/02/11 CN
Exhibit # | | Page 1 of 1

INVOICE

DATE	INVOICE NO
12/15/2010	166170

1000 LAWRENCE ST.
LOS ANGELES, CA 90021-1620
TEL. (213) 627-8575 • FAX (213) 627-9837
E-mail: Defrancomp@aol.com

BILL TO

(b) (4)

SHIP TO

(b) (4)

Product of	P.O. No.	TERMS	DUE DATE	REP	SHIP DATE
USA	283436	(b) (4)	1/14/2011		12/15/2010

CODE	SHIPPED	DESCRIPTION	QTY	U.P.	AMOUNT
400-326 PALLETS	(b) (4)	50 LB FILBERTS PALLETS (b) (4)	(b) (4)	(b) (4)	(b) (4)

Thank you for y(b) (6)

TOTAL (b) (4)

he Perishable Agricultural Commodities Listed on this invoice are sold subject to the atutory trust authorized by section 5(c) of the perishable agricultural commodities act, 30 (7 U.S.C. 499 e(c)). The seller of these commodities retains a trust claim over these mmodities. All inventories of food or other products derived from these commodities, and y receivables or proceeds from the sale of these commodities until full payment is eived.

L ACCOUNTS PAYABLE WEEKLY - NO DISCOUNTS - FREIGHT COLLECT

3 DRIVER is responsible for all merchandise when invoice is signed

Parimar, Inc. dba D. Defranco & Sons
1000 Lawrence St.
Los Angeles, CA 90021
FEI: 3004655865
Dates of Investigations: 02/25/11- 03/02/11 CN

INVOICE

DATE	INVOICE NO
12/6/2010	166019

1000 LAWRENCE ST.
LOS ANGELES, CA 90021-1620
TEL. (213) 627-8575 • FAX (213) 627-9837
E-mail: Defrancomp@aol.com

BILL TO

(b) (4)

SHIP TO

(b) (4)

Product of	P.O. No.	TERMS	DUE DATE	REP	SHIP DATE
USA	281920	(b) (4)	1/5/2011		12/6/2010

CODE	SHIPPED	DESCRIPTION	QTY	U.P.	AMOUNT
400-327 400-334 400-326 00-423 400-111 PALLETS	(b) (4)	50 LB ALMONDS 50 LB BRAZILS 50 LB FILBERTS 50 LB IMPERIAL MIXED NUTS 50 LB JUMBO WALNUT PALLETS (b) (4)	(b) (4)	(b) (4)	(b) (4)

(b) (6)

k you for your bus

TOTAL (b) (4)

erishable Agricultural Co... are sold subject to the ory trust authorized by section 3(c) of the perishable agricultural commodities act, 7 U.S.C. 499 c(c)). The seller of these commodities retains a trust claim over these odities. All inventories of food or other products derived from these commodities, and ceivables or proceeds from the sale of these commodities until full payment is id.

CCOUNTS PAYABLE WEEKLY - NO DISCOUNTS - FREIGHT COLLECT

Parimar, Inc. dba D. Defranco & Sons
1000 Lawrence St.
Los Angeles, CA 90021
FEI: 3004655865
Dates of Investigations: 02/25/11- 03/02/11 CN

D DE FRANCO & SONS
ransaction Detail By Account
September 1, 2010 through February 25, 2011

Type	Date	Num	Name	Memo
B-SALES-NUTS				
SALES-MIXED NUTS				
Invoice	9/15/2010	(b) (4)	(b) (4)(b) (4)	
Invoice	9/15/2010			
Invoice	9/16/2010			
Invoice	9/17/2010			
Invoice	9/22/2010			
Invoice	9/22/2010			
Invoice	9/23/2010			
Invoice	9/27/2010			
Invoice	9/27/2010			
Invoice	9/27/2010			
Invoice	9/30/2010			
Invoice	9/30/2010			
Invoice	9/30/2010			
Invoice	10/4/2010			
Invoice	10/4/2010			
Invoice	10/5/2010			
Invoice	10/5/2010			
Invoice	10/7/2010			
Invoice	10/7/2010			
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Invoice	10/18/2010			
Invoice	10/18/2010			
Invoice	10/19/2010			

Parimar, Inc. dba D. Defranco & Sons
1000 Lawrence St.
Los Angeles, CA 90021
FEI: 300655865
Dates of Investigations: 02/25/11- 03/02/11 CN
Exhibit # 16, Page 1 of 9

277

D DE FRANCO & SONS
Transaction Detail By Account
September 1, 2010 through February 25, 2011

Type	Date	Num	Name	Memo
Invoice	10/20/2010	(b) (4)	(b) (4)	(b) (4)
Invoice	10/20/2010			
Invoice	10/20/2010			
Invoice	10/20/2010			
Invoice	10/20/2010			
Invoice	10/20/2010			
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Invoice	10/29/2010			
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Invoice	11/1/2010			
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Invoice	11/5/2010			
Invoice	11/5/2010			

02/25/11
Accrual Basis

Parimar, Inc. dba D. Defranco & Sons
1000 Lawrence St.
Los Angeles, CA 90021
FEI: 3004655865
Dates of Investigations: 02/25/11- 03/02/11 CN
Exhibit # 14 Page 9 of 0

2:33 PM
02/25/11
Accrual Basis

D DE FRANCO & SONS
Transaction Detail By Account
September 1, 2010 through February 25, 2011

Type	Date	Num	Name	Memo
Invoice	11/8/2010	(b) (4)	(b) (4)(b) (4)	
Invoice	11/8/2010			
Invoice	11/9/2010			
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Invoice	11/22/2010			
Invoice	11/22/2010			

Parimar, Inc. dba D. Defranco & Sons
1000 Lawrence St.
Los Angeles, CA 90021
FEI: 3004655865
Dates of Investigations: 02/25/11- 03/02/11 CN
Exhibit # 1A Page 3 of 8

D DE FRANCO & SONS
Transaction Detail By Account
September 1, 2010 through February 25, 2011

02/25/11
Accrual Basis

Type	Date	Num	Name	Memo
Invoice	11/22/2010	(b) (4)	(b) (4)	(b) (4)
Invoice	11/22/2010			
Invoice	11/22/2010			
Invoice	11/22/2010			
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Invoice	11/24/2010			
Invoice	11/26/2010			
Invoice	11/29/2010			
Invoice	11/29/2010			
Invoice	11/29/2010			
Invoice	11/30/2010			
Invoice	12/1/2010			
Invoice	12/1/2010			
Invoice	12/1/2010			
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Invoice	12/6/2010			
Invoice	12/7/2010			
Invoice	12/7/2010			
Invoice	12/8/2010			
Invoice	12/8/2010			
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Invoice	12/8/2010			
Invoice	12/8/2010			

Parimar, Inc. dba D. Defranco & Sons
1000 Lawrence St.
Los Angeles, CA 90021
FEI: 3004655865
Dates of Investigations: 02/25/11- 03/02/11 CN
Exhibit #14-Page 4 of 9

D DE FRANCO & SONS
Transaction Detail By Account
September 1, 2010 through February 25, 2011

Type	Date	Num	Name	Memo
Invoice	12/8/2010	(b) (4)	(b) (4)	(b) (4)
Invoice	12/9/2010			
Invoice	12/9/2010			
Invoice	12/9/2010			
Invoice	12/9/2010			
Invoice	12/10/2010			
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Invoice	12/22/2010			
Invoice	12/22/2010			
Invoice	12/22/2010			
Invoice	12/30/2010			
Invoice	12/31/2010			
Invoice	1/12/2011			
Invoice	2/3/2011			
Invoice	2/17/2011			
Total SALES-MIXED NUTS				
Total B-SALES-NUTS				
TOTAL				

D DE FRANCO & SONS
Transaction Detail By Account
September 1, 2010 through February 25, 2011

Type	Date	Num	Name	Memo
B-SALES-NUTS				
SALES-FILBERTS				
Invoice	9/13/2010	(b) (4)	(b) (4)(b) (4)	
Invoice	9/15/2010			
Invoice	9/30/2010			
Invoice	10/4/2010			
Invoice	10/5/2010			
Invoice	10/5/2010			
Invoice	10/7/2010			
Invoice	10/7/2010			
Invoice	10/7/2010			
Invoice	10/11/2010			
Invoice	10/11/2010			
Invoice	10/12/2010			
Invoice	10/12/2010			
Invoice	10/13/2010			
Invoice	10/13/2010			
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Invoice	10/18/2010			
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Invoice	10/20/2010			
Invoice	10/20/2010			
Invoice	10/20/2010			
Invoice	10/26/2010			
Invoice	10/26/2010			
Invoice	10/27/2010			
Invoice	10/28/2010			
Invoice	10/28/2010			
Invoice	10/29/2010			
Invoice	11/1/2010			
Invoice	11/1/2010			
Invoice	11/1/2010			
Invoice	11/2/2010			
Invoice	11/3/2010			
Invoice	11/3/2010			
Invoice	11/5/2010			
Invoice	11/5/2010			
Invoice	11/5/2010			

02/25/11
Accrual Basis

Page 1

Parimar, Inc. dba D. Defranco & Sons
1000 Lawrence St.
Los Angeles, CA 90021
FEI: 3004655865
Dates of Investigations: 02/25/11- 03/02/11 CN
Exhibit #14 Page 6 of 9

D DE FRANCO & SONS
Transaction Detail By Account
September 1, 2010 through February 25, 2011

Type	Date	Num	Name	Memo
Invoice	11/8/2010	(b) (4)	(b) (4)	(b) (4)
Invoice	11/9/2010			
Invoice	11/9/2010			
Invoice	11/10/2010			
Invoice	11/11/2010			
Invoice	11/11/2010			
Invoice	11/11/2010			
Invoice	11/12/2010			
Invoice	11/12/2010			
Invoice	11/12/2010			
Invoice	11/12/2010			
Invoice	11/15/2010			
Invoice	11/15/2010			
Invoice	11/16/2010			
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Invoice	11/30/2010			
Invoice	11/30/2010			
Invoice	12/1/2010			
Invoice	12/1/2010			
Invoice	12/1/2010			
Invoice	12/2/2010			
Invoice	12/2/2010			
Invoice	12/3/2010			
Invoice	12/3/2010			
Invoice	12/6/2010			
Invoice	12/6/2010			

D DE FRANCO & SONS
Transaction Detail By Account
September 1, 2010 through February 25, 2011

Type	Date	Num	Name	Memo
Invoice	12/6/2010	(b) (4)	(b) (4)	(b) (4)
Invoice	12/6/2010			
Invoice	12/6/2010			
Invoice	12/6/2010			
Invoice	12/7/2010			
Invoice	12/7/2010			
Invoice	12/8/2010			
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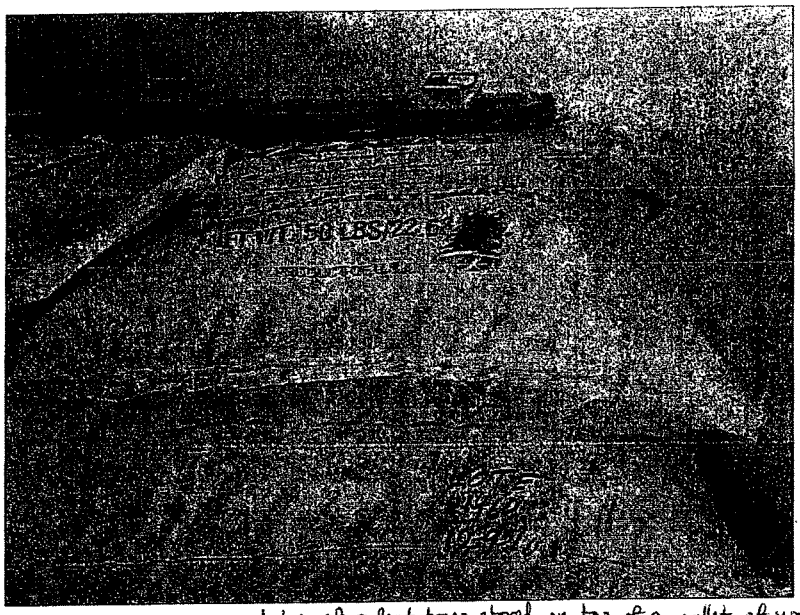
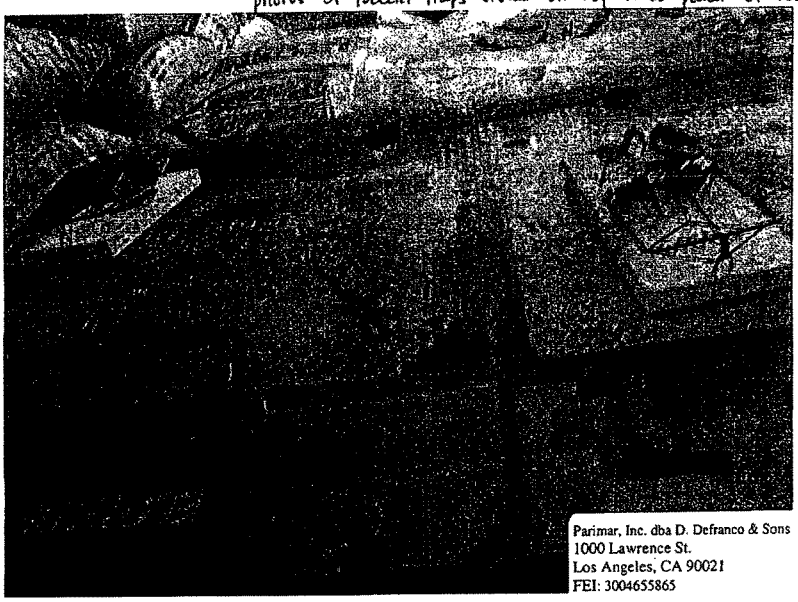
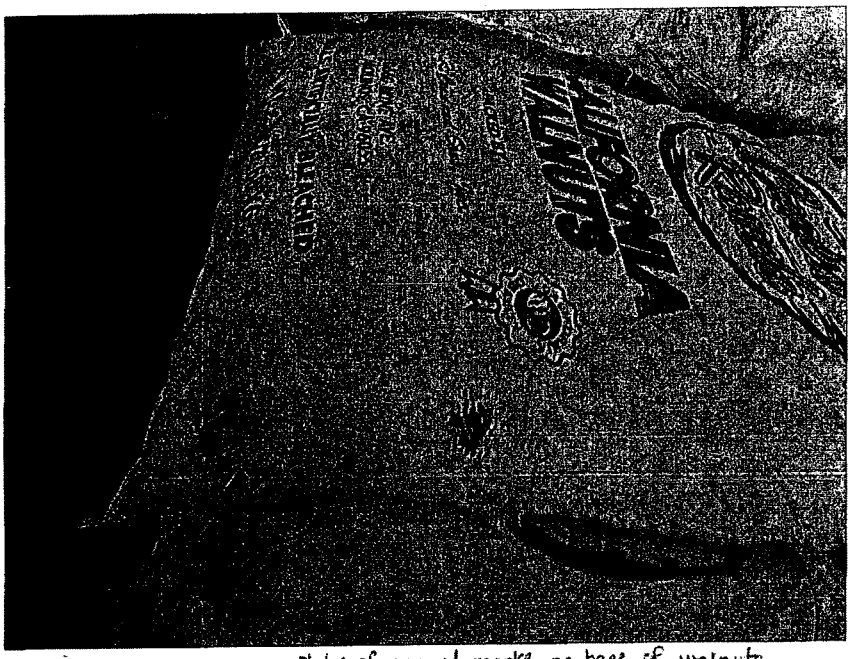
Invoice	12/15/2010			
Invoice	12/16/2010			
Invoice	12/17/2010			
Invoice	12/20/2010			
Invoice	12/21/2010			
Invoice	12/22/2010			
Invoice	12/22/2010			
Invoice	12/23/2010			
Invoice	12/31/2010			
Invoice	2/9/2011			
Total SALES-FILBERTS				
Total B-SALES-NUTS				
TOTAL				



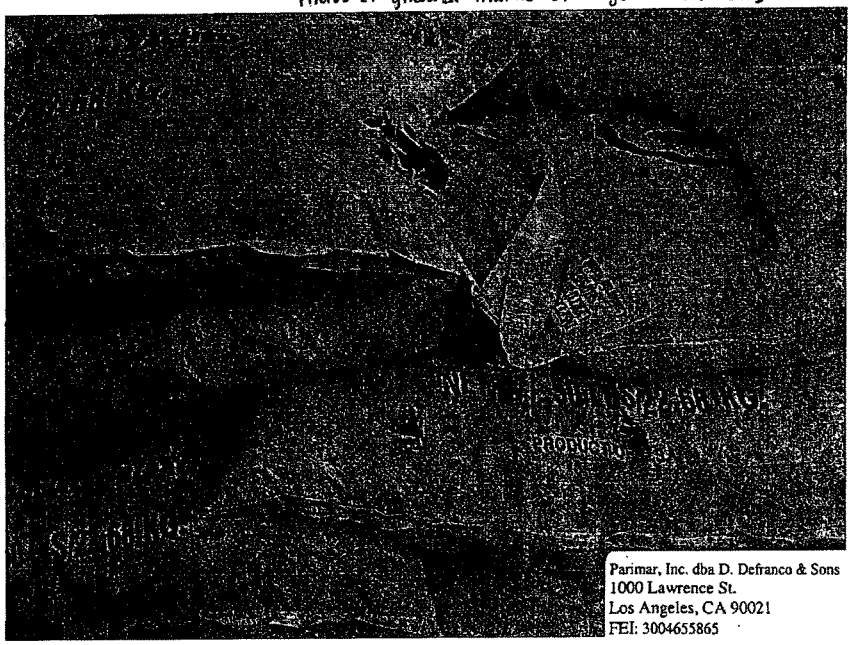
photos of rodent traps stored on top of a pallet of walnuts



Parimar, Inc. dba D. Defranco & Sons
1000 Lawrence St.
Los Angeles, CA 90021
FEI: 3004655865



Photos of gnawed marks on bags of walnuts



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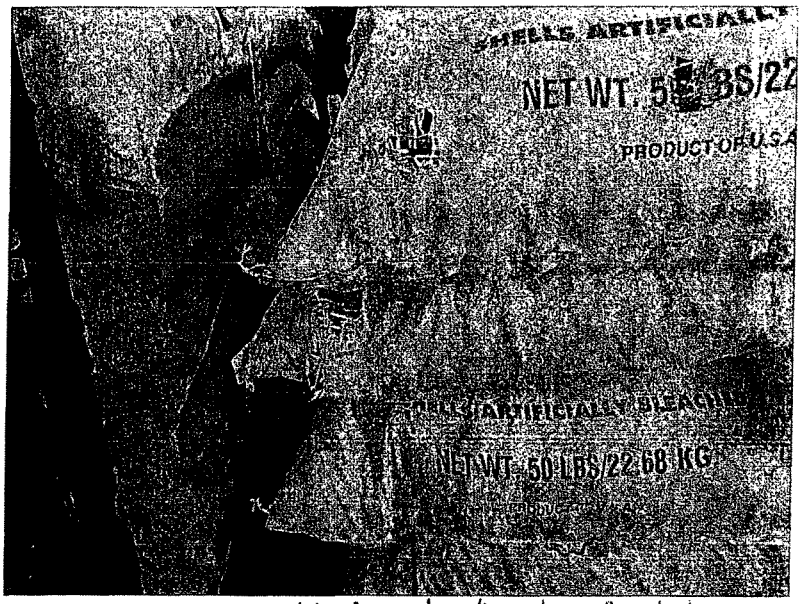
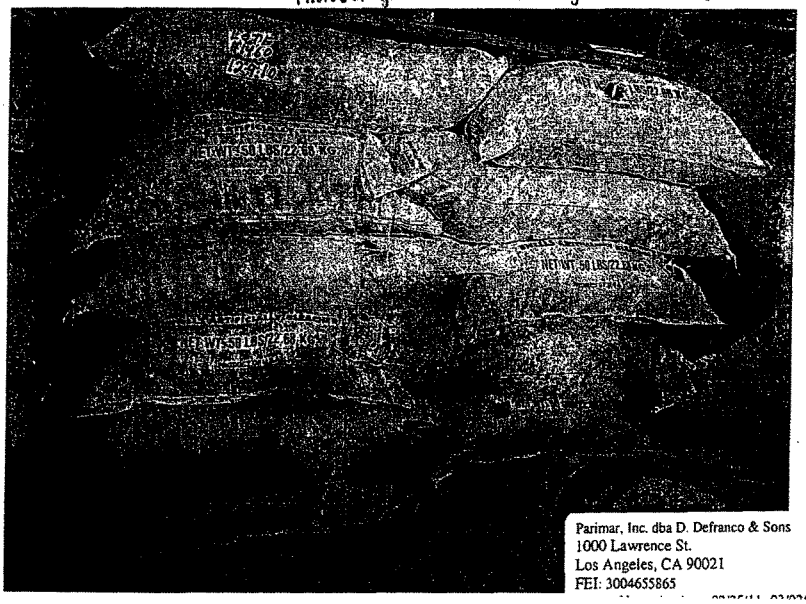
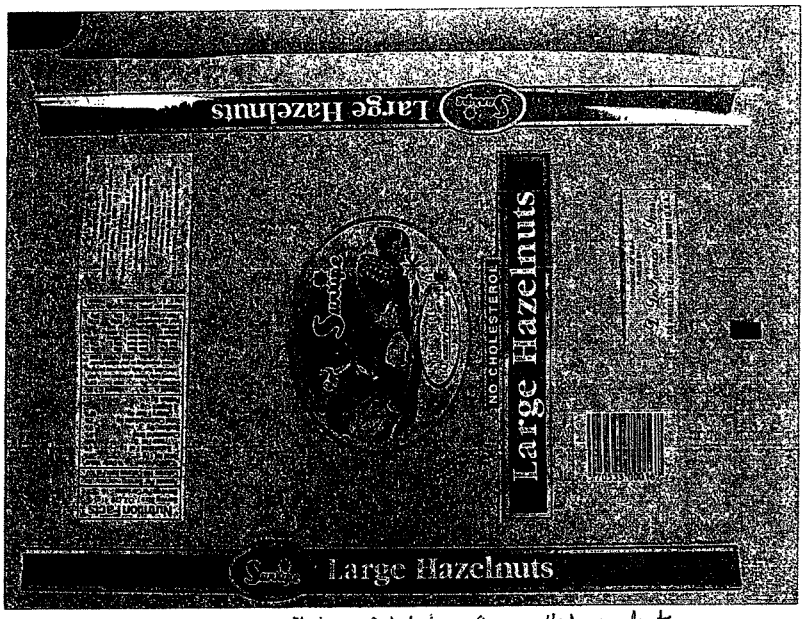
1000 Lawrence St.
Los Angeles, CA 90021
FEI: 3004655865



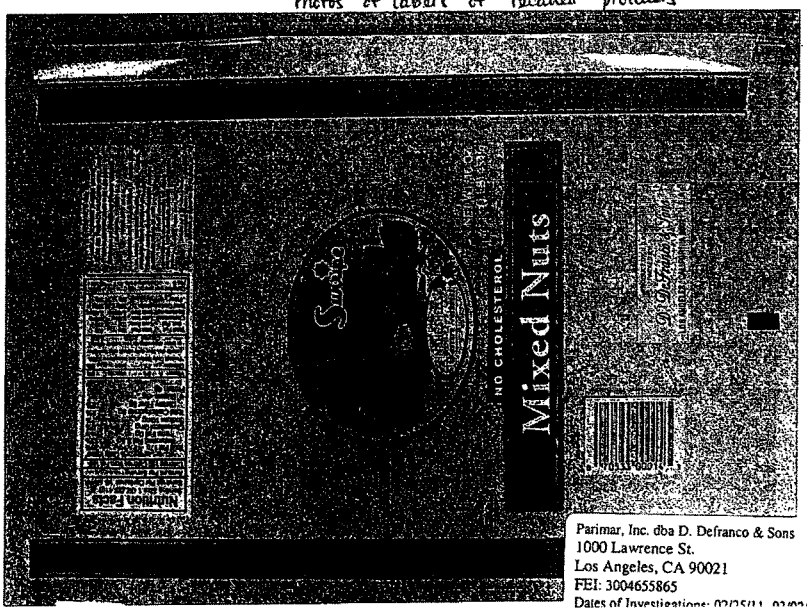
Photos of gnawed marks on bags of walnuts



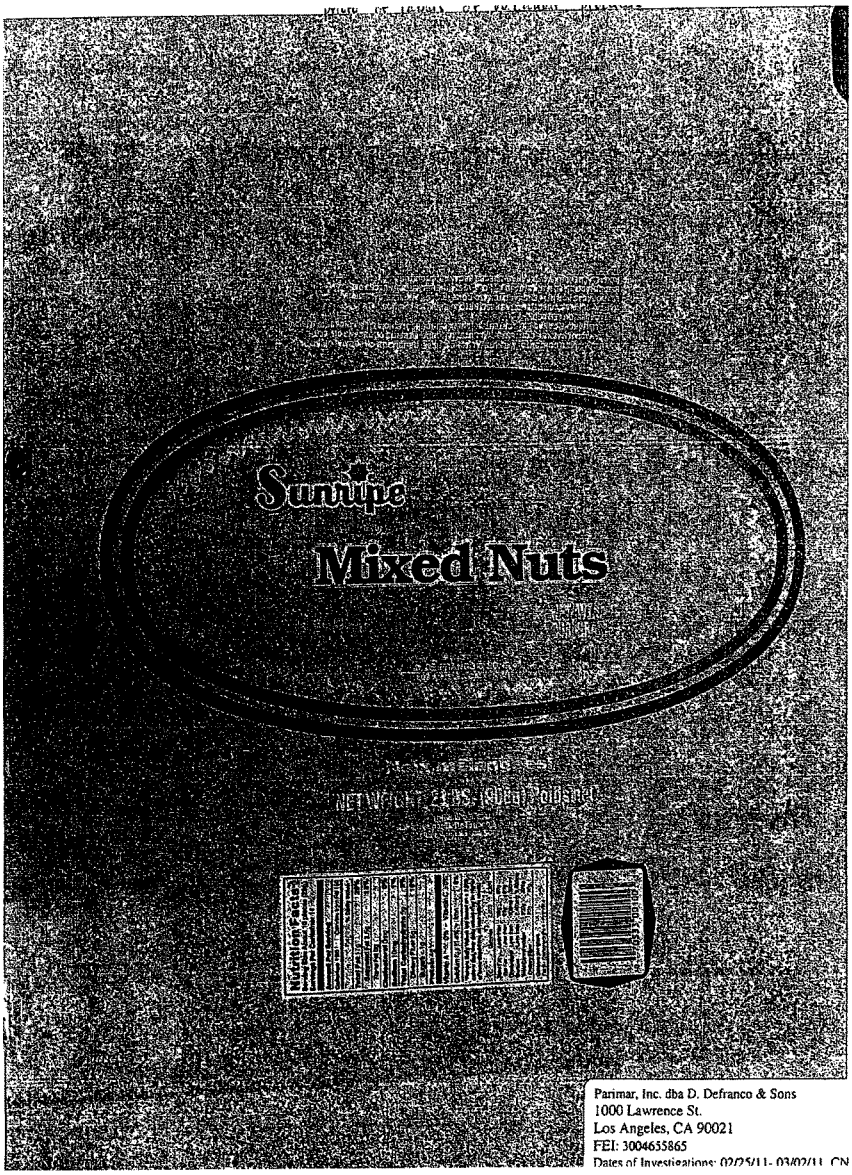
Parimar, Inc. dba D. Defranco & Sons
1000 Lawrence St.
Los Angeles, CA 90021
FEI: 3004655865

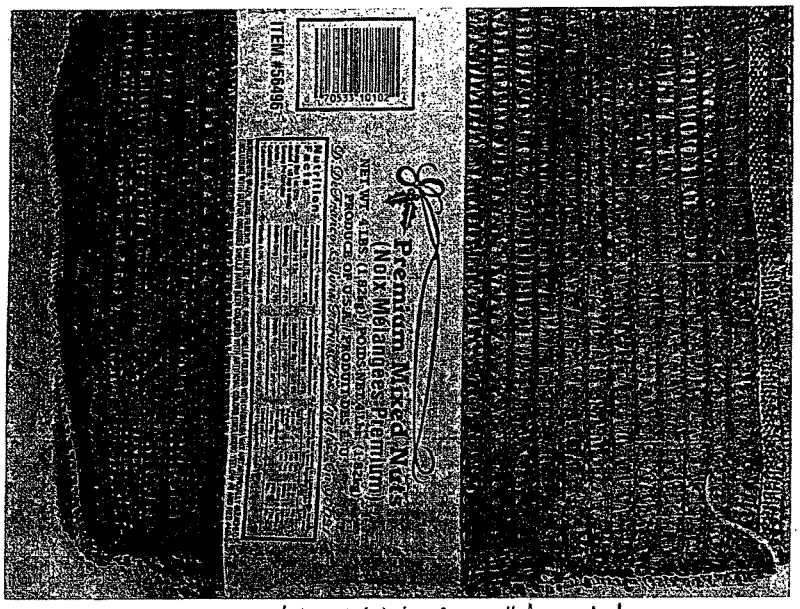


Photos of labels of recalled products

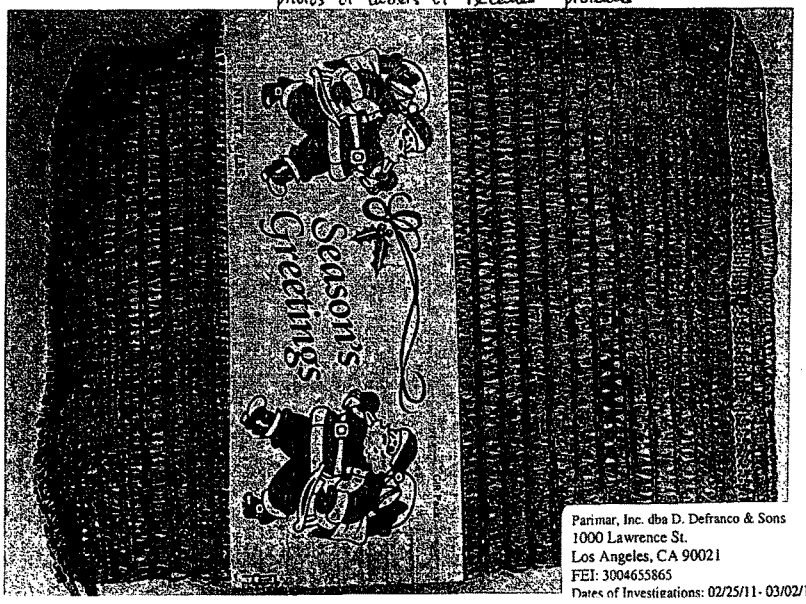


Parimar, Inc. dba D. Defranco & Sons
1000 Lawrence St.
Los Angeles, CA 90021
FEI: 3004655865
Dates of Investigations: 02/25/11 - 03/03/11

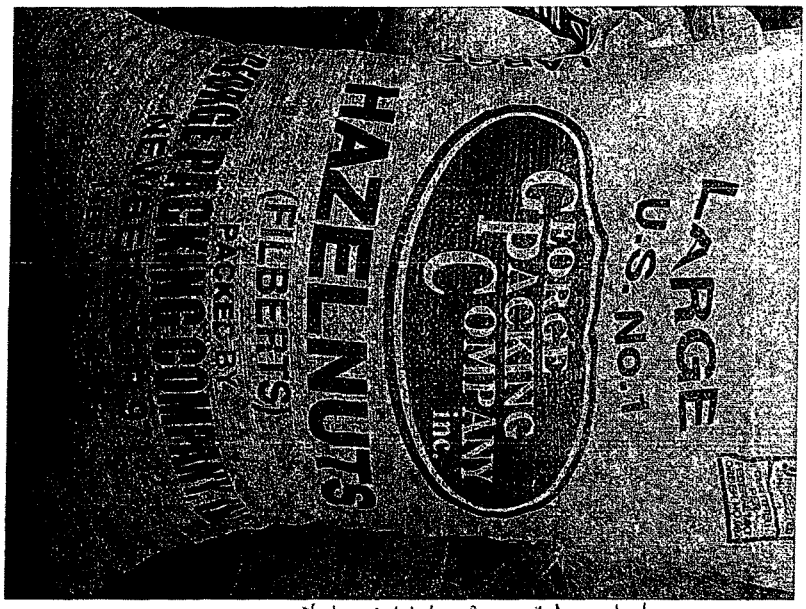

Sunripe
Mixed Nuts
Parimar, Inc. dba D. Defranco & Sons
1000 Lawrence St.
Los Angeles, CA 90021
FEI: 3004655865



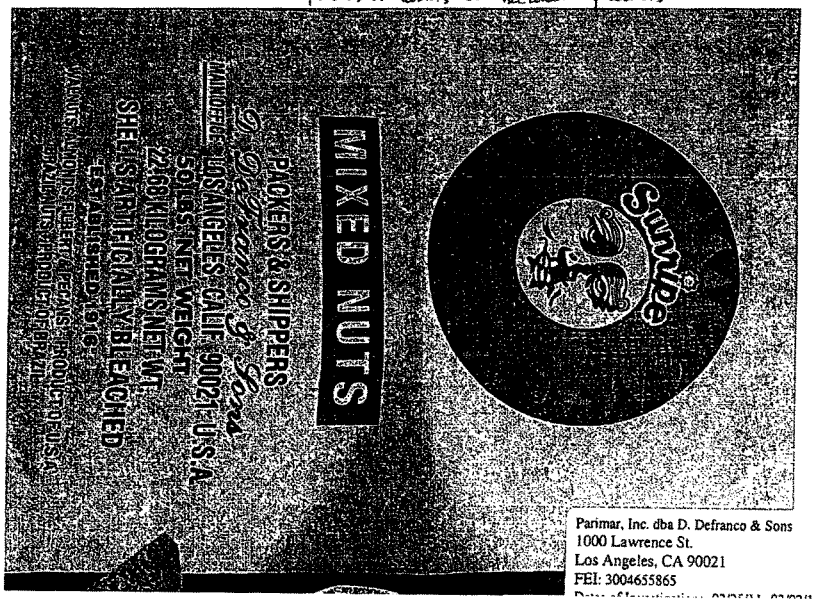
photos of labels of recalled products



Parimar, Inc. dba D. Defranco & Sons
1000 Lawrence St.
Los Angeles, CA 90021
FEI: 3004655865
Dates of Investigations: 02/25/11- 03/02/11 CN



Photos of labels of recalled products



Parimar, Inc. dba D. Defranco & Sons
1000 Lawrence St.
Los Angeles, CA 90021
FEI: 3004655865

Please note that the California Department of Public Health was the lead agency for the March 3, 2011 inspection. Although the inspection report has not been completed at this time, CDPH was able to provide a Notice of Violation and Embargo Notice from the attached March 3, 2011 inspection:

State of California—Health and Human Services Agency | Department of Health Services

EVIDENCE/SAMPLE RECEIPT

Food and Drug Branch

Firm name	Date	Time
New England Tomato Company/De Franco & Sons	2/25/11	1735
Address	**City**	**State** / **ZIP code**
1000 Lawrence St. LA, CA 90	Los Angeles	CA / 90021
Person interviewed	**Position**	
Richard De Franco	Owner	

Items listed below were collected as official samples/evidence on this date as authorized by California Health and Safety Code, Division 104, Section 110150, or Section 108370(b)

QUANTITY	UNIT SIZE	LABEL OR DESCRIPTION	I.S. NUMBER
(b) (4)	50 lb	Crain Ranch CA Walnuts	08202251 1H
	50 lb	George Packing Co. Hazelnuts	08202251 1I

REMARKS

Walnuts - possible contamination due to rodent gnaw marks

Hazelnuts - possible contamination → surveillance sample

Receipt acknowledged by: [signature] | Investigator: Christina Grant #082

DHS 8030 (7/05)

State of California—Health and Human Services Agency | Department of Health Services

EMBARGO NOTICE

Food and Drug Branch

District office	Telephone number	Date
Long Beach	(562) 570-3380	2/25/2011
Address (number, street)	**City**	**ZIP code**
11 Golden Shore #420	Long Beach	90802

Embargoed: on the premises of New England Tomato Company

in the possession of De Franco & Sons

1000 Lawrence Street Los Angeles, CA 90021

Owner (if different) Richard De Franco

1000 Lawrence Street LA, CA 90021

You are hereby notified that the following materials have been embargoed by this Department on the above date under the provisions of the California Health and Safety Code, Division 104, Chapter 8, Article 3, Section 111860.

QUANTITY	SIZE OF UNITS	MATERIAL	I.S. NUMBER
(b) (4)			
[redacted]	50 lbs.	Costa Ranch California Walnuts #1460	0820225111A
[redacted]	11	DeFranco Mixed Nuts	0820225111B
[redacted]	11	Costa Ranch California Jumbo Walnuts #1426	0820225111C
[redacted]	11	Blue Diamond Growers Almonds #1429	0820225111D
[redacted]	11	North Valley Nut Almonds #1365	0820225111E
[redacted]	11	Costa Ranch California Walnuts #1485	0820225111F
[redacted]	11	DeFranco Brazil Nuts	0820225111G
Total			

WARNING: ***It is unlawful for any person to remove, sell, or dispose of this material without permission of the Food and Drug Branch or of the court. Violation of this order is a misdemeanor.***

Embargoed by:

Authorized signature: C. Grant | Investigator name and badge number: Christina Grant #082

Embargo acknowledged by:

Signature: [signature] | Printed name: JOHN DE FRANCO

Title: Co-Partner | Firm name: DEFRANCO AND SONS

DHS 8028 (7/05) Page 1 of 1

State of California—Health and Human Services Agency

California Department of Public Health

NOTICE OF VIOLATION

Food and Drug Branch

Direct responses to: 7025905394 (Fax)

Supervisor	Telephone number
June Nakagawa Attn: Christina Grant	(562) 590 5387
Address (number, street) 11 Golden Shore #420	City Long Beach ZIP code 90802
Firm name New England Tortilla Co/ De Franco & Sons	Date 2/25/11
Address (number, street) 1600 Lawrence St	City Los Angeles ZIP code 90021
Person interviewed Richard De Franco	Position Owner

The conditions or practices noted below were observed on subject premises this date. These are alleged to be violations of one or more provisions of California law pertaining to the manufacture, processing, holding, sale, labeling, or advertising of a food, drug, medical device, cosmetic, or hazardous substance. The Department may seek administrative, civil, or criminal action for each of the violations. This report has been prepared to alert the management of the investigator's findings. It is the responsibility of the firm to assure compliance with all applicable laws and regulations.

1) Walnuts and other nut products were held under insanitary conditions whereby it may have become contaminated with ~~rodent~~ filth, due to the following:

a. Two rodent traps observed stored on top of a pallet of walnuts

b. Numerous (10+) gnaw marks and holes were observed on bags of walnuts.

Signing this notice does not indicate admission of a violation but only receipt of the Notice of Violation.

Firm's authorized representative signature	Authorized representative position
Authorized agent signature	Authorized agent name and badge number (printed) Christina Grant #082

EH 62 A (4/07)

OSP 09 114190

State of California-Health and Human Services Agency — Department of Public Health

NOTICE OF VIOLATION

Food and Drug Branch

Direct responses to:

Supervisor		Telephone number
Jeanne-Marie Weathers		818-548-3078
Address (number, street)	City	ZIP code
500 N. Central Ave. Suite 300	Glendale	91203
Firm name		Date
Parimar Inc. dba New England Tomato Co. dba DeFranco & Sons		March 3, 2011
Address (number, street)	City	ZIP code
1000 Lawrence Street	Los Angeles	90021
Person interviewed	Position	
Mr. Jerry S. DeFranco + Paul DeFranco (Richard DeFranco)	Vice-President + President + Secretary	

The conditions or practices noted below were observed on subject premises this date. These are alleged to be violations of one or more provisions of the California Health and Safety Code, Division 104, pertaining to the manufacture, processing, holding, sale, labeling, or advertising of a food, drug, device, cosmetic, or hazardous substance. Criminal conviction on these charges carries the penalty of imprisonment for up to one year in county jail and/or a maximum fine of $1,000 per violation. A second or subsequent conviction carries the penalty imprisonment for up to three years and/or a maximum fine of $10,000 per violation. Additionally, the Department may seek administrative or civil action, with maximum civil penalties of up to $1,000 per violation. This report has been prepared to alert the management of the investigator's findings and act as a permanent record of conditions noted.

1. The food processing facility, used to package in shell nuts, failed to be maintained in a clean, healthful, or sanitary condition, as follows:
   a) 50 lb. bags of nuts, specifically walnuts, were observed in the cold room (adjacent to green bean processing line) with evidence of exposure to vermin filth. The bags exhibited gnaw marks (>10 gnawed holes observed) which went through the outer packaging, exposing the nuts. The bags also exhibited urine stains as determined by black light examination.
   b) Rodent traps (x2) were observed stored directly on top of a pallet of walnuts.

2. Machinery used in the food processing establishment failed to be maintained in a clean, sanitary condition, as needed to adequately protect food in contact with machinery from dust, dirt, foreign objects, or injurious contamination, in that:
   a) In-shell nut re-packing machines (hoppers, conveyors, tumbler) were observed with an accumulation of dirt, dust, and old nut residue (left from from the last production run on December 5, 2010) on the machinery surfaces and collected in exposed cracks and crevices.
   b) Nut re-packing machines were observed with heavily rusted metal parts; corroded metal grates, cracked ladders with loose pieces of rubber; chipping paint inside nut hoppers and on conveyor surfaces; and duct tape attached to metal siding on a conveyor belt.
   c) Pallets of nuts in the cold room were exposed to overspray from floor cleaning operations, as evidenced by dirty water marks observed on the FDB Embargo tape.

Signing this notice does not indicate admission of a violation but only receipt of the Notice of Violation.

Authorized representative (print and sign)	Authorized representative position
Paul DeFranco	Pres.
Authorized Agent	Authorized agent name and badge number (printed)
Nicole Zugsmith	#054

NOTICE OF VIOLATION - Continued

3. The firm failed to protect processed foods (trimmed green beans, husked cut corn) from potential contamination, as follows:
   a) An employee was observed handling corn at the 'cleat line' with unsecured jewelry (wrist watch) exposed.
   b) An employee on the packaging line was observed directly contacting corn and packaging material with the sleeves from their street clothing.

4. The food processing facility where fresh, cut and packaged produce was handled failed to be maintained in a clean condition or good repair, as follows:
   a) Peeling paint and/or brown colored debris were observed on cooler walls behind boxes of corn; and on the wall behind the 'corn cleat' line.
   b) The corn husking conveyor belt was observed with numberous cracks and crevices.
   c) Old nut residue was observed on the floor adjacent to repacking equipment near the corn husking line.

3-9-11

STATE FOOD SAFETY INSPECTION PROGRAMS AND CONTRACTS

FDA contracts with various states to conduct food safety inspections. In fact, most of the food safety inspections currently being reported by FDA are being conducted by states. The National Integrated Food Safety System currently being promoted by FDA seems to expand its reliance on states to conduct food safety inspections. FDA has had difficulty in the past providing oversight over the state contracts. The notorious salmonella outbreak involving the Peanut Corporation of America in 2008-2009 exposed failures in both Georgia and Texas state inspection programs to prevent adulterated products from getting into commerce.

Ms. DeLauro: How is FDA planning to improve its oversight of the state inspection programs?

Response: FDA agrees that the credibility of an integrated national food safety system depends upon regular program oversight and accountability at all levels. To meet this objective FDA continues to work to improve its oversight of the state inspection programs. In support of enhancing implementation of the Manufactured Food Regulatory Program Standards, or MFRPS, FDA has established two teams who will interact with the states and work to improve FDA oversight of the state inspection programs. The Development and Integration Branch of the Office of Regulatory Affairs, also known as ORA, will work directly with state programs to provide outreach and technical assistance on MFRPS implementation, develop and share implementation aids and training tools, and will assist the states with MFRPS self-assessment and improvement plans. This team will identify gaps, challenges, and barriers to MFRPS implementation and will work to facilitate successful adoption and implementation of the standards among the states. In addition, ORA is staffing a Review and Evaluation Cadre, a team of auditors who will provide assessments and verification of state compliance with the program standards. During their audits this team will review: manufacturing inspections accomplished by the states; the states' regulatory foundations, education and training files for field investigators, inspection reports, the states' self review and evaluation reports, and compliance and enforcement actions and aspects of state preparedness and response.

Ms. DeLauro: How much staff is going to be devoted to provide that oversight?

Response: Currently, FDA devotes 13 FTE to provide oversight and auditing capabilities of state inspection programs.

Ms. DeLauro: How much funding is going to be required to provide adequate oversight?

Response: Several factors preclude us from identifying a specific value at this time. FDA is making advances with the states on implementing the Manufactured Food Regulatory Program Standards. The universe of FDA functions and activities under this program is not truly known at this time, and the schedule for state adoption of the

programs is unknown as well. For these reasons, we cannot estimate the cost to provide adequate oversight.

Ms. DeLauro: What will FDA do should a state program not meet FDA inspection standards?

Response: If a state program does not meet FDA inspection standards, FDA will work with the state to assess their existing program and assist the state to implement a program that will meet FDA standards. In doing so, FDA may provide training, developmental opportunities, and local and national support. During this time, FDA would also assess the ability of that state program to meet obligations for inspectional activity. If necessary, FDA may shift resources to address any potential inspectional shortcomings once FDA's risk model has been applied. Additionally, under rare circumstances where performance is unacceptable, FDA can withhold payment for contracted work until corrective actions are taken and corrected work is submitted.

Ms. DeLauro: Will federal FDA inspectors be assigned to fill the void should a contract be withdrawn

Response: Our objective is to create a strong and credible food safety oversight system that ensures comprehensive and coordinated inspectional coverage of the food supply. Such a program requires developing and implementing uniform, national standards for regulatory and public health programs and implementation of uniform training and certification programs. Oversight of such a program requires maintaining integrity through regular program oversight and accountability at all levels. Under such a system if a state contract is withdrawn due to not meeting program standards, then FDA would re-prioritize the overall work needed in that particular state to assure FDA focused our resources on the highest risk work.

Ms. DeLauro: Most states are experiencing severe budget crises. Many have been forced to furlough or lay off inspection and public health personnel. How will FDA's reliance on state inspection programs be impacted by the budget problems being faced by the states?

Response: The budget problems being faced by the states has the potential to impact FDA's level of assurance that regulated industry is operating in compliance with our regulations. Continued state budget cuts could potentially trigger further reductions in state workforces, resulting in fewer state FTE to support both FDA contracted and state food safety inspection work. This could severely impact an integrated food safety system. We are currently seeing during outbreak situations that some states are unable to respond immediately because staff are on furlough. Currently, approximately one third of a state manufactured food program's total inspection work is counted towards FDA inspection mandates. If these scenarios were to become a reality, we could see diminished food manufacturing facility inspections which could impact FDA's level of assurance that products are manufactured in accordance with our requirements and do not pose a threat to the public health.

Ms. DeLauro: Will FDA funding of state contracts distort state inspection programs so that food safety inspections normally done by states (e.g., restaurants, health care facilities) will not be done in order to fulfill FDA contractual requirements because that is where the money is?

Response: FDA funding of state contracts should not distort state inspection programs. FDA state contract monies serve to supplement not replace existing state funding to ensure that certain inspections relevant to compliance with FDA regulation and law and conducted by state agencies are adequately funded. This funding is not intended to replace state funding to cover inspections mandated by state or local law.

REAGAN-UDALL FOUNDATION

Recently, the board of the Reagan-Udall Foundation (RUF) sent a letter to the Hill requesting that Congress support the federal funding of the Foundation, and to lift the ban that I put in place to block the transfer of funds from the FDA to the Reagan-Udall Foundation.

The letter noted that to the Foundation's integrity, the Board established, as part of its by-laws, "Provisions to Protect Against Conflicts and Undue Influence."

Ms. DeLauro: One of the provisions of the by-laws states that industry representation on the Board is limited to four of the 14 members. But most of the members of the Board have consulting relationships with industry or are major stockholders, is that correct?

Response: It is not FDA's understanding that most of the Board members have consulting relationships with industry or are major stockholders.

Moreover, as a protective measure against actual or perceived conflict of interest, the bylaws of the Reagan-Udall Foundation, also known as RUF, define interest more expansively than just consulting and stock holding. They by-laws prohibit Board members from participating in any aspect of any matter in which he or she has an interest. The interests of certain family members, such as spouses and minor children, and business partners are attributable to the board member in enforcing this recusal policy. Board members must update their disclosures annually. Once RUF is able to support a website, it has committed in its bylaws to posting Board disclosure information, as well as information about all recusals.

Detailed questions on RUF Board members' financial interests and RUF's disclosure and recusal policies may be obtained from RUF.

Ms. DeLauro: Another provision of the by-laws indicate that the Foundation may not accept donations that reflect unfavorably on the integrity of the Foundation. But the Foundation received a major grant of more than $100,000 from the PhRMA Foundation, correct?

Response: As FDA understands it, the PhRMA Foundation has provided RUF with an unrestricted grant of $150,000 for 2010 and 2011. The PhRMA Foundation is a not-for-profit organization with a 45-year history of providing grants for training and research. The amount that you identify is a small part of RUF's total funding. RUF has also been awarded small, unrestricted grants from 15 other not-for-profits totaling approximately $100,000. The RUF has also received a $1 million, 3-year grant from the Bill & Melinda Gates Foundation.

Full, detailed information on RUF finances and gift acceptance decisions are available from the Foundation.

Ms. DeLauro: Last year, FDA and the National Institutes of Health unveiled an initiative designed to accelerate the process from scientific breakthrough to the availability of new, innovative medical therapies for patients.

Is this not similar to the goals of the Reagan-Udall Foundation? What would the R-U Foundation do that would be different from the joint FDA-NIH initiative? Would FDA funds be better spent on the FDA-NIH initiative?

Response: The FDA-NIH Initiative is significantly different from the work of the RUF.

As stated in its charter, the FDA-NIH Initiative will work on joint research planning between the two agencies. The goal of the Initiative is to leverage the strengths of each agency toward the common goal of ensuring that regulatory considerations are an integral component of biomedical research planning, and that the latest science is integrated into the regulatory review process. The Initiative is not a vehicle for scientific partnerships such as those that the RUF would develop.

The mission of the RUF covers all FDA-regulated products, not just medical products for human use. For example, one area the FDA has asked RUF to consider is addressing food safety science.

In 2010, the FDA-NIH Initiative also served as a joint mechanism for allocating roughly $6M in federal grants. In contrast, the RUF is not a mechanism for dispersing federal grant funds. RUF is intended to develop consortia of diverse stakeholders and leverage private funds to address scientific priorities.

Finally, RUF can develop types of programs, such as a visiting scholars program or a fellowship program that are not related to the NIH-FDA Initiative. Further, there are important scientific issues of interest only to FDA and not NIH, such as food safety science and scientific hurdles in manufacturing quality.

Ms. DeLauro: The Brookings Institution's FDA work is led by the same person as the chair of the RUF Board. Can you give any specific examples of projects that the

RUF could do that would contribute to the public health mission of FDA that are different from what Brookings or other think tanks could do?

Response: Brookings' mission and activities are to stimulate policy debates and make public policy recommendations. In contrast, the RUF is prohibited from providing policy advice to FDA. The RUF's mission and activities are to identify, fund, and support scientific projects and programs that will help equip FDA staff with the highest caliber science. In contrast, organizations like the Brookings Institution, do not engage in operational scientific work.

Ms. DeLauro: Does the RUF staff have any particular FDA expertise that sets them apart from existing Foundations or nonprofits?

Response: From FDA's perspective, we are pleased that the Board demonstrates unique FDA expertise and understanding of FDA-specific scientific issues, ranging from a former Commissioner to patient advocates who focus on consumer-related FDA matters.

Similarly, the executive director has decades of experience across an array of FDA matters, including food manufacturing standards, while she was an employee of Proctor & Gamble and a consultant in the food industry. The executive director is also well versed in drug development matters through her involvement with patient advocacy groups and service on an FDA Advisory Committee. Her work with the FDA Office of Special Health Issues and the National Cancer Institute to bring together oncology patient advocates, industry, FDA and NCI to create appropriate Compassionate Use and Expanded Access patient programs demonstrates her ability able to bring together diverse groups of stakeholders to work together on common goals that support FDA and regulatory science.

Full, detailed information about RUF employees and Board members is available through RUF. Once RUF has the funds to support a website, it has committed to posting the resumes of all Board members and employees.

QUESTIONS SUBMITTED BY REPRESENTATIVE BISHOP

FOOD INSPECTION CAPACITY

Mr. Bishop: What is your view of the State role in food inspection, particularly given an expectation of continued budget reductions and where the Federal inspection foot print is largely dependent on the State partners? How can we more effectively support the state inspection process, especially in the area of training assistance to States?

Response: The domestic food supply chain is overseen by a mix of Federal, State, territorial, tribal and local regulatory and public health agencies. To successfully ensure the safety of the food supply, we need an integrated national food safety system that leverages resources and strengthens collaboration with all these regulatory and public health partners.

An integrated national food safety system requires building the capacity of state, territory, tribal, and local agency programs so they can meet national program standards to ensure uniformity in inspectional coverage and collection and analyses of samples. An integrated national food safety system also needs to develop training and certification programs to ensure uniform and consistent approaches to food safety throughout the system and a highly skilled workforce. We believe the best approach is through funding of state and local regulatory and public health partners linked to defined performance standards.

Mr. Bishop: As you know, the over the years, Department and the State of Georgia work cooperatively on food inspection activity. Given the fiscally restrained environment we're facing today, there actually may be ways to broaden and expand the cooperative relationship between State inspection activities and Federal. I know the Commissioner of Agriculture for the State has expressed an interest in building on our current relationship with the Federal government. Any thoughts on where we might be able to build on existing synergies and/or create new ones?

Response: One approach that has been successful is the Food Protection Rapid Response Team and Program Infrastructure Improvement Prototype Project. This is a 3-year cooperative agreement that awards $500,000 a year to each selected recipient to build state program infrastructure and rapid response capabilities for all-hazards food and feed emergencies and implementation of the Manufactured Foods Regulatory Program Standards. Through a competitive process, programs in the following nine states were selected: California, Florida, Massachusetts, Michigan, Minnesota, North Carolina, Texas, Virginia, and Washington. This project engages each of these partners to develop innovative programs and tools, both within each individual program and jointly, among the nine pilot teams.

The continuation of funding for nine rapid response teams in addition to expansion of the funding to include additional states will serve as a significant step toward creating a fully integrated national food safety system that includes enhancements

to state and local food inspection and food borne illness response programs. The synergies realized with this funding would strengthen collaboration among states and FDA.

PROPOSED FUNDING REDUCTIONS

Funding for the Food Safety Modernization Act has been an area of particular controversy. The FDA has said that implementing the legislation would cost about $1.4bn over five years, but the GOP budget proposal for the remainder of fiscal 2011 includes significant spending cuts to food regulatory agencies, including the FDA, the Centers for Disease Control and Prevention (CDC), and the Agriculture Department's Food Safety Inspection Service (FSIS). FDA's budget is reduced by $130 million.

Mr. Bishop: If we're faced with having to reduce or curtail mandatory inspections at the Federal level as a result of these reductions, what, if any options do you have at your disposal to maintain the national food inspection apparatus at an effective operating level?

Response: FDA provides funding of $13,151,600 in FY 2010 to state and local regulatory agencies to support inspection activities in the food and feed programs. Unfortunately, if the FDA budget is reduced, FDA may also have to reduce or eliminate funding to our State and local partners. This would come at a time when States and localities are also struggling to balance budgets and have already reduced state and local inspection programs. Therefore, we believe that it would be difficult for States and localities to compensate for these losses and maintain effective operating levels to oversee the food safety system. The result will be greater risk of foodborne illness for American consumers.

FOLLOW-UP PROPOSED FUNDING REDUCTIONS

Mr. Bishop: Does it make sense to expand the use of State food inspection services in the short term, should severe reductions in our food safety programs survive?

Response: Protection of the U.S. food supply is a shared responsibility between federal, state, and local public health and regulatory authorities. The increased use of state and local inspections to augment FDA's ability to inspect the food industry is something that we are considering, but will be influenced by our available resources.

IMPORTED FOOD INSPECTIONS

As a result of the Food Safety Modernization bill, exporters to the US as well as domestic importers should will face much closer scrutiny of their food safety controls, including requirements that imported foods be inspected and subjected to the same standards in place for U.S. foods.

Mr. Bishop: Can you give us a sense of where the FDA is in terms of implementing the new requirements for the inspection of imported food?

Response: To implement this legislation with the FDA FY 2012 budget and to achieve the many statutory requirements, FDA has established priorities, one of which is a high priority on implementing the import provisions of the law. FDA has established an executive leadership group and established six implementation teams, one of which is the Imports Team. The Imports Team is charged with implementation of the key statutory and operational deliverables and has formed additional workgroups and task groups to implement these key provisions. The group is on track to meet the statutory time frames.

We will also place high priority on engaging stakeholders, including members of the import and export community. As a first step, FDA hosted a public meeting on March 29, 2011, entitled, "FDA Food Safety Modernization Act: A New Paradigm for Importers." This meeting provided an opportunity to discuss implementation of the import safety provisions of FSMA. FDA is seeking input to inform the development of regulations and guidance on importer verification, the Voluntary Qualified Importer Program, import certifications for food, and third-party accreditation by providing multiple opportunities for individuals to express their views through presentations, participating in breakout sessions on the provisions discussed at the meeting, and submitting written comments to the designated docket(s) within 30 days after this meeting.

FDA is also hosting a public hearing on March 30-31, 2011, entitled, "Ensuring the Safety of Imported Foods and Animal Feed: Comparability of Food Safety Systems and Import Practices of Foreign Countries." This Hearing will provide stakeholders the opportunity to discuss FDA's use of international comparability assessments as a mechanism to enhance the safety of imported foods and animal feed and lessons learned through equivalence determinations

FOLLOW-UP IMPORTED FOOD INSPECTIONS

The FDA now has the authority to block foods from facilities or countries that refuse FDA inspections. Additionally, it is expected that the FDA will increase its inspection of foreign facilities that produce foods imported into the US.

Mr. Bishop: Has the FDA begun to have conversations with the governments of major exporting county's [to the U.S.] regarding our new requirements and what has been their response thus far?

Response: Yes. On February 15, Deputy Commissioner for Foods Michael R. Taylor met with key staff of the European Union to discuss our new requirements. The Deputy Commissioner later met with the Agricultural Attaches for the European Union stationed in Washington, D.C. On February 23, FDA sponsored a foreign embassy briefing in Washington. A panel of executive leaders provided information to staff from 53 embassies and responded to questions. In addition, FDA's foreign offices in China, India, Costa Rica, Mexico, and Chile have all provided preliminary outreach on the new requirements. On March 29, FDA will provide an Information Session on FSMA for member delegations to the World Trade Organization and will hold a public meeting on the import provisions of Food Safety Modernization Act, also know as the FSMA, to listen to stakeholder input.

In addition to outreach about FSMA, FDA policy is to communicate with the embassies and competent authorities in the foreign countries in which we plan to conduct inspections. Explanation of new authorities under FSMA will be presented and shared as part of the fiscal year 2012 foreign inspection planning cycle which will begin with the next few months.

Governments have been very interested in learning more about our new law since Canada, Australia, and New Zealand are modernizing their food laws as well. Our major trading partners appear to understand the impetus for the new law. However, some countries are concerned about the seeming incongruity between FDA increasing foreign inspections while at the same time relying more heavily on third-party auditing and import certification to help ensure the safety of imports. Also, we have received a number of very specific, detailed questions about implementation which are being funneled to the FSMA implementation teams.

We have received a report that China intends to raise FSMA as a trade barrier at the next session of the WTO committee that deals with food safety. We have not yet received the text of their concerns.

FISH MERCURY

Some concern has been expressed that the 2004 FDA advice about eating seafood did not strike the right balance of promoting the benefits of seafood while limiting intake of certain higher-mercury species. Since the FDA advice first came out in 2004, it has been widely misinterpreted as a warning for all Americans and pregnant women in particular, to simply avoid seafood based on concerns over mercury. However, it would appear that more recent scientific evidence suggests that the potential harm to pregnant women is not as prevalent as once thought. This was also reflected the latest USDA/HHS - 2010 Dietary Guidelines for Americans (DGAs).

Mr. Bishop: Should FDA change or modify its 2004 advice regarding seafood?

Response: FDA is aware of concerns that the 2004 FDA and EPA advisory on fish consumption has become outdated since it does not take into account new science that has become available since 2004. The 2004 advisory was designed to protect the developing fetus and young children from neurotoxic effects from methylmercury. FDA recognizes that advice on seafood consumption by pregnant women should also enable a developing fetus and young child to obtain the maximum neurodevelopmental benefits that fish can provide. FDA has been engaged in a quantitative risk and benefit assessment for commercial fish that takes into account the research germane to both risks and benefits, including research published since 2004 that was reflected in the 2010 Dietary Guidelines for Americans.

The FDA risk and benefit assessment was published in draft in January 2009. It has been under further development since that time to take into account comments from the public, other government agencies, and scientific peer reviewers, as well as to incorporate additional risk and benefit modeling as recommended by many who commented. After the assessment is completed, FDA will evaluate the 2004 FDA and EPA advisory, review new research, and determine if updates or modifications to the advice may be appropriate based on the best science available. In so doing, FDA will continue to consult with scientific agencies and the public through a transparent process in which all views can be thoroughly aired and considered. FDA expects to complete its assessment in the coming year.

TOMATOES

Dr. Hamburg, the tomato farmers in South Georgia and northern Florida are still reeling from the FDA's tomato salmonella recall debacle from a couple years ago. As you'll recall, in Georgia alone, tomato growers loss over $14 million from tomatoes grown, and in some cases harvested, but could not be sold since consumers 'quit buying tomatoes' on the recommendation of FDA and the CDC. It is conservatively estimated growers nationwide lost over $125 million from this false indictment from our own federal government. More importantly, many of the tomato producers in my district have yet to recover.

The Food Safety Modernization Act, which was signed into law last December, authorizes payments to producers harmed by "future" government decisions which ultimately prove to be incorrect or ill-founded. I would certainly be interested in working with you to find a way to provide some assistance to our tomato producers, given the precedent set under this legislation.

Mr. Bishop: Is this a question or task for FDA?

Response: FDA intends to cooperate with the development of the report by the Comptroller General under Section 206 of the Food Safety Modernization Act. This report will consider, among other things, models for farmer restitution in other nations.

FDA also intends to cooperate with the U.S. Department of Agriculture should it, in turn, conduct a study of the feasibility of implementing a farmer indemnification program to provide restitution to agricultural producers for losses sustained as a result of a mandatory recall of an agricultural commodity by a Federal or State regulatory agency that is subsequently determined to be in error.

FOLLOW –UP TOMATOES

Under the new Food Safety legislation, the FDA is required to establish, as appropriate, "a product tracing system to receive information that improves the capacity to effectively and rapidly track and trace food that is in the United States or offered for import into the United States."

Mr. Bishop: How do you expect this process to work for imported fruit and vegetables?

Response: FDA is currently examining the new authorities in the Food Safety Modernization Act, also known as the FSMA, related to product tracing. FDA is gathering data and information and intends to conduct pilot projects as set forth in the law. As required by the law, to the extent practicable, FDA will evaluate international product tracing practices in commercial use and consider international efforts. As FDA moves forward to implement FSMA, it will engage its stakeholders to help the Agency develop a product tracing system that improves FDA's capacity to rapidly track and trace food that is in the United States or offered for import into the United States, including imported produce.

NEW LUPUS DRUG APPROVAL

Madame Commissioner, I was very pleased to learn yesterday that the FDA approved the first treatment designed for lupus in the past half century. As you know, it is estimated that some 300,000 to 1.5 million Americans have lupus - a majority of which are African American or other minorities. If fact, I have several friends who either have lupus or have family members who have been stricken by the disease.

The new drug, Benlysta - - when used in conjunction with other drugs, will offer a way to combat this very difficult disease.

There is no known cure for lupus, which as you know is a chronic and often debilitating disease in which the immune system attacks the body's organs. Symptoms such as inflammation, pain and tissue damage are typically treated with steroids and immunosuppressant therapies.

I'd like to compliment the FDA on this accomplishment, and pray that this breakthrough will not be the last, particularly in terms of diseases which disproportionately impact the minority community.

USER FEES

Under the president's proposed 2012 budget, the Food and Drug Administration would receive $2.7 billion - $147 million more than it got in the 2010 budget. The agency also would receive an estimated $1.6 billion in user fees paid by pharmaceutical, medical device and tobacco companies, for a total proposed budget of $4.4 billion.

Much of the increase, about $100 million, would be used to implement the far-reaching food safety law Congress approved last year that requires the FDA to increase inspections of food facilities, among other things.

Mr. Bishop: The Congressional Budget Office estimates that it will cost the government $300 million a year over the next five years to implement the legislation. Assuming that the Administration will not be able to make up the difference through proposed user fees on food companies, how will the FDA achieve the required expansion of inspections?

Response: FDA will use the resources provided and take a risk informed approach to maximize the number of inspections of the food safety system even though it may not meet the required inspection frequency in the legislation. We will use the best data available to try to determine which firms to inspect. FDA will focus to the greatest extent on firms producing high risk products, but may also include other targeted strategies to try to obtain the highest rate of compliance with our prevention based standards. FDA would also look to leverage resources with other trusted regulatory partners both domestically and internationally. FDA would also plan to obtain the greatest efficiency possible in the conduct of inspections by investing in enhanced IT systems and focused inspection approaches.

PREMARKET APPROVAL/DRUGS

Mr. Bishop: What is the FDA's process for a sponsor to request and pursue an appeal of a PMA (Premarket Approval) denial outside of the Center that denied the PMA?

Response: Under the Federal Food, Drug, and Cosmetic Act, the sponsor of a Premarket Approval Application, or PMA, may appeal denial of approval of a PMA by requesting an open public hearing or a hearing before an advisory panel. The appeal must be filed within thirty days of the denial of approval and must be filed under the procedures described under 21 CFR 10.33, which is the regulation that governs requests for reconsideration. Upon completion of any open public hearing and considering the hearing record, or upon receiving the recommendation from the advisory panel, the Secretary shall issue an order upholding the denial or reversing the denial and stating the reasons for upholding or reversing the denial.

Mr. Bishop: What is FDA's statutory response time to a petition requesting reconsideration of a PMA denial?

Response: Sections 515(d)(4) and 515(g) of the Federal Food, Drug, and Cosmetic Act describe the processes for requesting reconsideration of the denial of approval of a Premarket Approval Application, or PMA. These provisions do not provide a timeline for FDA to respond to petitions for reconsideration.

Mr. Bishop: Are FDA's timelines for response and its processes satisfactory and transparent to ensure an efficient and effective appeal process in support of the agency's public health mission?

Response: These statutory provisions create alternate appeal mechanisms for requesting reconsideration of a denial of approval of a Premarket Approval Application, or PMA. The person requesting reconsideration may seek review in a formal evidentiary public hearing or review by an advisory committee of experts. The formal evidentiary hearing is an administrative adjudicative proceeding with trial-type procedures, while review by an advisory committee of experts entails appointing panel members with appropriate expertise to provide a recommendation of the reconsideration and other administrative procedures to ensure the fairness of the proceeding. Both of these processes require significant investment of resources on the part of both the Agency and the person requesting review. Any attempt to impose timeframes on these processes could interfere with the procedural protections that are in place to ensure fairness and to ensure there is sufficient time for those making recommendations or issuing final decisions to fully understand the matter under review.

Both types of proceedings are public and in both cases, the Center for Devices and Radiological Health, or CDRH, makes information about the reconsideration public beforehand. This information includes the review memorandum describing the scientific and regulatory bases for the denial and information about the proceeding.

TOBACCO

It appears March 23rd is an important day for FDA, particularly the Center for Tobacco Products. The Tobacco Products Scientific Advisory Committee (TPSAC) has been working for nearly a year to develop a report and recommendations on the use of menthol in cigarettes as mandated by the Family Smoking Prevention and Tobacco Control Act (P.L. 111- 31).

Mr. Bishop: Can you provide us with an overview of FDA's next steps once it receives the report?

Response: The Federal Food, Drug, and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act, also known as the Tobacco Control Act, requires that the Tobacco Products Scientific Advisory Committee, referred to as the TPSAC, produce a report and recommendations on the impact of menthol cigarettes on public health, including such use among children, African-Americans, Hispanics, and other racial and ethnic minorities. The statute required that FDA refer the topic of the

public health impact of menthol cigarettes to TPSAC immediately upon the establishment of the Committee, with the report being due one year after the committee is established.

The final report and recommendations was finalized and submitted to the FDA at the final TPSAC meeting regarding menthol. The report is considered submitted to the Secretary of HHS once received by the FDA. The final report and recommendations will also be made available to the public at the FDA Center for Tobacco Products' Website once it has been reviewed for redaction of all commercial confidential or trade secret information.

Leading up to the submission of the report, FDA has begun to educate various stakeholders, including industry and unions, public health advocacy groups, and stakeholders with interest in minority health issues about what is likely to occur upon receipt of the report by FDA. The Center for Tobacco Products, or CTP, also has created a Web page called "Menthol Report: What to Expect" that provides information on the outline of the report.

Now that the report has been received, the Secretary and FDA will consider the report and recommendations of the committee, as well as other relevant scientific evidence concerning menthol cigarettes, and make a determination about what actions, if any, are warranted. There is no statutory deadline or timeline for the FDA to act on the recommendations provided by the Committee in the report. FDA intends to provide its first progress report on the review of the science in approximately 90 days from the TPSAC report due date. Any actions taken by the FDA that led to restrictions on the sale or distribution of tobacco products or the establishment of a tobacco product standard requires rule making that includes public notice and comment.

TOBACCO

Commissioner Hamburg, when Congress passed the Family Smoking Prevention and Tobacco Control Act in 2009, it required FDA to issue a report on the impact of the use of menthol in cigarettes. It was the Congressional intent in requesting this study that FDA look at whether menthol deserved special regulation or not, based on whether menthol made cigarettes any more dangerous than other cigarettes. Congress intended for the FDA Advisory Committee evaluate whether menthol cigarettes were any more harmful than other cigarettes based on epidemiological and toxicological evidence -- in other words, based on hard science.

Congress also specifically directed the FDA's Scientific Advisory Committee to consider how any actions specific to menthol would impact the "creation of a significant demand for contraband" products that do not meet the health requirements of the new law. I know you are expecting a report later this month from the Advisory Committee and probably can't comment in detail. But I just wanted to express my strong view that FDA needs to follow the law when evaluating the upcoming menthol report.

Mr. Bishop: I would be pleased to hear any reaction you may have at this early stage.

Response: FDA's Tobacco Products Scientific Advisory Committee has held eleven meetings, as well as two additional meetings of the Menthol Report Subcommittee, to review the evidence regarding the impact of the use of menthol in cigarettes and develop its report. In these meetings, TPSAC has received data from a variety of sources, including peer review literature, industry presentations, legacy database document reviews, secondary data analyses from existing data sources, marketing data reviews, industry document submissions, the development of a model on the effect of menthol on initiation and cessation, and public comments at the open public hearings held at each meeting.

The Federal Food, Drug, and Cosmetic Act, also referred to as the FD&C Act, as amended by the Tobacco Control Act, requires that, in its review of the public health impact of the use of menthol in cigarettes, TPSAC address the considerations listed in specified provisions of the FD&C Act that relate to the risks and benefits to the population as a whole, the increased or decreased likelihood that existing users of tobacco products will stop, the increased or decreased likelihood that those who do not use tobacco products will start, technical achievability of compliance with a proposed standard, and the countervailing effects of a proposed standard on the health of tobacco users or users, such as the creation of a significant demand for contraband.

The menthol report consists of eight chapters that address menthol in a comprehensive manner.

There is no required timeline for FDA consideration of the menthol report and its recommendations, the FDA's review of other relevant scientific evidence concerning menthol cigarettes, or an FDA determination about what actions, if any, are warranted. Any actions taken by the FDA that lead to restrictions on the sale or distribution of tobacco products or the establishment of a tobacco product standard requires rule making that includes public notice and comment. As with all of FDA's tobacco regulation activities, FDA will comply with the Tobacco Control Act.

QUESTIONS SUBMITTED BY REPRESENTATIVE KAPTUR

FY12 BUDGET REQUEST

For FY 2012, FDA proposes an increase of $326.0 million for the Transforming Food Safety and Nutrition Initiative. This increase includes $225.8 million in budget authority and $100.2 million for user fees, including the four new user fees enacted in the FDA Food Safety Modernization Act.

Madam Commissioner, in your testimony you highlight an important development at FDA regarding nutrition labeling of restaurant menus. You identify that the medical costs of obesity at $147 billion present a difficult challenge for all Americans.

Ms. Kaptur: Please update the committee on the timeline for implementing this new $8.8 million initiative?

Response: FDA expects to be well on its way to full implementation of the $8.8 million program by the end of December 2012. During the next 21 months, FDA will be conducting a host of activities to inform and educate consumers, industry, and other stakeholders about the implementation of the new nutrition labeling initiative to help consumers make more informed dietary decisions. More specifically, FDA expects to issue two proposed regulations that outline requirements for calorie and other nutrition labeling in chain restaurants and similar retail food establishments and for certain vending machines. Following publication of the proposed rules, FDA will focus on the regulatory review activities necessary to finalize the menu and vending machine nutrition labeling regulations.

Once FDA issues the final rules, FDA activities will focus on initiating education and outreach activities for consumers, industry, and other stakeholders to inform and educate them about the new requirements and how nutrition information can be used to make better dietary choices. During this time, we also plan to work with state and local agencies to develop compliance strategies. FDA expects to contract with state agencies, or subdivisions of state, county, or city governments, with regulatory authority to inspect restaurants and similar retail food establishment chains covered by the menu labeling regulation. FDA intends to stagger the award of contracts, and commission, credential and train state and local officials so that work can begin by the end of December 2012.

Ms. Kaptur: Madam Commissioner, in your testimony you propose funding levels where you reduce FDA staffing by 46 FTE's. For an agency where most of your budgeting costs are borne by salaries and expenses, what will the impact be for this cut?

Response: FDA's goal is to implement FTE reductions associated with the FY 2012 Contract and Administrative Savings without adverse consequences for FDA public health activities. The reduction of 46 FTEs will come from the FDA field operations

within the Office of Regulatory Affairs across all FDA program areas. The Office of Regulatory Affairs will achieve these savings by reducing administrative support staff and by identifying and eliminating redundancies.

Ms. Kaptur: For the past number of years, this committee has provided unprecedented investments to FDA and I want to ensure that cutting FTE's is targeted and not a haphazard plan to meet an artificial top line target. In an effort to reach the administration targets for your agency and still implement the important programs under your authority, could there be unintended consequences for this proposed cut?

Response: FDA is proposing $29.7 million in contract and administrative savings designed to achieve reductions and cut costs across all FDA program areas. In addition to reducing some administration staff though field administrative staff efficiencies, FDA plans to achieve Agency-wide savings in acquisition of support services, including information technology, workforce planning, financial services, consolidated purchasing agreements, and by reviewing research support mechanisms. FDA plans to achieve contract and administrative savings by increasing competition, using FDA-wide contracts to combine resources and reduce cost, replacing traditional classroom training with online training, achieving savings in information technology procurement, and reducing administration support FTE. FDA does not anticipate unintended consequences from FDA's proposed cost-reduction efforts.

Ms. Kaptur: While some have claimed that implementing the Food Safety Legislation is not worth the cost, the numbers clearly show that food safety legislation is critical and must be fully implemented. Sure, the CDC recently lowered its estimates of the annual number of cases of foodborne illness from 76 million to 48 million and that shows the success of this committees work in ensuring that FDA has the resources to create consistency in the market. Even with just 48 million cases of food borne illnesses, the cost per case of $1,851 per case of foodborne illness is still dramatic. With simple math, these 48 million annual cases times $1,851 per case, the result is $88.8 billion annually nation-wide. $88.8 billion! Think about the impact of that to our economy.

How many jobs would that amount of money result in if that much money wasn't sucked out of our economy?

Response: Although FDA does not have a jobs estimate associated with foodborne illness, I agree that 48 million cases of foodborne illness are too many. FDA intends to reduce foodborne illness numbers through the new tools we have been given in the Food Safety Modernization Act. FDA is committed to a risk-based decision-making system for resource allocation that focuses resources where we can be most impactful for public health, reducing foodborne illness with preventive standards and assurance of compliance with those standards.

H.R. 1 BUDGET CUTS

The H.R. 1 budget cut of $400M to FDA programs for FY 2011 will have profound consequences, because a cut to FDA's budget is a cut to America's health. A $400M budget authority reduction is a cut to FDA of 16 percent, compared to the FY 2011 budget request.

Ms. Kaptur: If enacted would this legislation result in furloughs?

Response: H.R. 1 proposes cuts that would sharply undermine core FDA public health protection programs and activities, including protecting America's food supply and securing the supply chain for critical medical products. A cut of this magnitude could lead to furloughs and other actions required to achieve the $400 million reduction so close to the end of the fiscal year.

Ms. Kaptur: Should a scare like heparin occur again during the period of HR 1, how would FDA's response be compromised?

Response: Under H.R. 1, there would be a reduction of $400 million compared to the FY 2011 President's Budget request for FDA. A reduction of that magnitude would result in far fewer safety personnel and resources to address a potential crisis similar to heparin.

CDER's drug safety program would be reduced by approximately 129 FTEs if a $400 million cut is enacted in H.R. 1. Cuts in personnel for the drug safety program could limit CDER's ability to conduct accurate and timely post market surveillance as well as inspections of manufacturing facilities. This reduction to drug safety could also delay CDER's progress in constructing an active surveillance system to monitor adverse events and improve safe use of medical products, which may prevent crises similar to heparin.

Ms. Kaptur: Would FDA be forced to close down offices overseas or suspend inspections?

Response: The House-passed version of H.R. 1 would impose a reduction of $400 million on FDA. The overseas inspectional impact under H.R. 1 is approximately 130 fewer foreign food and medical product inspections. Reduction of this magnitude will also result in the closure of one operating overseas post and the cancelation of plans to establish offices in major trading partners such as Brazil and Canada. This budget reduction would further restrict FDA's ability to engage in existing cooperative agreements and to initiate new agreements with various multi-lateral organizations such as the World Health Organization, and with federal government agencies with complementary missions such as the U.S. Agency for International Development. These cooperative agreements are the best mechanism for FDA to leverage the work accomplished by other federal agencies and other foreign governments to support and achieve the FDA mission.

Ms. Kaptur: Would FDA be forced to cancel contracts or cease certain activities under the proposed level?

Response: Under H.R. 1, there would be a reduction of $400 million to FDA's budget. A reduction of this magnitude may result in cancelling or reducing contracts or ceasing certain activities where operationally feasible and legally permissible. Each measure would be evaluated consistent with FDA's public health priorities.

Ms. Kaptur: Would FDA be required to suspend analysis of certain drugs or devices under the proposed cuts?

Response: Under the proposed H.R.1 budget level passed by the House of Representatives, FDA would not suspend the review of premarket device applications. However, under the proposed H.R.1 budget level the Device Program cannot maintain its current premarket review time performance. Based on the funding level in H.R. 1, Medical device innovations will take longer to reach the market, thereby delaying benefits to patients that suffer debilitating or life-threatening illnesses.

Under H.R. 1 as passed by the House of Representatives, approvals of new drug products would be delayed as the review time would increase under the H.R. 1 funding levels. FDA would be limited in implementing data standards and using advanced scientific computing techniques to efficiently complete drug reviews. FDA also cannot add staff to conduct generics reviews, which will cause the number of pending generic applications to continue to increase. The result would be greater delays in patient access to safe, affordable treatments.

Ms. Kaptur: According to a letter recently sent to my office by a coalition of groups including the American Public Health Association, Center for Foodborne Illness Research & Prevention, Center for Science in the Public Interest Consumer Federation of America, Consumers Union Food & Water Watch, Government Accountability Project, National Consumers League, Safe Tables Our Priority, Trust for America's Health, United Food and Commercial Workers International Union, U.S. Public Interest Research Group "Cuts to FDA and FSIS [in fy 2011] could have a significant impact on a large and critical sector of our economy: food contributes nearly $1.2 trillion to our economy, or 8% of the U.S. gross domestic product." Please respond to this claim.

Response: I agree that cuts to FDA could have an impact on the food sector of our economy. In the past, outbreaks of foodborne illness have had serious consequences for the affected segment of the industry. The recalls of peanuts and peanut products as a result of illnesses linked to the Peanut Corporation of America in 2009 are estimated to have cost the peanut industry $1 billion. In many cases, it takes time for sales to rebound to pre-outbreak levels, if they do. Cuts to FDA below the FY 2011 budget level could have a negative impact on the food sector by impacting FDA's ability to prevent foodborne illness.

HEPARIN

Ms. Kaptur: As we have discussed at length in previous hearings, our response to the Heparin scare is critical. For the record, please estimate the cost to the American taxpayer of the heparin investigation?

Response: FDA does not have a comprehensive estimate of cost to the American taxpayer associated with the heparin investigation because some of these costs were incurred by entities other than FDA. However, FDA staff expended substantial time and resources managing this crisis.

Once FDA was notified of allergic-type reactions associated with heparin manufactured by Baxter, FDA immediately began its investigation. FDA developed analytical methods to respond to this problem, and FDA collected and testing of heparin samples. FDA work continued with an investigation into the supply chain for heparin to identify the unknown contaminant. FDA staff worked around-the-clock to investigate and find the problem, monitor the recall, keep the public informed about the status of the safety of the heparin supply, work with international partners to define the scope and nature of the problem and ensure that an adequate supply of heparin was available to patients who needed it.

FDA's Office of Regulatory Affairs estimates that the cost to the American taxpayer for their efforts at approximately $2,750,000, supported by 14 FTE.

Ms. Kaptur: According to an October 2010 GAO report FDA conducted 37 domestic and 1 foreign investigation related to the heparin scares from January – June 2008. What is the cost estimate for these investigations to the American tax payer?

Response: FDA expended considerable resources to investigate and manage the entire heparin matter, both in the active days of the scare, and still today. To date, we have not estimated the total cost to the taxpayer for this effort.

For reference, FDA's Office of Regulatory Affairs, also known as ORA, estimates that the cost of ORA's work in terms of dollars and staff resources is approximately $2,750,000 and 14 FTE. This represents the field estimate for ORA heparin-related investigations $400,000 and 2 FTE, inspections $2.1 million and 11 FTE, and criminal investigations $250,000 and 1 FTE. Please note that this estimate only represents ORA's expenses during the specific time frame noted in your question.

Ms. Kaptur: With only one investigation conducted abroad, how can FDA truly determine the nature of the heparin scare?

Response: Since the time of the heparin crisis, FDA has conducted many inspections of heparin manufacturing facilities abroad, including approximately eighteen inspections of heparin manufacturing facilities in China.

FDA also engaged in other significant activities to address this concern. In the midst of the heparin crisis, FDA analyzed the active pharmaceutical ingredient of heparin from the manufacturer – Baxter – and found it to contain something not seen before in typical analytical results. Our scientists then worked to identify the contaminant and found it to be oversulfated chondroitin sulfate, also known as OSCS. Once OCCS was identified, FDA and scientists outside the agency conducted further studies using animal models. These studies showed that the animals exhibited similar reactions as the adverse events reported that FDA received. This study was published in the New England Journal of Medicine. For the details of this study, see "Contaminated Heparin Associated with Adverse Clinical Events and Activation of the Contact System," N. Engl. J. Med. 358; 23, June 5, 2008, found at http://www.nejm.org/doi/pdf/10.1056/NEJMoa0803200.

Following our initial actions to determine the root cause of the heparin contamination, FDA has taken proactive steps to secure the heparin supply. Because FDA cannot predict the intentional adulteration of heparin or other drug products, special methods and subject matter experts are necessary to detect serious problems in the supply of the material used in the manufacture of heparin. Such methods are intended to identify any wrongdoing and breaches in manufacturing quality systems and controls. FDA also has tested samples of incoming crude heparin to detect contamination and sought information from its regulatory partners in other countries. All information gathered through this inspectional regimen supports the conclusion that OSCS contamination that manufacturers of crude heparin introduced into the heparin supply chain in China caused the heparin scare.

Ms. Kaptur: For both the domestic and international investigation of the heparin scare, what is the estimate of cost to the American taxpayer for the heparin investigation in terms of dollars and staff resources?

Response: FDA does not have a comprehensive estimate of cost to the American taxpayer associated with the heparin investigation because some of these costs were incurred by entities other than FDA. However, FDA staff expended substantial time and resources managing this crisis. FDA's Office of Regulatory Affairs estimates its costs at approximately $2,750,000, supported by 14 FTE.

The heparin investigation had a broad impact because both during and after the crisis, the increased oversight of heparin firms resulted in more domestic and foreign heparin related inspections, investigations, and monitoring efforts as compared to this same level of heparin related activity prior to the crisis. The goal of these increased efforts was to ensure the safety and efficacy of heparin and to re-establish confidence among American taxpayers in the safety of the heparin supply.

Ms. Kaptur: In the same 2010 GAO report on the Heparin scare, FDA identified that only one other country, Germany, reported significant impacts among its population related to Heparin. What are the estimates in terms of lives lost for the Heparin scare?

Response: CDER's Office of Surveillance and Epidemiology, also known as OSE, completed a review of adverse event reports from the FDA Adverse Event Reporting System in June 2009. OSE's analysis considered as much data as possible on the adverse event reports with use of heparin. However, we are not able to definitively attribute deaths to heparin administration due to confounding factors or lack of detail in the reports submitted to FDA. We continue to monitor for adverse events that are reported with the use of heparin. FDA does not have details of the reports from Germany that you refer to, and therefore we cannot confirm the number of lives lost in Germany.

Ms. Kaptur: While FDA has indicated that beyond the figure of 19 people killed and potentially hundreds impacted by tainted heparin, it is impossible to provide further details about how many people have been killed by this drug. What steps would FDA need to take to create a system in which this type of data could be collected or to better analyze the true impacts of this drug tainting scandal?

Response: There is no way of accurately assessing the number of fatalities, if any, that were directly caused by contaminated heparin because the reports received were spontaneous reports with underreporting, and the reports submitted to FDA do not have sufficient detail to confirm a cause of death. The Adverse Event Reporting System, also known as AERS, is a useful surveillance system for detecting rare, acute serious events. FDA is taking steps to improve our surveillance system by encouraging the public and health care practitioners to increase reporting and increase the quality of the reports of adverse drug events by including critical clinical details and product information. FDA is also implementing enhanced analytic techniques such as data mining to improve our analysis of adverse event reports. Additionally, FDA has formed partnerships with sister federal agencies to collaboratively launch investigations of drug safety issues and share information. These are prospective measures, but the information submitted to FDA does not have sufficient detail to confirm a cause of death.

Ms. Kaptur: In the 2010 GAO report, FDA action to accelerate production of heparin by APP to fill gaps from recalled Baxter heparin enabled this company to fill potential gaps in the domestic heparin market. Where was the replacement APP plant located?

Response: There was not one replacement plant for APP, also know as APP Pharmaceuticals. APP augmented its production in its existing facilities. At the time Baxter recalled its heparin, APP had facilities in Illinois and New York. Since that time, APP also began making finished heparin products at a plant in Puerto Rico.

Ms. Kaptur: What steps did FDA take to ensure that the supply chain for this new product was free of alternatives?

Response: We would like to respond to this question by addressing how FDA could ensure that the supply chain for APP's product was free of contaminants. In the early days of the heparin crisis, APP ramped up production to fill the Baxter void. It then took some number of weeks to identify the contaminant. Once FDA determined that the

contaminant was OSCS, that it was introduced to the finished product through its crude, active pharmaceutical ingredient, also know as API, and that all contaminated API was sourced from China, FDA developed a comprehensive plan designed to ensure the quality of heparin drug products in the United States, including but not limited to the API, or finished dosage form drugs. FDA conducted an import sampling assignment that required that all heparin products, including APIs and finished products, entering the United States to be tested according to the test methods published by FDA on its website. FDA also requested that U.S. manufacturers analyze all APIs on hand according to these test methods and retrospectively analyze the API of any finished product distributed in the United States.

Additionally, FDA worked with United States Pharmacopeia USP to update the Heparin Monograph to include the new testing requirements.

By taking these steps, FDA took effective action in order to help safeguard against contaminated heparin entering into the United States, whether to APP or any other manufacturer.

Ms. Kaptur: For the record, please elaborate on the differences in the supply chain for this new production line of heparin to augment limited domestic supplies from the Baxter product that was recalled.

Response: Once FDA determined that the contaminant was OSCS, that it was introduced to the finished product through its API, and that all contaminated API was sourced from China, FDA developed a comprehensive plan designed to ensure the quality of heparin drug products in the United States, including but not limited to crude, active pharmaceutical ingredient, and finished dosage form drugs. FDA implemented an import sampling assignment that required that all heparin products, including APIs and finished products, entering the United States to be tested according to the test methods published by FDA in its website. FDA also requested that U.S. manufacturers analyze all APIs on hand according to these test methods and retrospectively analyze the API of any finished product distributed in the United States.

Ms. Kaptur: For the record, please outline for the committee the structure of the CDER's Heparin task force.

Response: CDER's heparin task force was led by the Office of Counter-Terrorism and Emergency Coordination, also known as OCTEC. Members included staff from the Office of Compliance, the Office of New Drugs including the Drug Shortage Program, the Office of Oncology Drug Products and Division of Medical Imaging and Hematology Products which reviewed new drug applications for heparin and is now known as the Division of Hematology Products, the Office of Pharmaceutical Sciences including the Office of Generic Drugs, the Office of New Drug Quality Assessment, the Office of Biotechnology Products, and the Division of Pharmaceutical Analysis, and the Office of Surveillance and Epidemiology.

Ms. Kaptur: While the October 2010 GAO report clearly states that during the lessons learned excercie conducted by FDA after the heparin crisis had abated show dedication of the FDA staff and success in removing dangerous materials from the market, the same report also identifies that "the lack of details in the ERP and the absence of the coordination at the agency level for the duration of the crisis may have led to some process delays and difficulty in internal and external communication". For the record, please respond to this claim and outline the steps that FDA has take to correct this flaw.

Response: The FDA Emergency Operations Plan or FDA EOP which was issued in August 2010 provides descriptions of the roles, responsibilities and procedures of the agency as a whole for responding to emergencies as well as those of FDA Offices and Centers. Following the requirements of the National Incident Management System, the FDA EOP provides organizational structures which are based on the Incident Command System or ICS to facilitate the coordination and management of responses to significant incidents. These structures include roles for agency senior level decision makers, incident managers and coordinators and emergency response staff. FDA will continue sponsoring ICS training for its senior officials and emergency responders, conducting training for agency staff on the use of the FDA EOP, conducting internal exercises to ensure the plan is an effective tool in guiding the agency's response to emergencies and updating it to reflect changes in national emergency preparedness and response requirements and agency procedures.

FDA maintained agency-level coordination for the duration of the Heparin crisis. The Office of Crisis Management, or OCM, performed the agency-level coordination lead role during the early part of the incident, followed by CDER as the response called for an increased focus on scientific efforts to identify the contaminant. OCM maintained situational awareness throughout the incident through its work with CDER's Heparin Task Force.

Ms. Kaptur: In responding to the Heparin crisis, FDA coordinated with outside experts to assist in rapid response to this crisis, yet, as the October 2010 GAO report identifies, "FDA officials were aware of the scientist's ties to heparin manufacturers but did not take adequate steps to consider whether these relationships exposed the agency to risks. For the record, please outline what steps FDA has taken to respond to these potential shortcomings and respond to this claims.

Response: By late January of 2008, a sharp increase in the reports of severe allergic reactions – including reports of fatalities – associated with the blood thinner heparin signaled a public health emergency that required FDA to quickly identify and assemble the scientific expertise of those who could help identify the source of this crisis. While the manufacturer, Baxter Healthcare Corporation, initiated a recall of various lots of the heparin, conventional tests available at that time failed to characterize and identify the contaminant. To protect patients and address the safety of the supply this medically necessary drug, the FDA quickly assembled a team of experts likely to be able to quickly identify and develop new testing methods to screen for the novel contaminant.

For FDA to carry out its mission to protect the public health, agency leaders had to act quickly in assembling the team of experts who could help FDA find the solution to a growing public health emergency. In obtaining the input of the outside experts, which was of critical importance, FDA acted with appropriate care. FDA was aware of their ties to industry, but was also confident that by engaging them in robust, detailed, and transparent discussions about the data and science, FDA's scientists could independently assess their input and maintain control over the investigation.

While FDA believes that it was appropriate, necessary, and within FDA's authority to obtain the services of the scientists, FDA has learned from the heparin crisis to improve its processes for responding to emergencies. For example, FDA has implemented a policy to address risks in using outside experts who provide services without charge in emergencies, a policy that is responsive to GAO's single recommendation in its October 2010 report on FDA's response to the heparin crisis. The policy provides that in an emergency, FDA will consider and obtain, as appropriate, external scientific experts as the agency respond to, and resolves, the crisis. FDA will obtain these resources expeditiously, while giving due consideration to risks that may be presented in collaborative arrangements with external entities, including conflicts of interest. Responsible FDA staff will consult internally with the appropriate FDA offices as the agency addresses such risks and will document its decisions about such issues. FDA also intends to disclose information about its use of external experts and any relevant conflicts of interest. The policy can be found on FDA's website, and is available at:
http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/StaffManualGuides/UCM236513.pdf.

Ms. Kaptur: Again, quoting from the 2010 GAO report, "FDA was unable to link any of the adverse events to contaminated heparin because it was unable to establish a causal relationship due to data limitations and confounding factors involving the individual patients. For the record, please elaborate on this claim and explain to the committee why these factors confounded a causal link.

Response: The quality of information available was variable, with many case reports lacking basic or critical clinical details or clear information about the heparin manufacturer lot numbers and their contamination status. Reports involving individual patients were confounded because many patients receiving heparin may experience adverse events related to their medical conditions, related to concurrent medications, or related to concurrent procedures. Reports often did not contain enough detail to determine whether the adverse event was drug related or not. If heparin, for example, is given as part of a coronary artery bypass graft, also known as a CABG procedure, or a kidney dialysis procedure, the procedure itself may have risks or adverse events. Therefore, patients may experience adverse events after heparin administration during the CABG or dialysis, but not necessarily because of the heparin. Factors that contribute to definitively determining causality in the setting of an individual case report are the extent of detail known on the medical background and events of the case, information about the product lot numbers and contamination status, and factors such as whether the drug was

given more than once followed by a similar adverse event. Therefore, we were unable to assess the adverse events as having a definitive or certain causal relationship with contaminated heparin. All of those events included in our case series were evaluated for this possibility.

Ms. Kaptur: Again from the October 2010 GAO report, HHS claimed that legislative action could be taken to help mitigate the cost for these types of scares and to further secure the nation's drug supply chain. Please elaborate on the details of these legislative proposals and describe, at least in the heparin case, how these legislative fixes could ensure that the wrongdoers are exposed.

Response: Additional authorities such as those included in bills under consideration by Congress provide FDA with new tools to secure our nation's drug supply chain. In particular, the bills provide for the following new authorities.

Drug supply quality and safety, to require foreign and domestic drug manufacturers to implement quality systems and adopt plans to identify and mitigate hazards.

Documentation of compliance for imports, to require the submission of information for a drug that is offered for import to the U.S. sufficient to establish that the drug complies with all US requirements related to identity, safety and purity.

Traceability, to require a "track and trace" and unique identification system for products throughout the supply chain to ensure transparency and accountability of product from manufacturing and through distribution.

Subpoena authority, to grant FDA authority to issue subpoenas to compel production of documents and witnesses related to possible violations.

Prohibition against delaying, limiting or refusing inspection, to grant FDA explicit authority to refuse admission of drugs to the U.S. if inspection is delayed, limited or refused.

Criminal and civil penalties, to modernize penalties for criminal violations of the Federal Food, Drug, and Cosmetic Act to include higher maximum prison sentences, and to grant authority to impose civil money penalties for violations relating to drugs and improper import entry filings.

Administrative detention and destruction, to grant FDA the authority to administratively detain violative drug products, an authority the agency already has for food and devices, and to allow for the destruction of drugs offered for import that are valued at $2,000 or less or that pose a reasonable probability of causing a significant adverse health effect.

Extraterritorial jurisdiction, to provide FDA with explicit legal authority to pursue prosecutions for conduct that occurs outside of the U.S.

WEDNESDAY, MARCH 2, 2011.

DEPARTMENT OF AGRICULTURE

WITNESSES

PHYLLIS K. FONG, INSPECTOR GENERAL, U.S. DEPARTMENT OF AGRICULTURE

ROBERT W. YOUNG, SPECIAL ASSISTANT TO THE INSPECTOR GENERAL ON RECOVERY ACT

GIL H. HARDEN, ASSISTANT INSPECTOR GENERAL FOR AUDIT

KAREN L. ELLIS, ASSISTANT INSPECTOR GENERAL FOR INVESTIGATIONS

JOHN LEBO, DEPUTY ASSISTANT INSPECTOR GENERAL FOR MANAGEMENT

Mr. KINGSTON. The committee will come to order. We certainly appreciate you being here, and wanted to welcome not just the inspector general, Phyllis Fong, but the deputy inspectors, Bob Young and Karen Ellis, and Suzanne Murinn.

Okay. We appreciate your being here today and appreciate your testimony, because I think it is one of the most interesting hearings that we ever have on the hill, and particularly in this committee. It is always well received. We have found that the op tempo right now on Capitol Hill is pretty fast, and everybody has not just one hearing at a time, but often three.

With that, let me yield to Mr. Farr, if you have any opening statement.

Mr. FARR. I am interested in hearing the testimony, and then I have a couple questions. Thank you, Mr. Chairman.

Mr. KINGSTON. So the floor is yours.

Ms. FONG. Okay. Well, good morning, Mr. Chairman, and ranking member Farr. Thank you for the opportunity to come up today and talk about our work at USDA. And I want to start out by acknowledging the appreciation that we in the OIG have for your interest in our work and your longstanding support for us, and we want to congratulate you on your new role in the leadership of this committee, and we look forward to working with you as we move forward in the next few years. So let me go ahead and introduce some of my colleagues today.

Mr. KINGSTON. I was hoping you would, because I sure dropped the ball on it.

Ms. FONG. Yes. We had some last minute changes, so let me help.

Sitting here at my far right is Jack Lebo, who is the Deputy Assistant IG for Management. Next to me is Karen Ellis, who is the Assistant IG for Investigations. On my left here is Gil Harden, who is the Assistant IG for Audit. And at the end of the table is Bob Young, who is the Special Assistant for Recovery Act, and the rea-

son they're all here today is because they're going to answer all the tough questions. So just feel free to direct them to them.

Well, you have my full written statement, so I just want to offer a few brief comments on three areas of Department activity where we have really been focusing our attention, and those three areas are, as you can imagine, oversight of the Recovery Act money; secondly, strengthening food safety; and, third, looking at improper payments within the Department, which is an issue of great interest to all of us. So let me start out with our work on the Recovery Act.

As you know, the Department received $28 billion across a broad range of program areas, and with your support we received $22 million to provide oversight. So we are looking at virtually every "Recovery Act" program to ascertain whether the recovery moneys have been spent efficiently and in accordance with the law. Currently, we are looking at program delivery. We are looking at whether the people who got the money should have gotten it, and we are looking at whether the funds went for the correct purpose.

Next year we are going to be looking at performance results to see how the performance measures were met. So this year I just want to highlight a few audits that were significant. We issued an audit on single family housing guaranteed loans, where we found that 28 out of our sample of 100 loans were made to ineligible borrowers.

We also issued a report on the single family housing direct loan program where we found that the agency did not ensure that calculations of borrower eligibility were current when they closed the loans. And then we did some work in the SNAP program where we found that the agency did not review state fraud detection units, which are a critical part of the management of that program.

Let me just turn to food safety next, which remains a top priority for us. We focus in this area on making sure that USDA programs safeguard the food supply. We have issued two audits. Let me talk about two audits. We have issued one on beef trim and E. coli where we found that the agency could do a better job of taking samples of E. coli in ground beef to ensure that the product is free of contamination.

We have also started work in the multi-state egg recall area. We are looking to see how effective USDA's system is for detecting salmonella; and, as you can imagine, this work is going to take us a little bit of time. We are in the middle of it, but we were very troubled to learn that of the 288,000 eggs that were recalled last fall, over 270,000 of them had the official USDA grade mark on them. And we are trying to understand how that could have happened and how the coordination between AMS, FDA, and others worked in that situation, so we are right in the middle of that work.

In the area of improper payments we are spending a lot of time, because we believe it is important that USDA programs deliver the correct benefits in the right amounts to the right people; and so, we have done a number of audits in this area over the past year. We looked at USDA's suspension and debarment program, and we found that that program is not working as well as it should. The Department could better protect its programs by debarring individuals and entities that have been convicted of committing crimes

against the government, and we found that the Department actually rarely suspends program violators in that sense.

We also are in the middle of looking at the BCAP program, the Biomass Crop Assistance Program. Some of our initial assessments in this area are that the program suffered from hasty implementation, and so the management controls in that program are not as good as they should be; and, as a result, it appears that USDA may have inappropriately made matching payments to some landowners, so we are in the middle of looking at that as well.

In the SNAP program, which is of course one of the Department's largest programs, we devote a lot of effort to looking at fraud committed by retailers. We have done a lot of investigations in the past year on benefits trafficking, which are situations where a recipient exchanges his or her SNAP benefits for less than face value with a retailer, and then the retailer redeems and claims full reimbursement from FNS. And we found that the amount of money involved in that kind of fraud can be very significant. It can be in the millions of dollars.

For example, we had a case in Florida where two retailers were involved in about $6 Million in trafficking. They were successfully prosecuted as a result of our investigation. We are also doing audit work on improper payments in FNS. As you know, the SNAP and the school lunch programs are high risk programs, and so we are looking at how the Department is addressing, how it plans to address these rates of improper payments, how it plans to bring down those rates, and we anticipate issuing some audit reports this year with some recommendations on that.

And so in conclusion, we look forward to answering your questions; but, before I end, I want to respectfully request your support for the President's request for us for Fiscal Year 2012. I understand that we are in a very difficult budget situation, and I understand that government-wide, we are all trying to deal with this issue of the deficit.

We do believe that our work provides value, and so we ask that you consider the request for our office as favorably as you can. So we look forward to answering your questions, and thank you.

[The statement of Ms. Fong follows:]

UNITED STATES DEPARTMENT OF AGRICULTURE

OFFICE OF INSPECTOR GENERAL

STATEMENT OF THE HONORABLE PHYLLIS K. FONG

INSPECTOR GENERAL

Before the

Subcommittee on Agriculture, Rural Development,
Food and Drug Administration, and Related Agencies

Committee on Appropriations

U.S. House of Representatives

March 2, 2011

Good morning, Chairman Kingston, Ranking Member Farr, and Members of the Subcommittee. Thank you for the opportunity to testify about the Office of Inspector General's (OIG) Fiscal Year (FY) 2012 Budget Request, and to provide information about our recent audit and investigative work. My testimony today will summarize a number of the most important oversight projects and investigations we performed in FYs 2010 and 2011 to date.

In FY 2010, our audit and investigative work obtained potential monetary results totaling nearly $184 million.[1] This includes 65 audit reports we issued to strengthen Department of Agriculture (USDA) programs and operations, which produced over $35 million in potential results when program officials agreed with our recommendations. In FY 2010, OIG investigations led to 459 convictions with potential results totaling almost $149 million.

I will begin my testimony with an overview of our work to assess and improve the Department's programs and operations under the American Recovery and Reinvestment Act of 2009 (Recovery Act). Next, I will cover our most significant recent audit and investigative activities under our major strategic goals. Then I will conclude with a summary of the President's FY 2012 Budget Request for OIG.

OIG Oversight of USDA's Recovery Act Work

As part of the Recovery Act, USDA received $28 billion in additional funding for areas including rural development, farm loans, and nutrition assistance.[2] With the support of this Subcommittee, the Recovery Act also provided OIG with $22.5 million over 5 years to oversee programs funded by the Act and administered by USDA.

In response, OIG initiated a number of short- and long-term actions to provide timely and effective oversight of the Department's expenditure of Recovery Act funds. As of February 25, 2011, we have issued 27 audit and 11 investigative Recovery Act reports. Since providing timely information is a priority, we are also issuing short-turnaround reports, known as Fast Reports, so USDA program managers can take corrective action as soon as we identify problems. As of February 25, 2011, we have also issued 48 Fast Reports, which we will incorporate into formal audit reports once we complete our work.

[1] Audit monetary impacts derive from funds put to better use and questioned/unsupported costs as established by Congress in the Inspector General Act of 1978. Investigation monetary impacts come from recoveries, court-ordered fines, restitutions, administrative penalties, etc.
[2] This $28 billion includes funds paid directly to recipients for such things as nutrition assistance and funds used to finance loan-making. For example, the Recovery Act authorized $133 million to finance over $10 billion in single-family housing guaranteed loans.

Our audit division is approaching its review of Recovery Act-funded programs in three phases. In the first phase, which we have nearly completed, we reviewed USDA agencies' documented internal control procedures relating to Recovery Act programs. In the second phase, which is in process, we are evaluating program delivery, reviewing participant eligibility, and ensuring that Recovery Act funds are being used for their intended purposes. To accomplish this, we are using statistical sampling where possible and when cost effective. In the third phase, which will start in FY 2012, we will evaluate program performance measures and the reporting of accomplishments and results.

Our investigation division is working to ensure the integrity of Recovery Act programs by taking up potential cases of fraud, pursuing prosecution where warranted, and investigating whistleblower allegations. As of February 25, 2011, OIG investigations staff have received 27 referrals relating to USDA Recovery Act contract awards and 49 hotline complaints.

Examples of our findings to date involving Recovery Act-funded programs include:

Eligibility Determinations for Single Family Housing (SFH) Guaranteed Loans

The Recovery Act included $133 million to finance over $10 billion in SFH loan guarantees in rural areas. Our statistical sample of 100 loans identified 28 loans where lenders had not fully complied with Federal regulations or Recovery Act directives in determining borrower eligibility.[3] We found borrowers who were ineligible for a variety of reasons such as having annual incomes that exceeded program limits or being able to secure credit without a Government loan guarantee. By guaranteeing loans for ineligible borrowers, other eligible borrowers may not have received guarantees that could have better achieved the goals of the Recovery Act. Based on the interim results of our statistical analysis, we estimate that 27,206 loans were ineligible for the program (over 33 percent of the portfolio)—with a projected total value of $4 billion.[4]

Controls Over Rural Development's Single-Family Housing Direct Loan Program

We also assessed the oversight and control Rural Development maintained over almost $1.6 billion in Recovery Act-funded loans to very low-income borrowers through its single-family housing direct loan program.[5] We found that the Rural Housing Service (RHS), which administers the program, did not

[3] 04703-0002-Ch(1), *Rural Development Guaranteed Single-Family Housing Loans Made by Lenders to Ineligible Borrowers*, Dec. 2010.
[4] We chose a sample size of 100 because we expected a moderate error rate and wanted the ability to report findings with a +/-10 percent precision (confidence interval) at a 95 percent confidence level.
[5] The Rural Development Recovery Act work summarized here and in the next paragraph can be found in: 04703-2-KC, *Single-Family Housing Direct Loans Recovery Act Controls — Phase II*, Sep. 2010.

ensure that calculations of borrower eligibility were current before closing loans. This increased the risk of making loans to ineligible borrowers if their circumstances changed. RHS reviewers also did not document the scope and timing of their second-party reviews. This reduced the effectiveness of the quality control process. We recommended that RHS ensure that supporting documents are updated before closing loans and that the scope and timing of reviews are specified.

We also found that comprehensive State office reviews of loan-making and loan-servicing were not being analyzed by RHS to identify nationwide trends in control weaknesses, or to track the effectiveness of corrective actions. We recommended that the reviews be aggregated into national, multi-year analyses, and that RHS train State staff to use the results to administer the program. RHS has initiated corrective actions in response to our audit. Currently, we are conducting a related audit to determine if Rural Development's staff is complying with internal control procedures designed to ensure that Recovery Act eligibility guidelines, such as income limitations, are being met.

States' Supplemental Nutrition Assistance Program (SNAP) Fraud Detection

USDA's Food and Nutrition Service (FNS) administers SNAP through State agencies, which are primarily responsible for monitoring recipients' compliance with SNAP requirements along with investigating cases of alleged intentional program violation.[6] We evaluated FNS' State-level controls to mitigate SNAP fraud, an area related to FNS' increased Recovery Act funding.[7] We determined that FNS performed reviews to evaluate how States manage SNAP, but the agency's reviews did not target State fraud detection units. Although FNS indicated that such reviews were unnecessary because State annual activity reports were adequate to oversee State fraud detection, we determined that these reports contained unreliable and unverified data. We also found that while FNS and State agency officials relied on hotline complaints and outside referrals to identify SNAP fraud, they did not make use of reports from electronic benefit processors that track participant and retailer activity to show potential fraud and misuse. FNS generally agreed with our findings and recommendations for those States we reviewed, but disagreed that they applied nationally. However, the agency did agree to review the electronic benefit reports and to encourage States to use them to identify SNAP fraud.

[6] SNAP is still known as the "food stamp program" to many in the public, although it was officially renamed in 2008.
[7] The SNAP Recovery Act work summarized here can be found in: 27703-2-Hy(1), *State Fraud Detection Efforts for the Supplemental Nutrition Assistance Program*, Jul. 2010; and 27703-2-Hy(2), *State Fraud Detection Efforts for the Supplemental Nutrition Assistance Program – Use of EBT Management Reports*, Sep. 2010.

Goal 1: Strengthen USDA's Safety and Security Measures for Public Health

One of OIG's most important goals is strengthening USDA's ability to protect public health and provide wholesome food for consumers. To achieve this objective, our audit and investigative work in FYs 2010 and 2011 to date has focused on helping to improve the programs that safeguard our food.

For example, we recently completed an audit that assessed how the Food Safety Inspection Service (FSIS) samples beef trim for *E. coli*, which can contaminate products such as ground beef.[8] Currently, FSIS' inspectors take 60 samples from large lots of beef trim to test. We found, however, that this procedure does not yield a statistical precision that is reasonable for food safety. Although 60 samples may be adequate to detect widespread contamination, more are needed when *E. coli* is less prevalent. FSIS' current sampling methodology results in detection of *E. coli* less than half the time when it is present in 1 percent of a beef trim lot. Accordingly, we recommended that the agency place its testing process on sounder statistical ground by redesigning its sampling methodology to account for varying levels of contamination. FSIS generally agreed with our findings and recommendations. In related audit work, we have initiated a review of the agency's *E. coli* testing protocols to ensure that beef trim is effectively collected and analyzed. Together, our beef trim sampling and testing audits should help bolster public confidence that FSIS' tests are accurately identifying *E. coli* and ultimately preventing contaminated meat from being distributed and consumed.

In the wake of the multi-State egg recall in 2010, we have also initiated an audit to assess USDA's system for detecting *Salmonella* in eggs. Our objectives are to evaluate USDA's controls over in-shell eggs to detect *Salmonella* and other contaminants, and to evaluate the effectiveness of USDA's coordination with FDA to ensure that eggs are wholesome.

Since knowing where food comes from and what it contains is critical to ensuring its safety, our investigations have addressed cases where companies resorted to a variety of schemes to mislead the public and the Government about the origin of marketed food. For example, we determined that one California company falsely claimed its products—chili peppers—were grown in the United States in order to obtain Federal clean health certificates from USDA. In fact, the peppers were imported from India and China, which should have made them subject to more stringent USDA inspections to ensure

[8] The particular strain of *E. coli*—i.e., *Escherichia coli*—that FSIS tests for is O157:H7, which causes about 70,000 illnesses a year, with 52 fatalities in 2009. (24601-9-KC, *Food Safety and Inspection Service N60 Testing Protocol for E. Coli, Phase I*, Feb. 2011.)

they did not carry foreign pests or diseases that could harm native species. In July 2010, a court fined the company $50,000 and ordered 3 years' probation for making false statements.

USDA also conducts research into genetically engineered animals and insects for a wide variety of purposes, such as increased productivity. From 2002 to 2009, USDA funded 63 research projects and grants, totaling over $22 million, which involved genetically engineered animals and insects. Our ongoing audit in this area is assessing whether USDA's regulatory framework provides the Department sufficient authority to control the research under its purview. We are also evaluating USDA's controls for preventing the inadvertent release of genetically engineered animals and insects.

Goal 2: Strengthening Program Integrity and Improving Benefit Delivery

OIG's work in this area is intended to save taxpayers' money by ensuring that USDA programs deliver the correct benefits in the right amounts to eligible participants. Our efforts in achieving this objective range from advocating that USDA take vigorous enforcement action against those who abuse its programs to evaluating how effectively agencies are reducing improper payments. Our investigations also pursue cases against those who defraud the Department's programs.

For example, in our audit of USDA's suspension and debarment program, we determined that the Department should better protect its programs by debarring those individuals and entities that abuse them.[9] Although the Department has authority to exclude those who commit crimes against its programs from doing business with the Government, we found that convicted program violators were rarely suspended or debarred. Between FYs 2004 and 2007, only 38 of 1,073 individuals convicted of crimes against USDA programs were debarred—less than 4 percent. In principle, USDA officials agree that suspension and debarment should be considered for convicted program abusers.

In practice, however, USDA had not implemented suspension and debarment in programs comprising $98 billion of the Department's $124 billion budget in FY 2007. USDA has historically excluded most of its programs from suspension and debarment requirements. Agencies maintain that these exclusions are in the public's best interest and are consistent with statutes and other guidelines balancing access to basic assistance, such as food, and enforcement against violators.[10] However, agencies have not provided statutory language or program rationales that, in our analysis, justify all of their exclusions. We concluded that the public's interest is best served by ensuring the integrity of funds and programs,

[9] 50601-14-AT, *Effectiveness and Enforcement of Suspension and Debarment Regulations in the U.S. Department of Agriculture*, Aug. 2010.
[10] Title 7 CFR 3017.

and by deterring program abuse. Further, since debarred individuals or entities are prohibited from participating in Federal programs outside USDA, vigorous and appropriate use of suspension and debarment provides for program integrity Governmentwide. Accordingly, we continue to work with USDA and its agencies to reach agreement on the corrective actions needed to employ suspension and debarment more effectively.

Our ongoing assessment of a recently implemented program, the Biomass Crop Assistance Program (BCAP), concluded that it suffered from hasty implementation that did not include management controls adequate to prevent abuses particular to the program.[11] The 2008 Farm Bill authorized BCAP, administered by the Farm Service Agency (FSA), to support renewable crops that could be used to produce energy. Despite spending over $243 million to implement the handling aspects of the program, such as collecting and transporting biomass, FSA did not institute a suitable system to provide oversight and ensure program integrity.

We found wide-ranging problems with BCAP, including inequitable treatment of program participants and improper payments. These issues occurred largely because FSA, in an effort to implement the program quickly, did not develop tools specific to the program's needs, such as specialized guidance. Instead, FSA attempted to use guidance and oversight mechanisms designed for other programs, which left BCAP vulnerable. For example, we found three cases where biomass suppliers and conversion facilities circumvented poorly written agreements to obtain payments to which they were not entitled. FSA has taken corrective action in response to our recommendations to develop program-specific guidance and to specify prohibited practices in its BCAP agreements.

OIG is also working to help USDA respond efficiently to future disasters by reviewing the adequacy of RMA's management controls over indemnity payments made to citrus growers in the wake of Hurricane Wilma. We have focused our work on how insurance providers processed the growers' claims and calculated the indemnity payments. Our work with the agency should offer an opportunity to strengthen how private insurance providers work with USDA in ensuring accurate indemnity payments.

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[11] 03601-28-KC(1), *Recommendations for Improving Basic CHST Program Administration, Biomass Crop Assistance Program Controls over Collection, Harvest, Storage, and Transportation Matching Payments Program*, Dec. 2010; and 03601-28-KC(2), *Recommendations for Preventing or Detecting Schemes or Devices, Biomass Crop Assistance Program Controls over Collection, Harvest, Storage, and Transportation Matching Payments Program*, Feb. 2011.

I would also like to highlight for the Subcommittee several noteworthy OIG investigations involving USDA benefit programs that achieved significant sentencing and restitution orders in FY 2010.

For example, OIG's investigations into fraudulent activities involving RMA and FSA are some of our most complex investigations because they often involve large monetary amounts and voluminous documentation. In FY 2010, for FSA and RMA combined, we opened 76 cases and issued 49 investigative reports, which led to 35 convictions and over $45 million in monetary results.

In a particularly complex FSA case, we determined that a woman who owned a grain trucking and marketing company in Missouri defrauded over 180 farmers out of at least $27 million. Between 2002 and 2009, she marketed and sold grain for farmers above market prices. As a result, she quickly became one of the largest grain dealers in her State. However, we uncovered evidence to prove that she was operating what is known as a "Ponzi Scheme"—essentially, she was using the money from later sales to cover her previous above market prices. Eventually, she ran out of money and left her later customers unpaid. Due to our investigation, she pled guilty to fraud and transporting stolen property across State lines among other crimes. In February 2010, she was sentenced to serve 108 months in Federal prison followed by 36 months' supervised release, and ordered to pay $27.4 million in restitution.

Unfortunately, there are also individuals who seek to defraud USDA programs designed to provide basic nutrition assistance to those most in need, such as the Women, Infants, and Children program (WIC) and the Child and Adult Care Food Program (CACFP), which are both administered by FNS. In FY 2010, we opened 26 investigations in these areas and issued 9 investigative reports. This work led to 28 convictions and almost $3 million in monetary results.

Since these programs work by reimbursing individuals or entities who provide benefits, one common abuse involves submitting inflated claims. For example, one investigation disclosed that an Oklahoma CACFP day care sponsor systematically claimed reimbursement for more meals than were served. The court ordered $1.6 million in restitution and sentenced the sponsor to 41 months' incarceration.

OIG investigations of criminal activity into another food program, FNS' SNAP, resulted in 212 convictions and nearly $36 million in monetary results in FY 2010.

SNAP is USDA's largest program, both in terms of the dollars spent and the number of participants. In FY 2010, recipients redeemed close to $65 billion in benefits. The latest available data show that in

October 2010 more than 43 million people received almost $5.8 billion in SNAP benefits. SNAP is also an important part of the food safety net for Americans, especially during times of economic hardship. During the recent recession, SNAP participation increased by about 20,000 persons daily—the program helped feed one in eight Americans and one in four children.

Given the considerable participation and funds involved, OIG devoted about 40 percent of its investigative resources in FY 2010 to SNAP-related criminal investigations—this is our largest allocation of investigative resources. Our main focus is on fraud committed by retailers, primarily because FNS directly reimburses retailers while States are responsible for ensuring that recipients are eligible. With few exceptions, our investigations yield tangible and direct benefits to the Government, including criminal prosecution, significant fines and penalties, restitution, and asset forfeiture.

The most prevalent crime against SNAP is benefits trafficking, which involves a recipient exchanging benefits for less than face value with someone who then claims reimbursement for the full amount. The money involved in this type of SNAP fraud can be significant. For example, our analysis of two Florida stores' SNAP transactions identified approximately $6.2 million in trafficking by their owners and other co-conspirators. Between March and May 2010, four defendants pled guilty to wire fraud and SNAP fraud, and were sentenced to prison terms ranging from 8 to 48 months along with restitution orders ranging from about $350,000 to $2.2 million.

In providing SNAP oversight, OIG audit staff also conducts reviews designed to improve FNS' overall management controls for this program and others. Currently, we are auditing FNS' compliance with reporting requirements related to reducing improper payments for SNAP and the National School Lunch Program (NSLP). According to the Department, improper payments for these programs in FY 2009 cost taxpayers nearly $2.2 billion for SNAP and $1.5 billion for NSLP.[12] Our objective is to assess NSLP's and SNAP's level of risk for improper payments, determine the extent of oversight needed, and provide recommendations, as warranted, to improve how FNS identifies and reports improper payments, and the agency's plan to reduce them.

[12] USDA's *FY 2010 Performance and Accountability Report*.

Goal 3: OIG Work in Support of Management Improvement Initiatives

OIG continuously monitors risks to USDA programs in order to help the Department address programmatic concerns, and to improve overall Department management. As part of this effort, OIG investigates potential criminal activity and allegations of employee misconduct. In FY 2010, our investigations included the following cases involving USDA employees and entities working with the Department.

- Our investigations uncovered a scheme by a Nebraska FSA employee to embezzle funds. The employee entered false repayment rates and backdated repayment dates when servicing FSA loans made to her and her husband. In total, she defrauded the agency of more than $44,000, which she agreed to repay as part of a plea agreement. In June 2010, she was sentenced to 8 months of house arrest and 36 months of probation; FSA no longer employs her.

- Working with other Federal investigators, OIG determined that a Massachusetts corporation collected millions of dollars from the Government for services it never provided. The corporation offered training on computer software and other information technology. Using a pre-paid voucher system, agencies paid up front for training that the company never delivered. We found that several USDA agencies were victimized by this scheme. In April 2010, the corporation agreed in settlement to return a total of $4.5 million.

- In response to requests, including those from a former Secretary of Agriculture and a U.S. Senator, OIG reviewed allegations against the United Soybean Board and the U.S. Soybean Export Council. In July 2010, we concluded that there was insufficient evidence to support the allegations, but recommended that the soybean board increase its oversight of the export council.

Along with our other work, OIG is required to annually audit USDA and some of its agencies' financial statements as well as USDA's information technology system security.

- Pursuant to the Chief Financial Officers Act of 1990 and guidance from the Office of Management and Budget, Federal OIGs are responsible for annual audits of Departmental and agency financial statements in order to provide reasonable assurance that the financial statements are free of material misstatements. USDA's FY 2009 and 2010 consolidated

financial statements received an unqualified opinion,[13] as did the FY 2009 and 2010 financial statements for five of six other USDA entities that are required to undergo a financial statement audit.[14] The sixth lacked sufficient support for transactions and account balances, and so received a disclaimer on its financial statements because an audit opinion could not be given.[15]

- As required by the Federal Information Security Management Act, OIG examined the security of USDA's information technology in FY 2010.[16] We found that improvements have been made but weaknesses remain. For example, the Department has not established a program to secure remote access to USDA information systems, or to oversee systems operated on USDA's behalf by contractors and other entities. In order to mitigate continuing material weaknesses, we recommended that the Department rethink its policy of attempting to achieve numerous goals at the same time in short timeframes. Instead, USDA and its agencies should accomplish one or two critical objectives before moving on to the next set of priorities.

The Secretary of Agriculture also requested that we examine the Department's civil rights process. Accordingly, we recently initiated an audit of USDA's progress in addressing civil rights complaints related to alleged discrimination in its programs. Specifically, we will assess USDA's decisionmaking process for settling with complainants who allege discrimination. We will also followup on our prior recommendations to improve USDA's civil rights process.

Goal 4: Improving USDA's Stewardship of Natural Resources

USDA provides leadership to help America's private landowners and managers conserve soil, water, and other natural resources. Our goal in auditing these activities is to increase the efficiency and effectiveness of USDA stewardship over natural resources.

For example, we are auditing Natural Resources Conservation Service (NRCS) controls over the Farm and Ranch Lands Protection Program in Michigan. This program helps keep land in agricultural use by sharing easement purchase costs with cooperating entities, such as nonprofit organizations, to acquire easements that prohibit developing the land for other purposes. Since NRCS can fund up to

[13] 50401-70-FM, *Department of Agriculture's Consolidated Financial Statements for Fiscal Years 2010 and 2009*, Nov. 2010.
[14] We issued the following financial statement audits in November 2010: 85401-18-FM, *Rural Development's Financial Statements for Fiscal Years 2010 and 2009*; 06401-25-FM, *Commodity Credit Corporation's Financial Statements for Fiscal Years 2010 and 2009*; 08401-11-FM, *Forest Service's Financial Statements for Fiscal Years 2010 and 2009*; 27401-35-Hy, *Food and Nutrition Service's Financial Statements for Fiscal Years 2010 and 2009*; and 05401-19-FM, *Federal Crop Insurance Corporation/Risk Management Agency's Financial Statements for Fiscal Years 2010 and 2009* (RMA operates and manages the Corporation, so they are included as a single entity for financial statement audits).
[15] 10401-4-FM, *Natural Resources Conservation Service's Financial Statements for Fiscal Year 2010*, Nov. 2010.
[16] 50501-02-IT, *U.S. Department of Agriculture, Office of the Chief Information Officer, Fiscal Year 2010 Federal Information Security Management Act*, Nov. 2010.

half the cost, properly appraising the land beforehand is critical to ensuring that the agency pays its fair share. Accordingly, our audit is focusing on NRCS' oversight of easement appraisals in addition to reviewing the agency's controls to ensure that participants are eligible for the program and that the land is properly monitored.

OIG's FY 2012 Budget Request

We appreciate this Subcommittee's continuing interest in using the results of OIG audits and investigations to identify needed improvements in USDA programs. We also share your goal of preventing improper payments of any kind and saving taxpayer dollars by improving USDA program effectiveness and efficiency. So that we may continue to provide this type of work to the Subcommittee and to USDA decisionmakers, we are asking today for your support of our FY 2012 Budget Request.

Over the last 5 years (with total appropriations of approximately $413 million), OIG audits made 1,441 recommendations for needed program improvements, and $946 million in recommendations to question costs or to put funds to better use. OIG investigations resulted in 2,610 successful convictions, and $489 million in court-ordered fines, penalties, and restitutions.

The President's $90.7 million budget request for OIG is conservatively set to support our current level of effort, with three relatively low dollar but high impact enhancements to our capabilities.

- $800,000 to support the costs involved in conducting audits that can statistically project the full dollar value of improper payments in programs under review. OIG's recent Recovery Act audit of Rural Development's SFH Guaranteed Loan Program—with a projected $4 billion in loans made to potentially ineligible borrowers—is a prime example of the benefit of statistical analysis. Because of the additional Recovery Act oversight funding, OIG was able to pay the additional staff hours and fieldwork required to use statistical sampling while evaluating this program. The requested funds will enable OIG to perform similar statistical audit work to identify the extent of improper payments in other USDA programs, such as SNAP, crop insurance indemnities, Rural Development loans, and payments resulting from the Department's agreement to settle the Pigford discrimination lawsuit, which together total about $82 billion in annual expenditures.

- $613,000 to provide oversight of USDA's multi-billion dollar international programs. Due to limited resources, OIG has not been able to perform significant oversight of USDA international programs for several years. We are seeking $613,000 to cover the increased staff hours and travel costs necessary to audit and investigate these programs, which continue to grow in funding and strategic importance. The programs we are considering for review include the Department's Food for Peace Program ($2.2 billion in FY 2010) and its Export Credit Guarantee Program ($3.1 billion in FY 2010). OIG is also required to provide oversight of approximately $100 million that the U.S. Agency for International Development has transferred to USDA over the past few years in support of reconstructing and strengthening agricultural and rural infrastructures in foreign countries.

- $162,000 to support investigator training requirements, including Federal law enforcement training for new hires (OIG has experienced significant turnover due to investigators who have retired), training for peer counselors for OIG's new Critical Incident Stress Management Program, and continuing legal training for special agents.

The President's Budget Request for OIG also includes $455,000 for the Council of the Inspectors General on Integrity and Efficiency (CIGIE), a council of Federal IGs established by the Inspector General Reform Act of 2008. CIGIE's mandated missions are to address integrity, economy, and effectiveness issues that transcend individual Government agencies, and to increase the professionalism and effectiveness of the IG workforce. The President's Request proposes to fund CIGIE by adding $455,000 to the budget requests of the 15 largest OIGs (including USDA OIG), which will then transfer the funds to the council. As CIGIE's first elected chair, I ask for the Subcommittee's positive consideration of this portion of our request. CIGIE has already proven particularly useful in providing cost-effective professional training for OIG staff Governmentwide; enhancing cross-agency effectiveness through identifying best practices; and improving program integrity, efficiency, and cost-effectiveness throughout the Federal Government.

We would be happy to provide the Subcommittee with any additional information the Members and staff find useful in considering our FY 2012 budget request.

This concludes my testimony. Thank you again for inviting me to testify before the Subcommittee. We would be pleased to address any questions you may have.

Mr. KINGSTON. Well, thank you very much, and in response to your last request, often those numbers are actually set by another committee, and so we don't have as much control on it as we want to ourselves. But we certainly plan to work with you, and we do recognize the importance of your good work.

One of the questions that I wanted to ask you about in terms of the error rate and improper payments, though, you have not mentioned farm payments, and I think that we should look very carefully at SNAP error rates and at farm payment error rates. And one of the reports that I have read, and it may have been last year's testimony, but it was one of your reports, it was just incredible to me the number of people who had broken the law fraudulently, and yet still were involved in the program.

And your number of 3981 that says FNS did not debar 3,981 SNAP retailers, I am just amazed. Why? Why is that so hard? Why is that even a thought process that if you break the law, you know, maybe we are not going to take you to jail? Maybe we are not the ones to prosecute you, but we are the ones who say you are not going to participate in the program anymore, and so that's it.

SUSPENSION AND DEBARMENT

Ms. FONG. Well, I think we agree with you that the suspension and debarment process needs a lot of work within USDA, and we feel very strongly that if a person has been convicted of a crime, especially involving a federal program, it makes perfect sense to debar them from participating in USDA programs as well as all government programs, and we are working with the Department to implement that.

I know that on our investigation side, whenever we have convictions and indictments, we provide a monthly report to the agencies within USDA and we make it known to them that here it is. Here is the list. Some agencies are more responsive than others; and, I think one of the issues that we are dealing with right now is working with the Department on its regulations, on suspension and debarment, to make sure that the exclusions that they have for certain program areas really make sense.

We do not have a basis for evaluating whether their exclusions make sense, but we do question them. So we are working on that.

Mr. KINGSTON. Who is responsive, and who is not?

Ms. FONG. I believe RMA has been responsive.

Mr. HARDEN. RMA is actually one of the agencies that is most responsive and uses suspension and debarment quite actively. FNS' explanation to us, which we are still working with them on, is that they put the retailers on it.

Mr. KINGSTON. RMA is who?

Mr. HARDEN. The Risk Management Agency.

Mr. KINGSTON. Yeah. I was thinking Risk Management.

Ms. FONG. Crop insurance?

Mr. KINGSTON. No, Risk Management is involved in SNAP.

Mr. HARDEN. No. You asked where in the department.

Mr. KINGSTON. Oh, okay. All right. Yeah. Okay. So you are talking farm.

Mr. HARDEN. It is outside of FNS.

Mr. KINGSTON. Yeah. I got it. We were blending farm payments. Okay. Who is not responsive?

Mr. HARDEN. One of the examples that you gave with FNS is they put their retailers on a list that takes them out of the program, but they don't share them with the actual list that debars them from all government programs. And that's where we are working at the department now on each one of the recommendations to work with the agencies as to their justification for excluding programs for suspension and debarment.

Mr. KINGSTON. Why is that so hard, though? Because here we are working with it and I understand your role is working with them; but, it still seems to me that under the management of USDA it shouldn't be that much of a mystery. Either you are doing this or you are not doing it, so I am asking your opinion of it. I am not holding you responsible.

Mr. HARDEN. I am kind of in the same boat you are. We don't understand why it is so hard. But when we start talking to the different agencies and counsel's office, and trying to see and provide us with evidence as to why something should be excluded, they have yet to provide that information, so we still have those recommendations open.

Mr. KINGSTON. Well, you know, it is interesting. In this town, both parties always talk about waste, fraud and abuse as a way to cut spending, and we are all in agreement with that. You are the folks who always have these unbelievable stories of waste, fraud and abuse, and yet in my years on this committee in Democrat and Republican Administrations, it always seems to be that we are working to get this under control.

I think right now we need to go ahead and get this under control, and any advice you can give us on, okay, here is how to do it, because these folks aren't going to do it on their own. You've got to go ahead and put a hammer on them and make sure it is done. So my time is up, but I want to continue that discussion.

Mr. Farr.

Mr. FARR. Well, thank you, Mr. Chairman. I will just follow up. I mean is the authority there for all the agencies to do it? Is the training, because it is sort of a legal role. You can appeal these, I imagine, so is it a lack of training among personnel? I mean what is it it takes to crack down? And it is universal in the department.

I mean you didn't go into any of the farm payment programs, and you know, we just hear abuses of that all the time, usually, reading about it in the press; but, you audit those payments as well? And nothing in your report here about it.

Ms. FONG. Let me address suspension-debarment at a more philosophical level.

Mr. FARR. Okay. Yeah.

Ms. FONG. This is an issue that it is very difficult, and we see it among many departments and agencies in the executive branch, because frequently IGs come in and say, "you need to really pay attention to this, you need to act against the bad actors." What you will hear from the program side is "Well, we understand that, we see where they made a mistake, but we depend on these entities to deliver the programs." And so if we were to debar them or suspend them, there would not be an adequate delivery.

Mr. FARR. But a lot of those you are talking about programs that go to private sectaries, and aren't they bidding on those programs competitively? Isn't there some competition out there who could pick up that bid if they were disbarred? And aren't you in charge of the counsel of all the AGs to be looking at this?

Ms. FONG. Exactly. Exactly. And the reason I am bringing this up is because a number of us as IGs have testified on this issue in the last year. There've been hearings in some of the other committees on the hill. We are all dealing with these issues. And so what we are trying to do as a group of IGs is to make sure that our internal processes work, that we are identifying parties that are appropriate for suspension or debarment, that we are providing notifications and lists of those parties to the departments, and that we are issuing reports that point out where the department really needs to do further work.

Mr. FARR. Is the procedure for this different with each department?

Ms. FONG. Well, each department has its own regulations.

Mr. FARR. Okay.

Ms. FONG. And I think USDA's are unusual.

Mr. FARR. Do they have enough authority? I mean there is nothing missing in congressional enactment that you need. It is just trying to get a standardized process, somewhat standardized process here, if they each have their own regulations; but, it seems to me that this sort of—all the reporting of contract frauds I mean—you know. Bill Gates is next door and I will bet there is a lot of discussion going on right now about defense contractors.

But, you know what? Your testimony is essentially the same as the testimony was made 20 years ago to this committee, and what is changing in this field? And I think the chairman is right about suspension and debarring of people.

Mr. KINGSTON. Will the gentleman yield?

Mr. FARR. Sure.

Mr. KINGSTON. And I am going to emphasize that there is a high degree of frustration here, because I think Mr. Farr is absolutely right. Ten years ago, different administration, different people at the table, different people on this panel but same testimony, and I think we really would love to see, you know, the end of all this, whatever.

Our constituents are crying for it, and I feel very strongly that whether it's "Red" state or "Blue" state politics, it should still be the same measurement. We have got to crack down on this. So we have a lot of unanimity, I guess, on that.

Mr. FARR. Do you need more authority?

Ms. FONG. I don't believe it is an issue of authority. And to add a little more nuance to this, we are engaged with the Department, the CFO's office, the chief financial officer's office is engaged with all of the agencies to move them forward on this and we are in consultation with them on their regulations.

We believe that progress is being made, although it is slow, and so we are continuing to engage with them. We are not going to let this issue drop, because it's a government-wide issue and we need to prioritize.

Mr. FARR. Do you prioritize? I mean there are some issues here about SNAP, and I am glad you are going after, sort of, the vendors, rather than just the individual, who may be poor and illiterate and may be misqualified; or, essentially, children who are in the wrong line in school, I mean, you are looking at the bigger cost issues.

I have some follow-up questions, but my time is running out. But I really get a sense of, I mean, what I think is what we are surprised to see; that there is nothing in here about the farm payments that are being made, and that whole list of categories that I think we yesterday pointed out that there were—what—32 different programs of dealing with where individuals could qualify for federal assistance.

Ms. FONG. Well, our testimony was developed, focused on sort of the highlights of what we have done in the last year. That's not to say that we are not looking at the farm programs. We have a lot of ongoing work in that area; and, in terms of improper payments, we have, as you know, responsibilities under the new improper payments law in the executive order to look at the Department's efforts across the board to make sure that each agency is identifying in where their improper payments lie and that they have good plans to remediate their improper payments. And so we are in the middle of doing all of that, and FSA, you know, is among our list of entities to look at.

We also have work going on in BCAP, which I think you might have noticed we highlighted in our testimony. We are very concerned about how that's all developing.

Gil, would you like to add?

Mr. HARDEN. Another area that we will be looking at improper payments for farm programs is the SURE program, which is a new program.

Mr. KINGSTON. Did you say SURE or sugar?

Mr. HARDEN. SURE, supplemental revenue. I am trying to remember what the acronym stands for.

Mr. KINGSTON. Well, is it a disaster program?

Mr. Latham.

Mr. LATHAM. Thank you, Mr. Chairman.

I guess somewhat to follow up on the topic here in your semiannual report, the second half of 2010, your investigation disclosed two brothers who were able to defraud SNAP of about $800,000 over three years by exchanging SNAP benefits for cash. And a similar problem was found in the WIC program. What we have been told for years, that this wasn't going to be happening, to the extent that apparently it is, what is happening? Is there something new going on, or what?

Ms. ELLIS. Is this on?

Mr. LATHAM. There is no button there or switch.

Ms. ELLIS. Okay. Good. It makes it easy for me. What we have found, I mean I think the idea being that going to the electronic benefit transfer would eliminate or reduce fraud. I think what we have found out in our work is that it has made it easier for us to build our investigations, because everything is done electronically, and there is a record now.

We get to a point now when we do our investigations where we can literally sit in our office, and on a computer watch transactions occurring. So it may have had a deterrent effect, maybe, at first. But what we have found is that for us the crime has just become more sophisticated, more technologically advanced, making it much easier for us to build our cases more so on paper; whereas, before, our EBT cases, or at the time our food stamp cases, were more field work intensive. So it has just raised the level of technology.

Mr. LATHAM. So it is easier for you to track, but we still have very innovative people out there trying to do.

Ms. ELLIS. Yes, and they do try to find different ways to circumvent the system.

Mr. LATHAM. In your opinion, are there things that we could do legislatively or whatever to help you or to really crack down further?

Ms. ELLIS. I think for our purposes the tools are there for us with regard to legislation and laws. I think it is a matter of working closely with the agency and the agency working with the states, and where my audit counterpart can help out with finding where there are weaknesses or loopholes and make suggestions to the agency.

I do have to say though that in my years of working at USDA and working with FNS, they are always very open to our side of the house to investigations. When we find problems, they will work with us to try to remedy them.

FRAUD IN RECOVERY ACT PROGRAMS

Mr. LATHAM. In the same report, rural development and the "Recovery Act" had $1.56 billion in loans that were meant for buyers of very low incomes for the single family housing direct loan program, if you look over here, where the answer is over here. Okay. And, apparently, there were some people getting loans that their incomes were not being verified or too high to qualify, or something, what is the reason for that or what needs to be done?

Mr. YOUNG. Well, in that particular case, the rural development or rural housing service wasn't getting the documentation they needed to review. They hadn't set up a second party review, so loans were being approved, but they didn't have that second party review to ensure that they had all the information ensuring that the people getting those loans were eligible for the loans. Their control process broke down and allowed some ineligible loans to be made.

Mr. LATHAM. Were there guidelines in place to verify?

Mr. YOUNG. Yes. There were guidelines. I think the reason some of this happened, you had a lot of money that needed to get out very quickly. And some of the people were somewhat overwhelmed because of the number of loans they were making. And, as a result, some of the controls fell by the wayside, such as second party review.

Mr. LATHAM. Who was rushing?

Mr. YOUNG. There seemed to be within the agency staff, a feeling that since this money was made available, they wanted to get that funding out or those loans out as quickly as possible to address the

recession, to address the farmers that needed help in the housing area.

Mr. LATHAM. Okay. So I mean was there a dictate from above, or something, that said no matter what, don't follow the rules. Get the money on a shovel and move it out the door?

Mr. YOUNG. No. I am fairly sure there was no one saying don't follow the rules. But I think just the sheer volume of the work they had to do, when you have so many people and so much work to do, sometimes some of those controls fall by the wayside because of the sheer volume of program participants.

Mr. LATHAM. Okay. My time is expired. Thank you.

Mr. KINGSTON. Ms. DeLauro.

Ms. DELAURO. There are a couple on your side over here before I was, so let them.

Mr. KINGSTON. Mr. Nunnelee.

Mr. NUNNELEE. No questions.

Mr. KINGSTON. Mr. Grace.

Mr. GRACE. I am listening in awe.

Mr. KINGSTON. Ms. DeLauro.

Ms. DELAURO. Thank you, Mr. Chairman. Just a couple of random observations.

SNAP PROGRAM ERROR RATE

First of all, I don't know, and if we could get this information, how the SNAP error rate of approximately 4.4 ranks in comparison to other government programs, and that is such as direct payment to farmers, oil subsidies, or mineral subsidies. I also understand there were serious mistakes that were greater than anything that we are talking about here, and the guaranteed housing program, that in fact were the errors. And the people who were responsible were bankers, and that is in your testimony.

So it would be interesting to note that 27,000 loans were ineligible for the program—33 percent of the portfolio with a projected total value of about $4 billion. So I think it would be useful to lay out, because there is always an abiding interest in what happens in the SNAP program. It is always interesting to me that that is the place where we direct our attention. But we have got some other serious offenders here, and quite frankly the error rate, I believe, since 2004 has gone from around 10 percent down to about now 4 percent.

We have had a tremendous rise in the number of people participating in SNAP, and as I congratulated Secretary Vilsack, yesterday, I think that managing that increase with an error rate that is a low one by some standards, but I think for the benefit of the committee, it might be useful to look at this information so that we can have an accurate picture and not just kind of cherry pick, either from the side of a farm payment issue, or from the side of the SNAP issue. So let me ask you to provide me with that information, if you can.

Ms. FONG. Okay.

Ms. DELAURO. And SNAP is USDA's largest program in dollars spent, number of participants, so we are looking at what is ostensibly a low error rate. That doesn't say we shouldn't correct what

we need to, but we ought to be equitable in our correcting and emphasize where the most egregious offenders might be.

And I don't know if you know something about what the percentage of error rate with regard to the guaranteed loan program, with the mineral subsidies. I don't know if you have that off the top of your head, now.

Ms. FONG. We can provide a chart, too, that the Department compiled in its Fiscal Year 2010 PAR——

Ms. DELAURO. That would be great.

Ms. FONG [continuing]. Which lists the improper payment rates for all of the agencies within USDA.

[The information follows:]

(Discussion of SNAP error rates, a list of improper payment estimates (error rates) for other USDA agencies.)

The table below, as cited on page 227 of USDA's Performance and Accountability Report for Fiscal Year 2010, provides the summary level information for all high risk programs outlining improper payment rates for the last two years and future reduction targets. When a number cannot be provided, an explanation is provided in the notes below. The table includes amounts from program sampling results. USDA programs report results the year following sampling activity. For example, results reported during FY 2010 represent measures of FY 2009 outlays and program activity.

Improper Payment Sampling Results ($ in millions)

	Results Reported in FY 2009			Results Reported in FY 2010		
Program	**Outlays**	**IP%**	**IP$**	**Outlays**	**IP%**	**IP$**
Marketing Assistance Loan Program, FSA/CCC [Note #3]	4,935	2.56%	85	4,151	0.81%	35
Supplemental Nutrition Assistance Program, FNS [Note #6]	34,611	5.01%	1,733	50,360	4.36%	2,195
National School Lunch Program, FNS [Note #1] Total Program Certification Error Counting/Claiming Error	9,436 9,436 9,436	16.44% 9.56% 6.88%	1,551 902 649	8,925 8,925 8,925	16.28% 9.40% 6.88%	1,453 839 614
School Breakfast Program, FNS [Note #1] Total Program Certification Error Counting/Claiming Error	2,273 2,273 2,273	24.62% 8.83% 15.79%	560 201 359	2,534 2,534 2,534	24.87% 9.08% 15.79%	630 230 400
Women, Infants and Children, FNS [Note #2] Total Program Certification Error Component Vendor Error Component	4,483 4,483 4,483	N/A N/A 1.27%	N/A N/A 57	6,480 6,480 6,480	N/A N/A 1.17%	N/A N/A 76
Child and Adult Care Food Program, FNS [Note #2] Total Program FDC Homes - Tiering Decisions FDC Homes - Meal Claims	2,214 713 713	N/A 2.07% N/A	N/A 15 N/A	2,461 911 911	N/A 0.99% N/A	N/A 9 N/A
Milk Income Loss Contract Program, FSA [Note #5] [Note #3]	2	N/A	N/A	602	0.66%	5
Loan Deficiency Payments, FSA [Note #5]	6	N/A	N/A	114	0.44%	0.5

	Results Reported in FY 2009			Results Reported in FY 2010		
Program	Outlays	IP%	IP$	Outlays	IP%	IP$
[Note #3]						
Direct and Counter-Cyclical Payments, FSA [Note #3]	4,948	0.42%	20	5,921	0.96%	56
Conservation Reserve Program, FSA [Note #3]	1,876	0.72%	11	1,814	1. 20%	24
Miscellaneous Disaster Programs, FSA [Note #3]	2,245	0.90%	19	108	4.60%	5
Noninsured Assistance Program, FSA [Note #3]	67	14.20%	8	59	11.65%	7
Wildland Fire Suppression Management, FS	1,016	0.00%	0.0	710	0.00%	0.0
Rental Assistance Program, RD	887	2.06%	18	979	1.39%	14
Federal Crop Insurance Corporation Program Fund, RMA [Note #4]	3,545	5.79%	205	8,680	6.05%	525
Farm Security and Rural Investment Act programs, NRCS	1,320	0.03%	0.0	1,505	0.41%	6
USDA Total	72,363	5.92%	4,283	93,853	5.37%	5,039

Note #1: Information has not been adjusted for interaction between the different sources of certification error and counting/claiming error. Improper payment rates (School Year 2008/09) times SBP outlays (FY 2009).
Note #2: WIC and CACFP tests components of their total program. WIC currently tests and reports on the vendor error component of the payment process. The WIC certification error component information should be available in 2011. CACFP currently tests and reports on the FDCH tiering decision component of the payment process. FNS continues to evaluate the measurement processes for the CACFP meal claim component. It has not set a date for measurement and reporting.
Note #3: The FY 2010 estimated improper payment dollar amounts for MAL, DCP, CRP, MDP, and NAP may reflect variances from the relationship between the improper payment percentage and the outlays amount. These variances result from the complex, multi-stage statistical sampling methodology developed by the contract statistician in calculating the independent projections of the dollars/percentages in error. The variances are a complex ratio estimate weighted with respect to the payments within their applicable county stratification. They reflect the variability within the payment data and occur with a 90-percent confidence level. The MAL, DCP, CRP, MDP, NAP, MILC, and LDP universe of payments for the FY 2010 was September 2008 through August 2009. The measurement period was adjusted to meet the report timeframe.
Note #4: RMA uses a three year running average to calculate the improper payment error rate. This is the fifth year RMA has used this process to measure the improper payment error rate.
Note #5: FSA did not measure MILC and LDP for the FY 2009 IPIA review and reporting cycle since sampling was not cost effective due to the very low outlay amounts ($2 million for MILC and $6 million for LDP). FSA measured MILC and LDP for the FY 2010 IPIA review cycle.

Note #6: The SNAP FY 2010 improper payments error rate and estimated amount of improper payments for payments made in FY 2009 reflect the ARRA requirement to exclude small errors of $50 and less. Future performance may be affected by the expiration of this provision. USDA and OMB continue to evaluate SNAP improper payment targets. The targets may be adjusted in consideration of increased need resulting in further growth in the program, which has been unprecedented in the last year, State budget constraints, and other related factors.

Ms. DELAURO. One of the things I wanted to follow-up, something that Mr. Farr said. Well, we are going to get another round, I am sure. What would you need? In other words, you make recommendations to the agencies, and this is every inspector general. And it is nice to see you all again, anyway. Thank you very much for being here.

You make the recommendations and then you rely on the agencies to carry out the recommendations. Correct?

Ms. FONG. Correct.

Ms. DELAURO. Is that right? Now I am also taken with, so then with your portfolio of the various audits, investigations, and what you have to do, and agency recommendations, and following up year in and year out, you need to have staff that deals with all of that for you to have accurate information and data to know what they have done and what they haven't done. Correct?

So I have got a two-part piece here. One is what else could we do for you that would allow you to have a greater opportunity for follow-up with the agencies to see where they are going and to be able to monitor that more closely. And then I would like to ask you is given that the OIG's office is cut by $8.7 million under the budget that was passed last week, it is a reduction of about 10 percent.

The USDA OIG's budget was cut more than any other IG office in other departments again, as I understand it. Treasury, Interior, a cut of one percent. The less, Defense IG, received an increase of 17 percent, because ACR would be enacted. So late in the fiscal year what would be the impact of the cut to your office? Would you have to furlough employees? If so, how many?

How would this impact the work of the OIG? Would audits, investigations have to be delayed or suspended? Would the office miss statutory deadlines for audits? How would your office have to reassess its priorities? Would your office have to shift away from investigating improper payments in order to focus on public health and safety priorities?

My time is up. I'll repeat them in a second go-round so that you can answer this for us, both from the point of view of what you need to continue to follow-up on these investigations and audits, and what would the majority's cuts to the OIG budget at USDA mean in terms of your workload and your personnel?

You can answer it in the next round. Mr. Chairman. Thank you. Thank you for your indulgence.

FRAUD IN FEDERAL PROGRAMS

Mr. KINGSTON. Thank you.

Ms. Fong, what I don't understand is it appears that the fraud is common. Would you say that that's true or false?

Ms. FONG. Fraud is common in any particular program?

Mr. KINGSTON. In all of them. I mean from the housing to farm programs to SNAP. Those are the three we have talked about. It seems to be common.

Ms. FONG. I think what I would say is that in general, if you have a federal program that has a lot of dollars and, in particular, in situations where dollars are going out quickly and people see an opportunity, it is human nature that there will be some element of the population who will look for a way to take advantage of a fed-

eral program. And so, I think, if you look government-wide, virtually every program will have some level of fraud. Now, that's not to say that while that's not surprising, that's why we are here.

Mr. KINGSTON. But would you say the government is easier to steal from than other places?

Ms. FONG. Well, I don't know if it is easier to steal from the government or other places.

Mr. KINGSTON. That is why I voted against a bailout. [Laughter.]

Ms. FONG. But I will say that I think the government has in place a structure to try and deal with those situations, and that structure is comprised of program managers on the very first level of defense who need to pay attention to make sure that their programs are run effectively and have the minimum potential for fraud. And then the next level of defense is the IG system, which, you know, is here to help the program managers get a third party objective look and advise on how they can tighten up. And, if in fact people get through and commit fraud, we are here to go after them so that there is a deterrent effect against future fraud.

LOAN GUARANTEE PROGRAMS

Mr. KINGSTON. Well, let's talk about the $4 billion in the loan programs, the loan guarantee programs. It said that a lot of people got loans that weren't eligible. Did any employees of the USDA lose their job because of that incompetency? Ms. Fong.

Ms. FONG. I would suggest—my sense is that the answer is no, but you might want to ask the undersecretary for RD that question.

Mr. KINGSTON. Okay. You know that is an interesting response, because last year I had a similar question to you, and you had said, "No. You need to ask them, because we only make the recommendations." Maybe there needs to be something that bridges your action with their action a little bit stronger, because it appears that if your recommendations are merely academic, and then from then on out somebody is not going to do anything about it, then we are going to continue to have these repetitive hearings.

I had a friend of mine, many, many years ago, right out of college, real smart guy, was the treasurer of his church. I mean he was like 23 years old, just out of college, a really bright kid, and figured it out that the preacher was stealing money out of the collection plate. And he went to the adults on the vestry and he told them. This was a preacher. Everybody loved the guy. He was great. How could he be stealing? It can't be possible.

So what they ended up doing is they planted $20 bills in the congregation and wrote down the serial numbers, and they did this several times. And the last person to get the collection plate was the preacher and those $20 were gone. So they went to the church, and the church said—their reaction, and this is my 23–year-old, idealistic friend who believes in everything good and great and the church says to him—the upper church says, "Well, don't do anything rash. You have to be careful about these things." This is a preacher stealing! And the message to the 23-year-old was, you know, you don't always have to play by the rules. They're optional.

And I wonder if we haven't sent that signal in the USDA that, you know, some fraud is going to happen, and maybe we are not

going to be that tough about it. I mean $4 billion in the loan guarantees and nobody gets——

Ms. FONG. Let me just clarify, a little bit. In that audit we found that it appeared that a number of borrowers who should not have gotten housing loans got them. Now, as it was pointed out, it was a guaranteed program, so the banks are the ones who bear the brunt of it.

Mr. KINGSTON. Did they get eliminated from the program, from eligibility?

Ms. FONG. I don't believe RD has taken action on that, and here we get into the whole issue of how the program agencies want to deliver their programs.

Mr. KINGSTON. But, the banks, just like the grocery stores, should be responsible for their own employees and they should not be eligible anymore. And if we are sending a signal, that is the option.

Ms. FONG. Well, I do not believe our office is sending that signal. We have gone up against the program.

Mr. KINGSTON. Does it drive you crazy?

Ms. FONG. Yes. We have continuing debates about this audit. We have briefed the Secretary and the Deputy Secretary, and they are committed to taking action.

Mr. KINGSTON. Well, my time has expired, but I think what would be really good is you guys turning up the volume to us and saying, "Okay, you people in Congress need to know we are giving the same testimony over and over again. And you are the bridge, and it is not getting through to the people who should be taking role and kicking tail. And it's not happening. We can't do it, but you all can." And I don't think we are hearing that from you, because what I'd like to get, we will have another round, is some recommendations where do we go from here.

[The information follows:]

(Recommendations for what needs to be done to strengthen "the bridge" between OIG recommendations and implementation.)

Agency leadership and staff have been very positive in responding to OIG's recommendations. OIG works closely with agency officials and staff to timely reach agreement (i.e., achieve management decision) and, in coordination with the Office of the Chief Financial Officer (OCFO), implement agreed to actions. However, issues do arise in reaching agreement and final action on some recommendations. When that happens, we follow established procedures to elevate our concerns.

In USDA's Departmental Regulation on Audit Followup and Management Decision, DR 1720–1, Appendix A (which is currently being updated), there are specific steps in place that agencies are to follow in reaching agreement on OIG recommendations. Included are elevation milestones if agreement is not reached within a 6-month timeframe. The timetable and actions described below do not preclude elevation to the next level at any time. The timeline follows.

- Within 60 days of the audit release date, the agency must propose a preliminary management decision to OIG for each recommendation in the audit report for which there was no management decision made at the time of report issuance.
- If an agreement with the preliminary management decision has not been reached within 90 days, both OIG and the agency will alert their respective senior officials of the differences and potential problems in reaching agreement.
- If agreement has not been reached within 120 days, OIG will prepare an Audit Decision Paper summarizing disagreement with the preliminary management decision, and will discuss the Audit Decision Paper with the management officials.
- If agreement with the agency head has not been reached within 135 days, the Audit Decision Paper will be elevated by OIG to the applicable Under or Assistant Secretary.

• If, after 150 days, an agreement has not been reached, the Audit Decision Paper will be elevated by OIG to the Department's Audit Follow-up Official, the Deputy Secretary, who will render a management decision.

If an agreement still has not been reached within 6 months (180 days) after issuance of the final report, the audit is reported in OIG's Semiannual Report to Congress.

In April 2010, the Secretary established an initiative to close out late OIG recommendations. The agencies have taken the Secretary's initiative very seriously. All agencies are working diligently with the Office of the Chief Financial Officer, who has been instrumental in this initiative, to reach final action in order to get old recommendations off the books. Agency staff have also been responding more timely to new recommendations reported by OIG.

Mr. Farr.

IG AUTHORITIES

Mr. FARR. To follow up on that, you don't take the legal action, you just point out the error or the misconduct, and then it's up to the agency's lawyer to prosecute? Or what is it, AG?

Ms. FONG. Or take whatever action. In this case, I don't believe we found fraud in any of those situations. It was not fraud. It was more oversight or not following the regulations, so it's not criminally prosecutable. And so, then the question is what is the agency going to do about it. Is it going to comply with its regulations or is it going to change its regulations?

I think that is a policy issue that they are struggling with right now. Let me just address, philosophically, the whole structure of what IGs do, and I think all of you are bringing this issue on the table out of a sense of frustration; and, certainly, we have that sense as well. As IGs under the law we report to you and we report to the Secretary, and we issue our reports directly to you and we testify before you.

We bring to you issues that we think are significant, and I am very pleased that at these hearings you are so interested in what we are hearing and you want to see further action—I think you are going about it the exact right way—that you are having these oversight hearings, that you are talking to the Department officials, the policymakers, and you are putting it on the table with them: What are you all going to do about this; because that is exactly the right role for you and for us.

Mr. FARR. But that goes to my question of the authorities. I mean you have authority to blow the whistle, but you don't have the authority to stop the game.

Ms. FONG. Precisely. The Inspector General Act very clearly says we cannot run a program. We do not make decisions on funding. We cannot fire employees unless they are within our own office. And it's there for a reason.

Mr. FARR. But you pointed out in your testimony what you are going to do with your additional money is you are going to increase the instruction on suspension and debarring. Is that the right word? To give the agency staffs the knowing how to do that properly, right, is that what it takes?

Ms. FONG. We can. Part of our role is to inform, to educate, to persuade, and convince. A part of our role is to provide information so that the agencies can act on that information.

Mr. FARR. But your responsibility then is to train people on how to use the authorities they have to take some legal action to stop the game, so to speak.

Ms. FONG. I would hesitate to use the word "responsibility," but I will say a role that we can play is to educate and train.

Mr. FARR. Well, I mean I think everybody on this committee is frustrated. And I am sure every committee and subcommittee of appropriations is frustrated in hearing this testimony, because yeah, we do like to hear the whistleblowers, but we are frustrated that once you hear it that the agencies aren't playing the role they're supposed to play to effectively remedy the situation.

STATE ENFORCEMENT OF SNAP

I mean throughout your testimony, that's what I kept understanding, and some of your audit responsibilities are, because some of the cops in this are not federal cops. We deal with states. What are the states that have the worst reputation of not being able to do enforcement?

Ms. FONG. You are talking about the nutrition programs?

Mr. FARR. SNAP is the biggest program in the whole USDA.

Ms. FONG. We may have to provide that information to you, because we don't know that.

Mr. FARR. I think you said you had that.

Ms. FONG. Well, we have the improper payment rates. We can provide you a chart on improper payment rates within programs.

Mr. HARDEN. That's not the state.

Ms. FONG. Right. Right.

Mr. FARR. Pardon me?

Mr. HARDEN. The listing of programs that have improper payment rates is not the same as the states that are the bad actors. That would be two different lists.

Mr. FARR. What is the one—we have some information about Texas and Indiana.

Ms. DELAURO. That is erroneous. The highest error rates, as I understand it, is Texas and Indiana.

Ms. FONG. That may be. They are on the watch list, yes.

Mr. FARR. So that is for error rates, but what we are talking about is weak enforcement. Right?

Ms. FONG. Well, they may be related. The fact that there are high error rates may, if a state has a very high error rate, then the agency needs to be focused on that and to employ whatever tools they have to penalize, as it may.

Mr. FARR. So walk us through the process. You have a SNAP program. It is the biggest program USDA has, the most money going out. You work for the states, because we don't administer it. It is state administered.

Mr. HARDEN. Right.

Mr. FARR. So what we do is monitor. So if you find an error rate, then what? Who slaps the hands of the state and how do you do it?

Mr. HARDEN. Well, where it starts, initially, is the Food Nutrition Service provides the oversight through their regional offices to the states, and states have high error rates. They have ways, for like the SNAP program, of administering sanctions to the different

states to encourage them to lower their error rates. And then they also have——

Mr. FARR. Encourage them to lower their error rate.

Mr. HARDEN [continuing]. Bonuses.

Mr. FARR. They just defrauded the Federal Government a lot of money and you are going to get encouraged. "Don't do this anymore." Is that all that happens?

Mr. HARDEN. I am not going to be able to speak all of FNS's process, but they are the first line of oversight in terms of——

Mr. FARR. But you are overseeing them.

Mr. HARDEN. And we would go in and look at how they are running the program and are they following up and carrying out the roles and responsibilities that they have. And if we find that they aren't, then we would be making recommendations as to how to strengthen those weaknesses.

Mr. FARR. My time has expired. Thank you.

Mr. KINGSTON. I think we're seeing a theme here.

Mr. Latham.

Mr. LATHAM. Thank you, Mr. Chairman.

In your testimony, there was a case in Massachusetts, a corporation that collected millions of dollars in government money for services they never provided. Apparently it was an IT training, or something like that. And it's just amazing to me that this is a prepaid voucher system, where they got the money ahead of time but never provided the service.

How widespread is this system? Is there no control over this? Or how did this happen?

Ms. ELLIS. This is to kind of explain, when you buy a computer, sometimes you prepay on your personal computer training. And sometimes we take advantage of it, and we actually go to the store where you bought the computer, and we get that training, and sometimes we don't.

And in this case, it was very similar. It was a large company that gave IT-type training, that the government had contracts with. And certain training aspects were not followed through.

The people did not go to the training. But still the company charged.

In answer to your question, we did work this case jointly with several other federal agencies. And within USDA, there were a number—I'm looking at my list, I'm going to say maybe about ten different USDA agencies, that also had contracts with this company.

So it was pretty widespread.

Mr. LATHAM. Ten different USDA?

Ms. ELLIS. USDA agencies that had contracts with this company for this training purpose. In addition to other federal agencies.

Mr. LATHAM. With similar results with all of them?

Ms. ELLIS. Yes. What had happened was our agency worked with other federal law enforcement agencies as a team, and we investigated this company and the various contracts.

So we were able to pull all of our information together.

GSA was one of them, Department of Commerce, and DOJ worked jointly with us.

Mr. LATHAM. Can you give me a list of the other agencies that were involved with this also?

Ms. ELLIS. Yes.

Mr. LATHAM. Please, if you would.

Ms. ELLIS. I'll supply that for the record.

[The information follows:]

(Listing of other agencies involved in investigation of the contractors and the pre-paid voucher false billings.)

Working with other Federal investigators, OIG determined that a corporation doing business in Massachusetts collected millions of dollars from the Government for services it never provided. The corporation offered training on computer software and other information technology. Using a pre-paid voucher system, agencies paid up front for training that the company never delivered. We found that several USDA agencies were victimized by this scheme. In April 2010, the corporation agreed in a civil settlement to return a total of $4.5 million to the Government.

This was a joint investigation by USDA-OIG, General Services Administration (GSA)-OIG, the Department of Commerce-OIG, and the Department of Justice. The investigation involved USDA agencies affected by the corporation's scheme, including: Agricultural Marketing Service, Natural Resources Conservation Service, Animal and Plant Health Inspection Service, Food and Nutrition Service, and Economic Research Service.

OIG was recently notified that GSA's Office of Acquisition Policy, Washington, D.C., determined it was not necessary to exclude the corporation or the president of the corporation from Federal contracting. The corporation is still providing services to GSA.

Mr. LATHAM. And you've made recommendations, I assume, to the Department as far as how to correct or keep the integrity of this—I have real concerns about a voucher program where, it's after the fact, the money's out the door.

Ms. ELLIS. Yeah. We work closely with the Department. What we did is we issued our reportive investigation, which then showed the results through DOJ of the sanctions that were taken in the sentencing.

We then send it to the Department, to ask them to take some sort of admin action. This one that I am not sure that they're in the process of debarring; because there are so many other agencies involved, especially GSA, who probably has the main contract.

My guess is——

Mr. LATHAM. Why would they have to wait for other agencies, other departments?

Ms. ELLIS. Well, we would work with them to make sure they are debarred. There is like a list that this company would go onto.

And that's why—I personally don't know right now who is actually taking the action, whether it's us or——

Mr. LATHAM. No. But I mean, you said that you were waiting for other agencies to act. If you knew the facts in this, why wouldn't you go ahead and respond?

Ms. ELLIS. Oh, because we can't enforce the actual suspension and debarment. We would have to wait for the USDA to take that action. And we would follow up with them. And my assumption is that they——

Mr. LATHAM. Are they acting?

Ms. ELLIS. I don't know the answer to that, offhand.

Mr. LATHAM. Okay.

In Puerto Rico in the Nutrition Assistance Program, apparently they're allowed to cash in 25 percent. And this is U.S. taxpayer dollars going down to support the program.

But you are able with your nutrition program to get 25 percent of your benefit in cash. So potentially there's about 250-some million dollars that could be used for other purposes, rather than nutrition.

Is there any way of knowing where the money's going? And now they're talking about being able to use it in restaurants and fast food places, and—anybody?

Ms. FONG. We did some work on that, the Puerto Rico program, a number of years ago. But I don't recall the results. And I hesitate to speculate.

But my guess is that Puerto Rico's delivery system is unique. I think it's the only jurisdiction that allows a cash takeout.

Mr. LATHAM. Right.

Ms. FONG. And I'm not sure if that's a federal——

Mr. LATHAM. I just hope this isn't a pilot program for the rest of the system. I mean.

Ms. FONG. It doesn't appear to be.

Mr. LATHAM. Okay.

Ms. FONG. I don't know if that's because of local law or a federal law. I just don't know that.

Mr. LATHAM. I think they have their own program that we pay for, yeah.

Ms. FONG. Yes.

Mr. LATHAM. Right. Thank you.

Mr. KINGSTON. Ms. DeLauro.

Ms. DELAURO. If I can, because I want to get in a question eventually about N60 testing, that you were engaged in. But let me just go back quickly to what I was asking about and answering the questions that I laid out.

BUDGET CUTS

I think it's clear that everyone wants to provide you with what you need in order to deal in terms of the followup. And it would be useful if we can have conversations about that, that would allow you to do your job better, given the nature of the law with regard to IGs.

But given the nature of the cut that is intended, particular to the OIG at USDA—and which is not the case for other IGs, the impact on your office.

And as I said, if you could tell me now. If you can't, I would like to know this. But I want an answer to this. Would you have to furlough people?

Ms. FONG. Okay.

Ms. DELAURO. Yes? Or——

Ms. FONG. Short answer, yes.

Ms. DELAURO. Okay. How many? Do you know that now?

Ms. FONG. We would be looking at our whole staff.

Ms. DELAURO. Whole staff?

Ms. FONG. Our whole staff for a period of time.

Ms. DELAURO. Your entire staff for a period of time, given the cut that was passed last week in the House of Representatives. How long would you have to furlough for?

Ms. FONG. Our preliminary numbers would show, I think we're looking at about six weeks.

Ms. DELAURO. Okay.

Ms. FONG. And I should say that, you know, we would do it on a rolling basis.

Ms. DELAURO. Fine. I understand. I'm just trying to get a sense of what we're dealing with here.

Obviously now maybe the next two questions are moot. How would it impact your work? Every audit, every investigation would, even if you rotated, it would have to scale back?

Ms. FONG. Yes. There would be a tremendous impact. As you know, because of the nature of our work, we don't have a lot of money in our budget. It's all pretty much tied up in staff salary and benefits.

Ms. DELAURO. Mm-hmm.

Ms. FONG. And so any significant reduction would impact our staffing levels, which means that our priorities would have to greatly change. We would only be able to address the very highest priority work.

Ms. DELAURO. Okay. And I really want this in writing. I want to hear from you about what this means. If we can't quantify this, then we're just dealing in speculation as to what this means.

And I think it's important for the members of this committee, and I think it's important for the rest of the members of the House to understand what the nature of this cut, as a ten percent cut to the OIG, and particularly in your case what that means.

And all of our discussion about improper payments, all the authorities, all that we would care about is really, it's gone. It's gone. We would not be able to follow up on any improper payment.

Thank you. Let me move to N60 testing.

Ms. FONG. I'll provide that, for the record.

Ms. DELAURO. Please, I would like that, for the record.

N60 TESTING PROTOCOL

I want to say a "Thank you" to you for completing that audit on the N60 testing protocol. Which is, for my colleagues, FSIS' samples beef trim for E. coli, taking 60 samples from large lots of beef trim to test.

This was an audit that I requested in November. The OIG finding that this procedure does "not yield a statistical precision that is reasonable for food safety" is astounding to me.

It confirms the concerns that have been expressed in that the sampling system is flawed. By recommending that FSIS redesign its sampling methodology to account for varying levels of contamination, it makes you wonder if it undercuts everything that they are working on now, since it seems like they have to start over.

Questions: Is there an estimate of how much the E. coli 0157 H7 levels in the FSIS regulatory sampling program have been understated by using the N60 sampling technique?

What would be a better sample to capture a more accurate picture of the levels of E. coli, 0157 H7, in a bin of trim?

FSIS adopted an industry-sampling technique, when it started to use N60. Industry has made claims that the levels of E. coli have been declining in beef. What would you advise the industry, based on your audit findings, for the FSIS sampling program?

Was OIG able to provide more specific recommendations to FSIS, beyond placing its testing process on sounder statistical ground, by redesigning its sampling technology?

Given that FSIS generally agreed with the recommendation, do you have a sense of how much time this process would take?

Mr. HARDEN. In response to the first questions, in terms of the prevalence rate?

Ms. DELAURO. Yes.

Mr. HARDEN. I mean, that's part of the whole problem. They do not know what the prevalence rate is, and they had not completed the underlying study to know how prevalent E. coli is in beef. So that's where they have to go back and really finish that study that was started, or start over with that.

And then they would have to decide for themselves what type of confidence level they would be willing to take, so that that would then drive the types of samples or the size of the samples they would need to take.

We did talk to them about that; it would be very resource-intensive, and we offered some alternatives that they could consider as they're going forward, such as maybe dedicating a specialized team to go in to do the sampling that is needed; and also to make themselves aware of what the industry is doing in terms of testing; because a lot of big beef plants and companies do their own testing.

Ms. DELAURO. Mm-hmm.

Mr. HARDEN. And we've encouraged FSIS through several——

Ms. DELAURO. My time has expired.

Mr. KINGSTON. Thank you.

Ms. DELAURO. And the Chairman has been generous. So we'll come back on it, so I can get the answers to the other questions.

Mr. KINGSTON. We will.

Ms. Lummis.

Ms. LUMMIS. Mr. Chairman, the committee can enjoy a rare reprieve from the sound of my voice today. Thank you. [Laughter.]

Mr. KINGSTON. You can always submit questions for the record.

Mr. Bishop.

Mr. BISHOP. Thank you very much.

I was just looking at an analysis of the effects of the CR that was passed last week on your office, the potential effects. And I heard the discussion with Ms. DeLauro just now.

CIVIL RIGHTS CASES

But last year, we also added some additional requirements for the Inspector General in connection with the Pigford case. And of course, there were several provisions that were put in there: Approval of neutrals, additional documentation, attorney certification, transparency of claims determinations, and distribution of funds and reports.

And I don't think there is a member of this subcommittee, or even in the Congress, who has any interest in seeing the Federal Government make one single payment to anybody who doesn't have a legitimate and proven claim under the settlement.

But I do have a couple of questions for you:

There has been a significant amount of attention to the fraud issue. And I'd like for you, if you could, to briefly share with the

subcommittee your office's experiences or your activities with respect to any fraud that was associated with the Pigford I claims.

Then I'd like to know whether or not your office has been a part of any ongoing discussions with the USDA or the Department of Justice with respect to executing the legislation, particularly the fraud provisions, and what were those discussions;

Whether or not it's your office's intention to focus potentially on Pigford, or we focus on fraud in the other classes of cases that were included in that legislation, and the bill requires that your office conduct a performance report audit of the claims processing. And I'd like for you to tell me how that is going to be accomplished.

And what methodology you're going to use in determining the processing in evaluating the validity of the allegations of fraud or fraudulent claims. How do you anticipate getting at that information?

And overall, if you developed a plan of action to pursue examining fraud?

And the final question: Do you have adequate staff and resources to carry out the responsibilities that were put on you by that legislation?

Ms. FONG. Okay. Let me offer a few comments about how we're going to approach the Pigford situation, and I'll invite Gil and Karen to chime in.

With respect to Pigford I claims and fraud, I believe our policy on that was to refer all potential fraud claims to the Department of Justice. And that mechanism has worked well. So we have not been involved in that.

Now with respect——

Mr. BISHOP. Did you make any referrals?

Ms. FONG. Yes, we did.

Ms. ELLIS. Yes, we received a number of hotline referrals throughout the years. And we just packaged them up and sent them over to the FBI.

Mr. BISHOP. Do you know how many of those were found to be meritorious, or valid?

Ms. ELLIS. We have that information, but I don't have that offhand. I could provide that for the record.

Mr. BISHOP. Thank you. Would you?

Ms. ELLIS. Yes.

[The information follows:]

(Provide information on the investigative results of the referrals you made to the FBI in Pigford I.)

Since January 2000, OIG has referred a total of 2,083 complaints to the Federal Bureau of Investigation (FBI) involving allegations of fraud related to the class action suit filed against USDA known as Pigford I. The complaints were received via telephone, mail, fax, and e-mail. While we do not generally receive updates from the FBI, we have learned that of the 2,083 complaints referred, 3 individuals have been convicted and sentenced to date.

Mr. BISHOP. Thank you.

Ms. FONG. With respect to Pigford II, as you point out, the claims Resolution Act of 2010 included a requirement that our office do a performance audit of all claims before the claims are paid out, in an effort to prevent improper payments.

And we have been working very closely with the Department and with Justice to get the timing on all of that correct, because we

can't actually start auditing until the settlement agreement has been approved by the judge. And I think that's still pending.

But assuming that all happens at some point, and we get the access to information issues all ironed out, we will be keeping a close eye on how those claims are processed.

And we are developing our audit plan to do a statistical and performance audit, which will be quite resource-intensive. And we believe this will hit our office some time by the end of this fiscal year into next fiscal year. So we will be quite busy in Fiscal Year 2012 doing this work.

In terms of the other classes who have claims against the Department——

Mr. BISHOP. That was the Native Americans and——

Ms. FONG. And the women?

Mr. BISHOP. The women.

Ms. FONG. Exactly.

Ms. ELLIS. The Hispanic farmers.

Ms. FONG. And the Hispanic farmers, yes. I think Secretary Vilsack announced recently that the Department has entered into an agreement with those classes. As part of that agreement, there is a provision, I believe, that says that the Secretary can make a request to our office to do a similar kind of audit, similar to the one that we are going to do for Pigford II, involving performance auditing, statistical sampling, to ensure that claims that are paid out are appropriate.

And we anticipate that we could very well get that request. And if so, we would give that request very serious consideration. And that would involve quite a bit of our audit resources as well.

Mr. BISHOP. Do you have the resources?

Ms. FONG. Well, you know, we haven't really answered that question for ourselves. We are committed to carrying out the requirements of the law. And we will do the audit. And what that will mean is that we will have to prioritize everything else.

Mr. KINGSTON. The gentleman's time has expired.

SNAP ERROR RATES

Ms. Fong, I want to make sure the committee has this for the record, in terms of error rates on the SNAP program, Texas and Indiana are high. Maryland is actually in the second slot. That would be for 2009. We don't know what it is for 2010.

Now 2008 you had up there Connecticut had a very high rate.

Ms. FONG. Five percent.

Mr. KINGSTON. 8.16 for 2008. However, it improved remarkably. And also I want to say there were all kinds of other ones. I see a lot of fluctuation in these.

Yeah, Iowa had a high one. Georgia's okay, though. I'm proud to say.

But the one I was real interested about, though, was Delaware had a very high rate in '07 of nine percent, and now it's 0.7.

Do you have any idea how they improved that much? I'll share this with—did you get involved in that?

Ms. FONG. We have not done any audit work in Delaware on their improper payment rates. But——

Mr. KINGSTON. Well, they certainly would win the most improved.

Ms. FONG. You know, I think you have a good point there. Maybe——

Mr. KINGSTON. And maybe we should get some Delaware folks to Texas. I don't know——

[Laughter.]

Mr. KINGSTON. We might put them on the road.

IMPLEMENTATION OF OIG RECOMMENDATIONS

Mr. Young, I want to ask you some questions, because I'm just picking on you. You're a reemployed annuitant? Right?

Mr. YOUNG. That's correct.

Mr. KINGSTON. And so you're probably the freest person in this room. You can say whatever you want to say. And you've seen a lot of things.

So whether it is guaranteed loans, whether it is fee cap, whether it's foreign payments, whether it's in SNAP, you've got to have thoughts on what needs to be done, from a recommendation standpoint. And they might be different in each program, we understand that.

Mr. YOUNG. As far as—I guess it's sort of a mixed bag amongst the agencies.

We make a lot of recommendations in the audits we do. I think some agencies are very receptive and move forth to try to address what we've asked them to do, and do a pretty good job.

I think there are others—and there's a whole variety of reasons—it could be anything from staffing to they don't necessarily, they've said they agree, but they don't truly agree—in other words, "I'm going to tell the IG that yes, we'll go forth and do it," but they're not really committed to doing that, for a variety of reasons.

It could be staffing, it could be they simply don't agree with the concepts that we've come up with.

But it's a very difficult thing, as far as getting action completed and getting it completed timely.

As I said, some agencies are great, they move very quickly. Others drag there feet. And then that's where we work with the Department and try to push them, work with the Secretary, work the office of the chief financial officer, in trying to push those agencies to implement what we've recommended and to do it within a timely fashion.

Mr. KINGSTON. Well, now Mr. Farr brought up, in terms of these programs, it's more the institution that is at fault. And it might just be incompetency. Maybe it's laziness. Maybe they're not doing their due diligence on applications.

But that's where we're concerned, because I'm assuming that's where the big money is.

You know, if a farmer participates, who isn't ineligible, shame on him. And he should be penalized for it. But there's also the other, you know, if there's a government employee who wasn't doing the paperwork right, and they're repeat offenders, we would be concerned about that.

If there's a grocery store chain, who has the employees, who are bilking the SNAP system, then it should be the chain that's out of it.

There should be a very high standard for that.

And what I would like—as my time is almost over—is if you could submit to us, for the record, what would be your recommendations? Not broad at recommendations, but very specific recommendations, perhaps per agency, or whatever.

Because we really, I think the tolerance level is very low at the moment. And there's a great opportunity for all of us to do something for the American taxpayers, and say, "Look, we just are not going to put up with this anymore."

Year in, year out, it's either fraud, or it's incompetence. But money's going out the door that should not be going out the door. And that money could be spent elsewhere.

And my time is up. And Mr. Farr?

Mr. FARR. Thank you, Mr. Chairman.

APHIS

Let's go to one of the agencies.

First of all, I want to thank you very much for doing the audit on APHIS, on the dog dealers. I've been interested in trying to eliminate these puppy mills, and I'm interested in APHIS doing a much better job.

And you pointed out that the APHIS had major deficiency in their enforcement of the Animal Welfare Act. Why is that?

Mr. HARDEN. It was basically the agency's approach or a lack of an effective approach for the inspectors' carrying out the program. They tended to want to try and educate the problem dealers into getting better, as opposed to issuing fines and penalties.

Mr. FARR. Well, that's laudable. But I mean, we all try to do that.

But that's not the way other agencies work. I mean, there's always some education in there. But some of these breeders are just awful. I mean, if they're going to try to make awful people get better, it's still awful.

Mr. HARDEN. Which is the point that we were trying to make with the audit report. And you know, in response to the recommendation, they agreed to take stronger enforcement actions. It will take us going back to see how well they do it, to know if they really changed how——

Mr. FARR. Well, you pointed out they didn't even accept all of your recommendations.

Mr. HARDEN. They have, at this point.

Mr. FARR. They have?

Mr. HARDEN. They have.

Mr. FARR. Including the ones that would confiscate animals that are dying, or seriously suffering?

Mr. HARDEN. We have gotten agreement on those recommendations. I can't tell you exactly what they've done.

Mr. FARR. And to count each animal as a separate violation in a case involving animal deaths and unlicensed wholesalers? Those were two that in the report that I got that they hadn't reached agreement on.

Mr. HARDEN. We didn't reach them at the time of report issuance. But we continued to work with the agencies after we issue it, if there is not agreement, to get that agreement. And I know that we have reached that agreement now.

Where they are in terms of implementing the corrective action, is what I don't have in front of me.

Mr. FARR. I'm curious. When you go out and do these audits, do you actually visit sites? Or do you just look over their paperwork?

Mr. HARDEN. No, we actually visited a number of sites, which is the pictures that were in that report, which were quite difficult, were from our people going on site, and what they saw.

Mr. FARR. This is something that I think goes to the Chair's question also, about implement. You do your work and you make these recommendations. And then some of them take them seriously, and others don't.

You know, an animal welfare committee I think is pretty interested in making sure that the laws that we've enacted get enforced.

How can we make it better? Is it to take an audit? Does it take Congress asking to do an audit to get people's attention?

I mean, we can't do that with everything——

Ms. FONG. I understand.

Mr. FARR. Where's your oversight rule?

Ms. FONG. You know, I will say that in the enforcement in the Animal Welfare arena, we have done a number of audits over a number of years. And we've found major problems three or four years ago, which is why we went back in and did this audit.

We wanted to make sure that APHIS actually corrected the problems we saw the last time, with respect to enforcing penalties and other issues.

And you know, the sad story is that with this audit, it's clear that there were still problems. They have said that they are going to take very specific actions in terms of developing training and hiring specialists, and developing new information systems.

We will probably need to go and look at this again. Maybe in a year or two, once we give APHIS a chance to actually take a look at this.

And I will remark that we understand that you have introduced legislation to address some of the loopholes that exist in the current AWA that deal with internet dealers. And we think that that's actually a very useful piece of legislation to address an issue that we did find.

Mr. FARR. Could I get a letter of endorsement from you? That would be terrific.

Ms. FONG. You have my public statement. [Laughter.]

Mr. FARR. Well, I appreciate that.

I mean, I think it would help this committee a lot if we would know, you know. Also I think what you've also, Mr. Chairman, raises, there is some as we go through the rest of the agency and through their departments, some questions that we ought to be drilling down on in the subsequent hearings.

Ms. FONG. Okay.

Mr. FARR. The last one—oh, I'm running out of time. I wanted to go the California Organic investigation——

Mr. KINGSTON. Can I ask unanimous consent that—go ahead.

Mr. FARR. It will be my last question, Mr. Chairman.

ORGANICS

If you could respond to the California Organic investigation of——

Ms. FONG. The fertilizer?

Mr. FARR. It was to deal with fertilizer dealer that was certified as organic, and then switched ingredients and didn't tell anybody. And so you ended up using improper protocols.

Or I mean, they did.

And you cracked down on the California—I mean, what happens is these people get certified by independent certifiers. And has this gotten cleaned up? Is it California's, CDF—what is it, Department of Food and? And Agriculture.

Ms. ELLIS. Yeah.

I could tell you, that was our first investigation. We do have a few more involving that. But in working with California, they are very proactive in getting out front on top of this issue.

And so I can't speak so much for state level as to what they are doing there with regard to legislation. But I do know that they are trying to make sure that they keep this from happening in the future.

Mr. FARR. And your role was what?

Ms. ELLIS. We conducted the criminal investigation into this matter, and ended up getting an indictment of the individual, which I believe was sealed up until very recently, because he had left the country, and several months ago actually came back into the country. And we were able to catch him and serve him with the indictment.

So it's still in the judicial process. We have not finished the investigation.

Mr. FARR. Thank you.

Ms. FONG. I would just like to mention that we do have a number of other audits planned in the organic program. We've got a couple ongoing, involving the dairy industry, and the list, the process for making the list——

Mr. HARDEN. The substances that go on and off the National List of Prohibited Substances, we'll be looking at that later this year.

And we also have work in the crop insurance area, because they have a pilot program, or a new program, for organic operators in insurance.

Mr. FARR. I appreciate those audits. And it's a program where they're labeled as very highly respected in the community, in the consumer community. And I think that we have to make sure that—there's a lot of people trying to take advantage of it, because they get a better price. And so they'll try to sneak stuff in and label it organic. And it does injustice to every legitimate grower out there, who's struggling to make sure that they can get their product to market and be legitimate.

So do those audits. Thank you.

Ms. FONG. Okay.

Mr. KINGSTON. Ms. DeLauro.

Ms. DELAURO. Thank you, Mr. Chairman.

Mr. Harden, let me come back to you.

I think we were talking about what would be a better sample, for a more accurate picture on this. What would you advise industry on the audit findings here, because industry has made claims that where E. coli 0157 H7 is declining?

And the specific recommendations to FSIS beyond, if you've made any beyond putting this on a sounder technical ground? And have they agreed? And if they have agreed, what's the timing this process is going to take, given that do not know what the level of contamination might be?

Mr. HARDEN. I'd have to get back to you on the specific time frame.

Ms. DELAURO. Okay.

Mr. HARDEN. But in terms of FSIS working with the industry and a better way to know the number, we've recommended to them to have the inspectors that are in the plant to look at the results and know how well a plant is checking for itself;

And if the test the plants are running to test for E. coli meet FSIS' standards, to maybe use those results as well in building how they know how prevalent E. coli is.

Also, we've talked to them about, and recommended, that they look in evaluating their plants and knowing which ones are at greater risk for having E. coli contamination, so they know that they're putting their resources at testing those plants may be more frequently than the ones that have a better system.

Ms. DELAURO. Mm-hmm. I just would make a quick comment on that. I think once again, we may be relying on an industry to share their data with inspectors, who are also talking about the potential for furloughing inspectors. That was done last week, as well, in the budget resolution.

And your last point was? I'm sorry, because I had—the industry?

Mr. HARDEN. Oh, having FSIS evaluate the——

Ms. DELAURO. Risk-based——

Mr. HARDEN. Risk-based——

Ms. DELAURO. Risk-based. I must tell you, if they don't know what the level is on terms of estimates, it makes it very, very difficult. Except if you have repeat offenders.

But it makes it very difficult if you don't have a way in which you're determining what the level of contamination is. Then it's to base your inspection on risk, because you don't know what the risk is.

So we've got more to talk about in this area, and how we do get to safe and uncontaminated beef.

Ms. FONG. I believe we have an audit going on, a second-phase to the FSIS audit of the N60 testing.

Ms. DELAURO. Okay.

Ms. FONG. And we're going to be going out into the field this spring to look at plants and how they actually do the testing.

And I think we'll have some more specific——

Ms. DELAURO. Beautiful——

Ms. FONG. Observations——

Ms. DELAURO. Thank you——

Ms. FONG. And we'll be happy to work with you.

Ms. DELAURO. Yes, this is an area of very high interest to me, as you know. And I thank you for the study. I really appreciate it.

Ms. FONG. Right.

Ms. DELAURO. Let me ask again—I know you addressed Salmonella in eggs, and that you're auditing AMS in terms of what happened with the Wright County egg outbreak? Is that right? You're auditing AMS?

Mr. HARDEN. Actually, we're looking at multiple agencies in the Department, AMS being one of them.

Ms. DELAURO. Okay.

Mr. HARDEN. The audit of eggs was generated out of one of the recalls, one of the big recalls. But we're looking at APHIS' role, FSIS' role, and AMS' role.

Ms. DELAURO. Okay.

Mr. HARDEN. The issue that we've recently brought to the table, that we talked about in the testimony, is one where AMS needed better coordination with other agencies. But we're working on that particular issue right now, but it will be broader——

Ms. DELAURO. Mm-hmm. Well, but as you know, inspection of in-shell eggs is the responsibility of FDA. This is why we need a single food safety agency, in order to be able to deal with it. Otherwise, we've got varying people looking at what is involved in food safety.

Just a word about the audit, how extensive is it? What are you doing?

And then my final question would be: Are you going to examine the memorandum of understanding between FDA and AMS that sets out each agency's responsibility, that make the recommendations for improving the coordination between the two agencies on in-shell egg safety?

Tell me about the scope of the——

Mr. HARDEN. The answer to that is yes. The basic objective of this particular audit is to look at USDA's control over shell eggs, to detect and report the presence of Salmonella and other contaminants, and also to look at how they coordinate with FDA on this.

Ms. DELAURO. Mm-hmm. And in each instance—in other words, we are going to get some idea of the level of overlap, or duplication, or lack of either, given that we have multiple agencies that are trying to deal with one function here, and what falls between the cracks?

Quite frankly, what falls between the cracks is the public health of the people of this country.

So thank you very much. Thank you, Mr. Chairman.

Mr. KINGSTON. Thank you.

Mr. Bishop.

Mr. BISHOP. Thank you very much, Mr. Chairman.

PEANUT PRICE REPORTING

Madame IG, in March of 2009, I think you completed an audit of in-shell peanut prices that are paid to farmers and reported to the National Agricultural Statistics Service, which data the FSA uses to calculate program payments.

Your office indicated that you believe that the price data supplied by the peanut buyers is unreliable, and that FSA should seek authority for mandatory price reporting for all in-shell peanuts.

And I look forward to the Department resolving this issue; but it would seem that any proposal to provide new FSA statutory authority on price reporting should be done in the context of the 2012 Farm Bill, as opposed to a stand-alone issue.

And of course, we expect that there will be substantial changes and modifications in the programs, which should really be a part of that discussion, whenever it happens.

But I did have some other questions I wanted to ask you: Is there any further activity on the part of the OIG's office on mandatory peanut pricing reporting? Or is it now just in the hands of the Secretary and FSA?

And well, the '02 Farm Bill and the '08 Farm Bill both encouraged USDA to use the world market price in determining peanut prices.

And I find it curious—and I don't know whether it came to your attention or you found it curious also—that the Department never followed through in exploring a world price option.

Many people in the industry, both producers and sellers, believe that a mandatory pricing requirement is really just an effort on the Department's part to lower the price of peanuts.

Last year, I asked you if you had any evidence that indicated that the information that the peanut shellers and others were providing to NESS was fraudulent. And you indicated that no, you answered no to that, that there wasn't any evidence of fraud.

Is the Department, from your determination and your audit, really certain that a mandatory pricing reporting requirement would elicit factual information, as opposed to just creating the possibility of options payments to large farmers, which are not included in the data? And do you think that the mandatory price reporting would ultimately result in the creation of a real futures market for peanuts, which would have the potential of destabilizing the prices for peanuts?

And the final part of that is whether or not you have information of any other industries or any other commodities, where that reporting is required?

Ms. FONG. That's a long question (laughing).

Let me just offer a few comments. You're right, we did do that audit a few years ago on the pricing for shelled peanuts.

And at that time, we felt very strongly—and we still do feel very strongly—that because of the way that reporting is structured, it's voluntary, there's no way to really verify that the prices that are reported are accurate; that it's not a good basis for the Department to set its prices.

And so we made our recommendation.

I think you're right that the Farm Bill is the right vehicle in which to address that issue from a policy basis. I don't believe that we have done any follow-up work since our audit was issued.

And I think you also indicated that there may be an issue with respect to other commodities, whether other commodities have a mandatory requirement for reporting. And as far as I know, others do not.

This is an issue actually that we took on for the first time with peanuts. And we understand that there may be implications for other commodities.

And my sense is that if we were to look at it, that we would, in the interest of having hard, good, verifiable data, upon which to make a decision, that our philosophy would be "Why wouldn't the Department want good, certifiable data?" from a philosophical standpoint.

Now I understand there may be some economic issues and some other policy issues that we have not addressed.

Mr. BISHOP. So you basically have not gone any further than the report that was issued in 2009? And I guess you're waiting for us to deal with it, for Congress to deal with in the Farm Bill.

Ms. FONG. That's correct. We believe it's basically a policy issue at this point.

Mr. BISHOP. Okay. Thank you very much.

Mr. KINGSTON. Thank you, Mr. Bishop. And if there aren't any other questions, then I'm going to move to adjournment.

And let me just say this, Ms. Fong. You have a lot of interests on this committee. We've always been very appreciative of your work. And I think we would like to get these follow-up questions answered. And there might be a few more that are submitted to you.

But we truly appreciate everything that you do. And with that, the committee stands adjourned.

Chairman Jack Kingston
Questions for the Record
USDA Inspector General Fong on the OIG Fiscal Year 2012 Budget Request
March 2, 2011
OIG Priorities, Concerns and Recommendations

(1) **Mr. Kingston**: What audits, investigations or issues have been so serious that you have taken them directly to the Secretary? What was the response?

Response: During the past year, OIG has not had any issues so serious that we had to bring them to the Secretary's immediate attention. We do, however, regularly brief the Secretary and Deputy Secretary on our significant audits and investigations. We have found both of them to be extremely supportive of the work of OIG.

(2) **Mr. Kingston**: What should be USDA's top management priority?

Response: OIG has identified several top management priorities which are reported each year to the Secretary. This information is also reflected in USDA's annual Performance and Accountability Report. (The most current version of these reports may be viewed on USDA's Web site at http://www.ocfo.usda.gov/usdarpt/usdarpt.htm (Performance and Accountability Report, FY 2010) and http://www.usda.gov/oig/webdocs/MgmtChallenges2010.pdf (USDA Management Challenges, dated August 2010).) OIG's August 2010 report identified the 10 top management challenges facing USDA. Of those listed, OIG considers the following to be the most significant:

- Improving interagency communication, coordination, and program integration
- Implementing strong, integrated, internal control systems in a secure information technology environment
- Identifying and eliminating material weaknesses in Civil Rights control structure and environment
- Improving controls for food safety inspection systems

(3) **Mr. Kingston:** What USDA programs, functions or agencies are of most concern to you? Why?

Response: As an agency whose mission is to identify and eliminate fraud, waste, and mismanagement, any USDA program with identified vulnerabilities is of significant concern to OIG. As referenced in past semiannual reports to Congress and annual reports of management challenges facing USDA, OIG's primary concerns are food safety and security, information security, identified vulnerabilities, and improper payments in agency programs. Improper payments in agency programs is being added as a top USDA management challenge for fiscal year 2011.

(4) **Mr. Kingston:** Please provide your top recommendations for each USDA agency.

Response: We are providing for the record a list of top audits with open and unimplemented recommendations. This information was developed by OIG and OCFO and compiled at the request of the Secretary. The list was updated by OIG and is current as of March 31, 2011.

USDA – OIG
"Top List"
Audits Containing Open and Unimplemented Recommendations
(as of March 31, 2011)

Agency	Audit Number	Title	Release Date	Non-Monetary Finding (See Note)	Estimated Cost Savings
Open Recommendations (pending achievement of management decision)					
Multi (OCIO)	**50501-02-IT**	**FY 2010 Federal Information Security Management Act Report**	**11/15/10**	**Yes**	**N/A**
We found that improvements have been made in the Department's IT security; however, we continue to note weaknesses in several critical areas. Therefore, we continue to recommend that the Department define and accomplish one or two critical objectives prior to proceeding on to the next set of priorities. OCIO has provided sufficient information to achieve management decision on 16 of the 19 audit recommendations contained in this report.					
NRCS	**10601-4-KC**	**Conservation Security Program**	**06/25/09**	**Yes**	**$4,895,958 QC and FPTBU**
The Natural Resources Conservation Service (NRCS) under the Conservation Security Program provided financial assistance to landowners/producers to support ongoing good conservation stewardship on their agricultural lands. We found that NRCS approved participants who were ineligible or made errors in determining eligible practices and/or payments. NRCS agreed with the monetary exceptions, but is still in the process of properly establishing the questioned costs against the participants.					
RMA	**05601-15-Te**	**Crop Loss and Quality Adjustments for Aflatoxin Infected Corn**	**09/30/08**	**Yes**	**$15,951,016 QC**
The Risk Management Agency (RMA) provides crop insurance to producers who may have suffered economic losses due to aflatoxin infecting their corn harvests. In adjusting the loss claims, we found that the approved insurance providers (AIP) accepted extremely low estimated values for the infected corn. We found that producers received far more than the values reported on their loss claims. Therefore, we recommended that RMA recover the improper payments totaling approximately $15.9 million from the AIPs. RMA agreed with the finding and recommendation. The questioned costs affected 2,000 loss claims.					
RMA	**05099-28-At**	**Hurricane Relief Efforts in Florida**	**03/04/09**		**$217,256,417 QC**
RMA provides crop insurance to producers who may have suffered economic losses due to hurricanes or other natural disasters. In adjusting the loss claims from the State of Florida nursery producers resulting from the 2005 hurricanes, we found pervasive errors in an AIP's underwriting, claims adjusting, and reporting processes. These errors resulted in large overpayments to the AIP's insured policyholders. At all phases of the insurance process, the AIP did not fulfill its contractual obligations to which it had agreed under the Standard Reinsurance Agreement (SRA), a cooperative financial assistance agreement,					

Agency	Audit Number	Title	Release Date	Non-Monetary Finding (See Note)	Estimated Cost Savings
between the AIP and RMA. Therefore, we recommended that RMA recover from the AIP the Government's share of the indemnities paid, the premium subsidies paid by the Government, and administrative and operating expenses reimbursed by RMA, totaling approximately $217 million. RMA responded that the Office of the General Counsel opined that denial of reinsurance can apply only to specific eligible crop insurance contracts for which violations have been confirmed by RMA. However, RMA agreed to conduct its own followup and investigation of the AIP's compliance with the SRA and take the appropriate warranted actions against the AIP. We are still waiting for the results from RMA's review.					
Unimplemented Recommendations (pending completion of final action)					
FS	**08601-54-SF**	**Forest Service Firefighting Succession Plans**	**03/31/10**	**Yes**	**$15,700,000 FPTBU**
We identified 4 findings and 20 recommendations. Two findings related to a national workforce plan to address future firefighter shortages and training for firefighting future needs. The other two findings concerned FS' ability to meet firefighting challenges due to lack of personnel participating in firefighting careers and unnecessary education requirements. Final corrective actions for recommendations 1 and 2 have been completed. FS has indicated to us that meetings have been scheduled to discuss estimated completion dates for corrective actions for recommendations 3-20.					
FSIS	**24601-1-Ch**	**Laboratory Testing of Meat and Poultry Products**	**06/21/00**	**Yes**	**N/A**
FSIS laboratory activities include analyses of official product samples obtained from meat and poultry establishments under a variety of testing programs. Although FSIS regulations require that bacon products be tested for the presence of nitrosamines, the agency did not have a list of establishments that produced those products and did not even know the number of such establishments under FSIS inspection. FSIS intends to publish a rule to convert nitrosamine requirements provided by 9 CFR 318.7(b) to performance standards under the establishments' HACCP procedures. As of March 31, 2011, the Federal Register document is in clearance.					
Multi (APHIS)	**50601-12-Ch**	**USDA's Controls Over the Importation and Movement of Live Animals**	**03/31/08**	**Yes**	**N/A**
Under the authority of the Animal Health Protection Act, USDA's Animal and Plant Health Inspection Service (APHIS) regulates the importation of live animals. We found animals bound for quarantine were not always properly handled and quarantine facilities had animal accountability deficiencies. APHIS agreed with the recommendations, but is still in the process of implementing the recommended management corrective actions.					
NRCS	**10601-1-At**	**Rehabilitation of Flood Control Dams**	**07/15/09**	**Yes**	**$15,208,001 FPTBU**
Congress authorized this program for the rehabilitation of aging dams and appropriated funding to NRCS to address "the threats to public safety posted by the aging system of flood control structures" and, thereby, ensure the safety of the public. Because of NRCS' inadequate strategy to implement the program and lack of regulatory authority, we found that NRCS expended funds for assessment of less hazardous dams, for assessment and rehabilitation plans where the dam owners did not implement their plans, and for the rehabilitation of less hazardous dams, before ensuring that all high hazard dams were completed. NRCS agreed with the recommendations, but is still in the process of implementing the recommended management corrective actions.					

Agency	Audit Number	Title	Release Date	Non-Monetary Finding (See Note)	Estimated Cost Savings
RBS	**34601-15-Te**	**National Report on Business and Industry Loan Program**	**09/30/03**	**Yes**	**$57,908,862 QC and FPTBU**
Rural Development administers the Business and Industry (B&I) Direct and Guaranteed Loan Programs to improve business, industry, and employment in rural areas. We examined 38 guaranteed loans totaling over $125 million and 18 direct loans totaling over $14 million. We identified instances where Rural Development had guaranteed questionable loans, failed to identify lender negligence in servicing existing loans, and honored guarantees in situations where lenders had not fulfilled loan obligations. Because of these conditions, we questioned almost $58 million of the $125 million in guaranteed loan funds included in our review. The questioned amount is a summary of 11 individual audit reports where we had reported questionable use of B&I guaranteed loan funds.[1] The agency is still working to resolve 5 of the 11 report recommendations that have yet to be implemented. Delays in implementing our recommended corrective actions have occurred, in part, because on September 21, 2009, Rural Development decided to withdraw its planned revision and consolidation to its guaranteed loan making regulations, which had included corrective actions for the Rural Business-Cooperative Service's (RBS) B&I guaranteed loan program. RBS is now drafting its own revisions to its B&I guaranteed loan program regulations, which should include the corrective actions recommend in our report. 1 Monetary recoveries were cited in audit reports 34601-2-SF, 34601-3-At, 34601-4-At, 34601-4-SF, 34601-8-Te, 34601-9-Te, 34601-10-Te, 34601-11-Te, 34099-2-At, 34099-5-Te, and 34601-7-SF.					
RUS	**09601-4-Te**	**Broadband Grant and Loan Programs**	**09/30/05**	**Yes**	**$331,965,484 QC and FPTBU**
During fiscal years 2001 to 2004, the Rural Utilities Service (RUS) administered Federal loans and grants for extending broadband service to rural America. RUS shifted the programs' focus away from those rural communities that would not, without Government assistance, have access to broadband technologies. This change in the programs' emphasis occurred for two reasons. First, in its loan program, RUS had not satisfactorily implemented statutory requirements for serving rural instead of suburban areas, nor did it have a system that could guarantee that communities without preexisting service receive priority. Second, RUS' inconsistent administration of the programs resulted in irregularities in approving and servicing grants and loans. Of the $895 million in loans and grants funded, we reviewed $599.1 million (67 percent) and questioned the use of over $340.4 million—almost 57 percent of the approved funds reviewed. RUS is still working to implement corrective actions for 10 of the report's 14 recommendations. RUS had delayed corrective actions to our report until the 2008 Farm Bill had been passed. On March 14, 2011, RUS issued a proposed rule to implement the requirements of the 2008 Farm Bill which the agency has stated will address OIG's unresolved audit recommendations.					
Legend QC – Questioned costs FPTBU – Funds to be put to better use **Note:** Audit includes non-monetary findings which may impact the safety and health of the public if recommendations are not timely implemented.					

USDA Suspension and Debarment Practices

As noted in testimony and the December 2010 Semiannual Report to Congress, USDA agencies are not suspending and debarring program participants when warranted. OIG reports that between 2004 and 2007, agencies did not suspend or debar 1,035 program participants even though they already had been convicted by criminal courts. Further, OIG reports that between 2004 and 2008, the Food and Nutrition Service (FNS) did not suspend or debar the 3,981 SNAP retailers and wholesalers that violated program regulations. USDA's agencies indicate that these exclusions are in the public's best interest and consistent with statutes balancing program access.

(5) **Mr. Kingston**: Please provide a list of the agencies that do not suspend or debar violators of program rules and regulations.

Response: Our review concluded that the following USDA agencies do not suspend or debar violators of their programs. In many cases, this is because they consider those programs to be excluded from suspension and debarment requirements. We have requested that the agencies provide adequate statutory language or acceptable program rationale to support their conclusion that the suspension and debarment authorities do not apply to their programs. In response to our recommendations, the agencies are presently consulting with the USDA Office of the General Counsel (OGC) and Office of the Chief Financial Officer (OCFO) regarding the basis and support for their program exclusions from application of the suspension and debarment authorities.

AGENCY	EXCLUSIONS/NOTES
Animal Plant and Health Inspection Services (APHIS)	All programs are excluded.
Agricultural Marketing Service (AMS)	Generally all programs are excluded.*
Agricultural Research Service (ARS)	All programs are excluded.
Farm Service Agency (FSA)	Prior to our audit, all FSA programs, with the exception of commodity procurements performed by Commodity Credit Corporation (Kansas City Commodity Office), had been excluded from suspension and debarment implementation. FSA's May 25, 2010, revised regulation, which became effective September 22, 2010 (Federal Register 75 FR 29183), provided that producers of agricultural commodities who receive farm ownership and operating loans will now be subject to the suspension and debarment authorities. However, FSA plans to continue to exclude most of its other programs from the suspension and debarment authorities as it has deemed these other programs entitlements.

AGENCY	EXCLUSIONS/NOTES
Food and Nutrition Service (FNS)	All programs are excluded, including: • Supplemental Nutrition and Assistance Program (SNAP) participants and SNAP wholesalers and retailers • National School Lunch and School Breakfast Programs (NSLP/SBP) • Child and Adult Care Food Program (CACFP) • Supplemental Program for Women, Infants, and Children (WIC) • Commodities Program We recognize that the SNAP, NSLP, and CACFP programs are entitlement programs and, as such, the program participants cannot be suspended or debarred from food assistance provided by these entitlement programs. Program participants, may, however, be suspended or debarred from other Federal programs which are not entitlement programs for violations of SNAP, NSLP, and CACFP.
Forest Service	All programs are excluded except for those under the Deputy Chief for the National Forest System (Timber Sales).
Food Safety and Inspection Service (FSIS)	All programs are excluded.
Grain Inspection Packers and Stockyards Association (GIPSA)	Generally all programs are excluded.*
Natural Resources and Conservation Service (NRCS)	All programs are excluded.
National Institute of Food and Agriculture (NIFA) – formerly CSREES	All programs are excluded.

*AMS and GIPSA were not part of our detailed audit coverage, however, the agencies informed us that they have programs excluded from suspension and debarment activities. We requested support for these exclusions and are in the process of evaluating that information.

(6) **Mr. Kingston**: What recommendations did OIG make to these agencies?

Response: Our primary recommendation to USDA addressed the Department's exclusions of many of its programs from the suspension and debarment requirements. The recommendation reads: *Direct USDA agency administrators to review their program statutes and operations to identify program transactions that are excludable from suspension and debarment implementation. For program transactions to be excluded from suspension and debarment, provide adequate statutory language justifying the exclusions or an acceptable program rationale supporting their noncovered (exclusion) status.*

(7) **Mr. Kingston**: Were they implemented?

Response: As of March 31, 2011, our recommendations regarding USDA's exclusions to the suspension and debarment requirements have not been implemented. Agencies are reviewing the applicability of the suspension and debarment authorities to their programs in consultation with OGC and OCFO.

(8) **Mr. Kingston**: What is the status of the implementation?

Response: Currently, we are assessing recent USDA responses to our recommendations containing the "exclusion" of agencies' programs from suspension and debarment. We are also working closely with the Department's OCFO; OCFO oversees non-procurement suspension and debarment activities where the Department has implemented these exclusions. The Federal Acquisition Regulation for procurement transactions does not provide for exclusions. We plan to continue this coordination and to meet with OCFO and the USDA agencies to discuss the exclusions and any statutory language or program rationale that may be offered by them to support their exclusions to the suspension and debarment authorities.

(9) **Mr. Kingston**: If they were not implemented, please describe why they were not implemented.

Response: USDA stated that OCFO and OGC have fully reviewed, with applicable agencies, all of USDA's suspension and debarment non-covered transactions (exclusions) in the latest round of regulation updates and that all transactions (programs) that remain not covered by suspension and debarment have been justified. Documentation to support these conclusions has not been provided to us for review. We are working closely with OCFO and OGC to obtain and assess each agency's statutory language or program rationale that is being used to justify the program exclusions to the suspension and debarment authorities.

Rural Broadband Program

USDA's fiscal year 2012 budget request proposes to continue its Rural Development Broadband Program, mostly using funding from the Recovery Act. The Federal Communications Commission recently proposed $1 billion for rural broadband. This is in addition to USDA's program. OIG has found significant problems with USDA's program, including funding for projects in communities close to major metropolitan areas and projects in areas with existing broadband service.

(10) **Mr. Kingston**: What is the status of OIG's investigations and audits on the broadband program?

Response: OIG will be starting an audit of the Recovery Act broadband funding in late spring 2011. The audit will include a review of the status of recommendations for USDA's Rural Utilities Service (RUS) made in our 2005 and 2009 audit reports. We will continue our coordination with the Government Accountability Office (GAO) and build on the work that

GAO has completed regarding the RUS Recovery Act broadband funds. We will also continue our coordination with the Department of Commerce OIG and its oversight of the National Telecommunications Information Administration.

OIG currently has three open investigations involving the Broadband Program. During FY 2010, one of the investigations resulted in one (1) conviction and $2,897,442 in monetary results. The OIG Hotline has recently received complaints alleging improprieties involving ARRA funds set aside for broadband. Some complainants have alleged that certain ARRA broadband loan and grant applicants have filed false information on their technical and managerial qualifications, as well as on the demographics and existing broadband service in areas they are proposing to serve. We have also received allegations that RUS has not established effective contract and grant mechanisms to ensure that its broadband awards are used to provide service to unserved or underserved rural areas without adverse consequences to already-operating broadband service providers which do not receive Government funds. Based on this trend, we anticipate conducting additional investigative work in this area in the future.

(11) **Mr. Kingston**: Has USDA made any improvements in its program?

Response: As of March 31, 2011, RUS has fully implemented 4 of the 15 recommendations that we made in our 2005 (14 recommendations) and 2009 (1 recommendation) audit reports. The 4 resolved recommendations addressed whether the law restricted RUS' definition of a "rural area" (which RUS concluded it did not); the collection of over $1.9 million in grant funds for unauthorized expenses from a grantee; the deobligation of another $762,000 from the same grantee; and the alignment of RUS' Broadband Loan and Grant Divisions to ensure that RUS is aware of the amount and type (loan or grant) funding that each community has received.

The remaining 11 open recommendations generally deal with RUS' definition of a "rural area" including its proximity to a metropolitan area; prioritization of broadband applications to serve the most needy rural communities; assessment of its practice of funding broadband projects that will compete with existing providers; improvement of the review and approval of broadband applications; recovery of $30 million for six defaulted pilot (fiscal years 2001 and 2002) broadband loans; development and implementation of procedures to deobligate, cancel, and reobligate unused broadband awards; development and implementation of an integrated information system to track both loan and grant applications and servicing actions; and definition of a "loan default."

(12) Mr. Kingston: Can you report that USDA's program truly is focused on rural areas?

Response: In both our 2005 and 2009 audit reports we did not report any instances of ineligible broadband loans or grants that were located in non-rural areas, based on the 2002 Farm Bill and RUS' regulatory definitions of "rural area." However, our concerns during these audits have been that some of the "rural areas" to which RUS has provided broadband services are affluent communities in close proximity to metropolitan areas that already have one or more broadband providers. We recognize that both the 2008 Farm Bill and the Recovery Act modified the

definition of "rural area," although implementing guidance related to the 2008 Farm Bill is still being finalized.

(13) **Mr. Kingston**: Does USDA's program duplicate other federal efforts, like the one just announced by FCC?

Response: To our knowledge, the Federal Communications Commission (FCC) broadband program differs from RUS' program as it is basically a subsidy program that is not involved in the construction and deployment of broadband facilities and service. We will obtain a better understanding of FCC's broadband program and how it is distinguishable from RUS in our upcoming planned audit work.

SNAP Fraud Detection

OIG has evaluated FNS's monitoring of the controls states have in place to mitigate fraud in SNAP. FNS performed reviews to evaluate how states managed SNAP, but that there were deficiencies in how the agency and states were collecting and analyzing information to detect fraud.

(14) **Mr. Kingston:** Please provide additional information about these audits and your recommendations to combat fraud in SNAP.

Response: We initiated the current audit concerning State Fraud Detection since we had found in a prior audit report (27099-68-Hy, Electronic Benefits Transfer System (EBT) State of Colorado, issued June 2008) that State officials were aware of EBT management reports; however, there was no evidence to suggest that the reports were used to monitor SNAP redemptions regularly. We have issued two Fast Reports, one of which had issues similar to our prior report.

Of the two States reviewed (Florida and New Jersey) in our current audit, we found that neither State used the management reports their EBT processors provided to identify potentially fraudulent activities for investigation or followup. Although FNS had not specifically required the States to use these reports, it considers them to be a tool for State fraud detection units in detecting the misuse of SNAP benefits.

Without a method of proactive enforcement focused on recipients, FNS' and the States' ability to ensure effective program integrity is reduced. Therefore, we recommended that FNS provide guidance to States in identifying and assessing available EBT management reports to determine which could be most useful to each State's fraud detection efforts and require that States implement procedures for the periodic review and analysis of management reports to detect and follow up on suspicious and unusual SNAP transactions.

In another Fast Report we found that neither State had developed a fully effective fraud detection unit. FNS had not conducted periodic reviews of the States' fraud detection efforts to verify their effectiveness. According to an FNS national office official, such reviews were not

considered necessary because information collected by States for FNS' annual State Activity Report was sufficient for FNS officials to ensure that States were devoting sufficient resources to their fraud detection efforts. However, FNS' assessment of State fraud detection activities could be limited by the accuracy of the State-reported information.

We recommended that FNS identify and implement a process for periodically assessing the States' fraud detection units.

(15) **Mr. Kingston:** Please provide a table that shows how much of your budget is spent on monitoring SNAP to reflect fiscal years 2009 (actual), 2010 (actual) and 2011 (estimate).

Response: The following tables reflect the cost of direct Audit and Investigative staff time for SNAP during fiscal years 2009 and 2010. The estimate for fiscal year 2011 is a projection based on work being performed on SNAP. For all 3 years, these amounts include OIG oversight activities pursuant to the American Recovery and Reinvestment Act of 2009.

SNAP AUDITS

Fiscal Year	% of Direct Audit Time Spent on SNAP Investigations	Cost *(in millions)*
FY 2009 (actual)	0.13%	$0.05
FY 2010 (actual)	5.89%	$2.5
FY 2011 (estimated)	6.00%	$2.6

SNAP INVESTIGATIONS

Fiscal Year	% of Direct Investigative Time Spent on SNAP Investigations	Cost *(in millions)*
FY 2009 (actual)	26.68 %	$10.1
FY 2010 (actual)	36.58%	$16.3
FY 2011 (estimated)	46.00%	$20.7

(16) **Mr. Kingston**: Please provide a table showing the number of SNAP cases that were issued, the number referred to the Department of Justice, and the number accepted by the Department of Justice, for fiscal year 2010.

Response: The information is as follows:

U.S. Department of Agriculture – Office of Inspector General
SNAP Referrals – FY 2010

State	Cases Issued	Referred To DOJ	Accepted By DOJ
Alabama	2	2	1
Arizona	2	1	0
California	3	1	0
Colorado	1	1	0

Connecticut	2	1	0
Delaware	0	0	0
DC	0	0	0
Florida	1	0	0
Georgia	1	1	1
Hawaii	0	0	0
Idaho	0	0	0
Illinois	3	3	0
Indiana	1	0	0
Iowa	1	1	0
Kansas	0	0	0
Kentucky	0	0	0
Louisiana	0	0	0
Maine	1	1	1
Maryland	0	0	0
Massachusetts	1	1	0
Michigan	4	3	1
Minnesota	0	0	0
Mississippi	3	3	2
Missouri	8	8	2
Montana	1	1	1
Nebraska	0	0	0
Nevada	0	0	0
New Hampshire	1	0	0
New Jersey	3	1	0
New Mexico	0	0	0

New York	14	11	3
North Carolina	1	1	0
Ohio	6	0	0
Oklahoma	3	1	0
Oregon	0	0	0
Pennsylvania	10	8	4
Rhode Island	1	1	0
South Carolina	0	0	0
South Dakota	0	0	0
Tennessee	1	1	0
Texas	2	1	0
Utah	1	1	0
Virginia	2	1	0
Washington	1	1	0
West Virginia	0	0	0
Wisconsin	0	0	0
Wyoming	0	0	0
Total	81	56	16

(17) **Mr. Kingston**: Please provide the committee with a description of your findings and recommendations in the review of state fraud detection units, FNS's response and what action FNS currently is taking to address this issue.

Response: As stated in response to a prior question [#14], we recommended that FNS provide guidance to States on EBT management reports and determine which could be most useful to each State's fraud detection efforts. In response to the findings, FNS stated it will encourage all States to use EBT management reports to determine which could be useful in detecting and

following up on suspicious SNAP transactions. In response to our recommendation that FNS require States to implement procedures for the periodic review and analysis of management reports to detect and follow up on suspicious and unusual SNAP transactions, FNS stated it will implement procedures, where appropriate, for the periodic review and analysis of such reports for this purpose.

We also recommended that FNS identify and implement a process for periodically assessing the States' fraud detection units. In its response, FNS stated it will work with the two states we reviewed, New Jersey and Florida, to address the reporting and documentation inconsistencies identified in the report. FNS will also work to determine the implications of those apparent deficiencies for the overall effectiveness of States' anti-fraud efforts, and share lessons learned with other States and FNS Regional Offices as appropriate.

We have not yet followed up with FNS to review the corrective actions taken. The results of the two issued Fast Reports will be included in our final audit report.

Global Trade Challenge

In OIG's issuance of "Major Management Challenges" in August 2010, the agency stated that it was reviewing USDA's global marketing strategy.

(18) **Mr. Kingston:** What is OIG's latest assessment of the Department's strategy and plans to more effectively respond to changing trends in global markets.

Response: In OIG's report on "Major Management Challenges" facing the Department, we reported that the Department needs to continue to develop a proactive, integrated strategy to help American producers meet the global trade challenge. In March 2010, the Department announced its global market strategy; however, it did not appear to include specific steps or mechanisms related to exporting genetically engineered (GE) crops. We believe that this is critical because of the increasing reliance of American agriculture on the global market (which was economically beneficial this past year) and the increasing importance of GE crops to the American agricultural sector.

In March 2011, we initiated a review evaluating the Department's efforts to enhance agricultural trade, specifically the implementation of the Administration's National Export Initiative and the Department's trade action plan and global market strategy. At the conclusion of our review, we should be able to make recommendations as to any additional steps the Department needs to take to facilitate or promote agricultural trade exports.

(19) **Mr. Kingston:** In addition, what actions is USDA taking to ensure greater efficiencies in the use of Departmental resources via their collaboration among USDA agencies and non-USDA agencies?

Response: In March 2011, we initiated a review to evaluate the effectiveness of the Department's recent efforts to enhance agricultural trade in response to the President's National

Export Initiative. Specifically, we will (1) assess the effectiveness of the Department's implementation of the agricultural trade strategy, including the global market strategy and FAS' use of Country Strategy Statements to increase agricultural exports; (2) evaluate FAS' efforts to coordinate with other USDA agencies, and the Department's coordination with other Federal agencies, in implementing the global market strategy; and (3) follow up on recommendations made in our previous audit report on international trade issued in March 2007. We specifically plan to review and evaluate whether the Department has aligned and allocated its resources in accordance with priorities established in these trade strategic plans. Based on those results, we should be able to make recommendations as to any additional steps the Department needs to take to ensure greater efficiencies in the use of resources through its collaboration and coordination among the USDA agencies and non-USDA agencies.

Woman and Hispanic Farmer Discrimination Complaints

USDA and the Department of Justice (DOJ) recently announced the procedures for female and Hispanic farmers who say they faced discrimination from USDA to claim a portion of a $1.3 billion settlement. If they can prove discrimination, they can receive up to $50,000. The announcement does not cap the amount of money that can be awarded and waives some application fees.

(20) **Mr. Kingston**: What role will OIG play in this process?

Response: Our usual role is to evaluate any allegations of fraud by claimants and mismanagement by the Department and make a determination as to any necessary investigation or audit work. Additionally, USDA OIG understands that there may be a provision in the Hispanic/Women Farmers Process Claims Framework that authorizes the Secretary to request OIG to conduct a performance audit within six months of adjudication of selected claims, and as appropriate thereafter. Either with or without such a provision, OIG will consider any such request by the Secretary.

(21) **Mr. Kingston:** What plans has OIG developed or is in the process of developing regarding this matter?

Response: We will consider any allegations or requests for review.

(22) **Mr. Kingston:** What should USDA to ensure legitimate complaints receive just compensation while fraud will be minimized?

Response: To ensure legitimate complaints receive compensation while fraud is minimized, USDA needs to implement strong internal control and oversight procedures. USDA then needs to make sure that its procedures are followed. Further, OIG should be able to make recommendations to the Department to implement, following any audits in this area.

OIG FY2012 Budget Request

(23) **Mr. Kingston:** Please explain the increase in average salaries for ES and GS positions included in the fiscal year 2012 budget request.

Response: On page 12-11 of our FY2012 Budget Request, OIG shows the average ES salary increasing by $1,000 between 2010 and 2011 and by $19,000 between 2011 and 2012. The $19,000 figure was a typographical error. The budget submission was originally prepared before the President announced his decision to freeze end of year pay adjustments for Federal employees for two years. Those end of year adjustments are the only pay increases available to ES employees, unless the ES employee assumes significant new duties. Barring unanticipated departures by OIG's highest ranking ES employees, OIG does not foresee giving such pay increases and, hence, OIG does not anticipate any increase in the average salary of its ES employees in FY 12 and 13. The incorrect average ES salaries are not used in support of calculations elsewhere in the budget request.

At the bottom of page 12-11, OIG shows the average salary for GS employees as $90,000 in 2010, $92,000 in 2011, and $97,000 in 2012. Similarly, the average grade and step of an OIG GS employee is projected to rise from a Grade 11, Step 5 in 2010, to a Grade 11, Step 6 in 2011, and a Grade 11, Step 8 in 2012. The average salary and grade of OIG's GS employees is projected to rise over the next two years because the pay freeze applies only to end of year pay adjustments. This means that all OIG GS employees performing at the fully successful level remain eligible for step increases based on time in grade. It also means that OIG's front line auditors and investigators, whose non-competitive career ladders rise from the GS-5 or GS-7 to the GS-13, will remain eligible for those promotions. As OIG does not anticipate being able to hire significant numbers of new entry-level employees to fill behind those employees who will advance in their career ladders, the net result will be an increase in OIG's average GS grade.

(24) **Mr. Kingston:** In USDA's FY 2012 budget request, the OIG requests an increase of $613,000 for oversight of USDA international programs program. Please explain OIG's concerns with USDA's international programs. Accordingly, provide more specific detail on which programs the OIG intends to audit and/or investigate as well as the goals of each respective audit.

Response: Due to limited resources, OIG has not been able to perform significant oversight of USDA international programs for several years. OIG is seeking $613,000 to cover the increased staff hours and travel costs necessary to perform additional audits and investigations of USDA international programs, which continue to grow in terms of dollars and strategic importance. Examples of international USDA programs where OIG would provide additional oversight include the following:

- USDA international assistance programs include $2.3 billion for the Food for Peace Program and $5.3 billion for the Export Credit Guarantee Program. OIG has not done significant audit work in these areas in several years.
- The McGovern-Dole International Food for Education and Child Nutrition Program was established in the 2002 Farm Bill. Even though USDA has provided almost $600 million

to this program since FY 2008, OIG has not audited the program because we could not fund the international field visits necessary to conduct a meaningful audit. Prior OIG audits of non-government organizations (NGO) involved with distribution of international food assistance have reported various problems, including NGOs' non-compliance with agreements.

- In the last few years, the U.S. Agency for International Development (USAID) has transferred under section 632(a) of the Foreign Assistance Act of 1961 over $100 million to USDA to be spent supporting the reconstruction and strengthening of agricultural and rural infrastructures in Afghanistan and Pakistan. Under section 632(a), USDA OIG is required to conduct periodic audits of these funds. Without the requested funds, OIG will not be able to provide the required oversight of the use of those funds.
- In OIG's FY 2011 investigations business plan, addressing fraud and misconduct in USDA's international programs is a priority. Currently, OIG has several ongoing investigations related to one of the Export Credit Guarantee Programs. We continue to monitor incoming complaints and coordinate closely with Foreign Agricultural Service (FAS) officials to identify alleged criminal violations and misconduct by USDA employees who are duty stationed internationally. Often, international investigations are difficult to conduct due to the fact that the subjects, witnesses, and documents are located overseas, and limited funding restricts our ability to conduct interviews or follow up on leads developed during the investigation. As a result, we typically decline these investigations.
- We would anticipate that investigative results could potentially yield substantial monetary results and recoveries. Additionally, investigative work in USDA's international programs would be beneficial in identifying individuals who have attempted to defraud USDA and prevent them from continuing to conduct business with the Department as well as other U.S. Government agencies. Pursuing suspension and disbarment of individuals attempting to defraud the program is a high priority for USDA.

(25) **Mr. Kingston:** Please explain OIG's proposal for increased funding to use statistically valid random samples instead of judgmental samples.

Response: The funds requested would be used to support the additional field work involved in conducting audits that could, with statistical reliability, project the full dollar value of potential improper payments. Programs where statistical sampling could yield significant information on program-wide improper payments include Supplemental Nutrition Assistance, Crop Insurance, and Rural Development, which total about $80 billion in expenditures each year.

With the funding available under its annual appropriation, OIG has only been able to provide audit coverage to USDA benefit programs by utilizing audits based on judgmental samples, rather than the statistically valid random samples necessary to support program-wide loss projections. Using judgmental samples has meant, for instance, that when performing an audit of a USDA loan program, OIG would determine which and how many local offices to visit and loan records to review based primarily on which sites it could visit to cover the greatest number of loan records at the lowest cost. Once the audit was complete, OIG could assess how the

program was handled at the sites visited. OIG could not, however, use the information collected to reliably project the extent of improper payments in the program, nationwide. While the use of judgmental samples has enabled OIG to stretch its funds to cover audits of a greater number of USDA programs, it has prevented OIG from reliably projecting the full scope of improper payment problems that may exist in those programs.

With the funds requested, OIG will be able to perform statistically valid audit work where it is beneficial in USDA programs rather than always relying on judgmental samples. Using statistical sampling, OIG would be able to utilize the information it collects during field work to project its findings onto the selected universe of program transactions, instead of only to the sampled units as is currently done with a judgmental sample.

(26) **Mr. Kingston:** Please provide additional information on OIG's proposed increased to support investigator training requirements.

Response: During late FY 2009 and FY 2010, OIG investigations staff experienced significant turnover through retirement and other attrition. Many of the individuals who retired held leadership or other key positions in OIG, such as qualified instructors for firearms or use of force training.

To address staffing needs in FY 2010, OIG hired additional criminal investigators. Many of these individuals were hired at entry level and were required to attend the basic Criminal Investigator Training Program (CITP) at the Federal Law Enforcement Training Center (FLETC). The CITP is a required 3-month program that provides basic and fundamental training in the techniques, concepts, and methodologies of conducting criminal investigations. Successful completion provides the basis for developing and maintaining a highly skilled and proficient special agent.

As noted above, OIG lost several of its "in-house" investigations instructors. It is imperative that we maintain sufficient instructors who can provide quality training in the safe handling, proficient application, and justifiable use of firearms to all basic and advanced sworn law enforcement personnel, as well as demonstrate and apply the proper use of force techniques. OIG must replace those instructors by identifying individuals to attend the Firearms Instructor Training Program as well as the Use of Force Instructors Training Program. Both of these training programs require refresher training every 5 years to ensure the instructors stay current on contemporary firearms and use of force issues, trends, tactics, and training techniques.

Additionally, all special agents are required to attend Continuing Legal Education every 5 years. The Continuing Legal Education Training Program is an advanced program designed to provide refresher training to field agents and officers in legal subject areas covering the 4th, 5th, and 6th Amendments, use of force, electronic law and evidence, civil liability, and recent statutes and rules changes.

OIG recently established a Critical Incident Stress Management Program (CISM) to help OIG employees in times of crises. Training of staff on how best to respond to and deal with a crisis is required before full implementation of the program can be completed. This program is important

to ensure the physical health, safety, and mental well being of our investigators, who face potentially dangerous and stressful situations on a daily basis.

Finally, to ensure that OIG maintains the ability to investigate complex investigations involving the use of computer and electronic technology, it is imperative that OIG has highly trained and certified computer forensic examiners and technical specialists who can process and obtain electronic evidence. OIG's National Computer Forensic Division provides expert computer forensic service, from on-site collection and preservation of digital evidence during search warrants, to analysis and court testimony. Due to the fast-paced changes in technology, a digital forensic examiner must constantly refresh his/her knowledge and develop new expertise as changes dictate, i.e. smart phones/iPad devices, advanced persistent threat (APT)/network intrusion, and legal updates. In addition, Federal and State courts expect examiners to acquire and maintain certifications pertinent to their profession.

(27) **Mr. Kingston:** In OIG's FY 2012 Explanatory Notes, page 12-10, the agency presents an object class breakdown for fiscal years 2010, 2011 and 2012. If the President proposed no pay increases for nearly all federal employees, what accounts for the approximately 15 percent increase in Object Class 11 (salaries).

Response: As noted above, OIG GS schedule employees, who comprise 98.5 percent of OIG's staff, remain eligible for both step increases and career ladder promotions. A further reason for this increase is that in 2009, OIG received an increase to its budget for the first time in three years. Because OIG had been effectively straight-lined through FYs 2006-2008, OIG had implemented a hiring freeze and other strict budgetary measures in order to perform its mission within the appropriated funds. In 2009 and 2010, OIG received some relief from these budget difficulties and was able to fill key management vacancies as well as hire and develop entry-level auditors and investigators. These new staff are essential to OIG's ability to function now and in the future, as a large portion of OIG's staff is now or will shortly achieve retirement eligibility. This new hiring largely took place over the course of 2010, with the OIG not reaching its full staffing level until late in the year. For FY11, OIG anticipates its staffing level will remain fairly constant for the full year.

(28) **Mr. Kingston:** Please explain how Object Class 12 (benefits) decrease as pay increases and benefit costs increase.

Response: OIG is anticipating that benefits as a percentage of salaries will decrease from approximately 36 percent in 2010 to 30 percent in 2011, and then rise again to 32 percent in 2012. As CSRS employees become a smaller proportion of OIG's staff on board, OIG's benefits costs decrease because a greater portion of CSRS retirement benefits are charged to the Government than are charged to the Government under the FERS system which replaced CSRS in the 1980s. Government employees adversely impacted by the economy tend to reduce their retirement fund contributions (thus also reducing the matching agency contributions for which they would otherwise qualify under FERS) and/or chose less expensive health care coverage (which has lower premiums for both the employee and the Government). As the economy

improves, we anticipate benefits rising against salaries in 2011 as employees begin to reinstate their full FERS retirement fund contributions, and become more willing to pay the employee costs associated with more extensive health care plans.

(29) **Mr. Kingston:** Why are costs for maintenance of facilities decreasing?

Response: The cost for maintenance of facilities decreased for FY 2011 because OIG has no major renovation requirements scheduled for this fiscal year. OIG's FY2010 maintenance costs were unusually high due to major facility renovations and repairs in our Headquarter and Beltsville offices. Additionally during FY 2010, several OIG field offices moved from lease to GSA space and/or reduced their square footage, resulting in cost savings to the Government. The moves also allowed OIG to include all remodeling and facility repairs in the new leased space agreements. For these reasons, OIG anticipates comparatively lower facility maintenance costs in FY 2011 and FY 2012.

OIG Audits, Investigations and General Information Requests

(30) **Mr. Kingston:** Please provide a table showing the financial statement audits OIG contracts for and those conducted in-house, as well as the cost of each audit for fiscal year 2009 (actual), 2010 (actual) and 2010 (estimate).

Response: For audits contracted to Independent Public Accountants (IPAs), OIG incurs the cost for monitoring the work of IPAs. The information below represents OIG's cost for monitoring the IPAs plus the contract cost paid to the IPAs to perform the audit.

Audited Agency	Method of Performance	FY 2009 Actual Cost	FY 2010 Actual Cost	FY 2011 Estimate
Federal Crop Insurance Corporation	Contract	$395,450	$394,440	$408,152
Commodity Credit Corporation	Contract	$1,792,026	$1,743,048	$1,846,180
Forest Service	Contract	$4,693,609	$3,841,684	$3,963,443
Food and Nutrition Service	**In-House**	$1,464,347	$1,000,722	$1,514,200
Rural Development	**In-House**	$1,816,359	$2,148,758	$2,288,598
Natural Resources Conservation Service	Contract	$2,067,191	$1,893,442	$2,361,091
USDA Consolidated	**In-House**	$2,155,387	$1,962,294	$2,123,891
TOTAL		$14,384,369	$12,984,388	$14,505,555

(31) **Mr. Kingston:** Please provide a table showing the amount of funds expended for public accountants hired under contract for fiscal years 2009 (actual), 2010 (actual) and 2011 (estimate).

Response: The information follows:

Financial Statements Audits Audited Agency	Method of Performance	FY 2009 Actual Cost	FY 2010 Actual Cost	FY 2011 Estimate
Federal Crop Insurance Corporation	Contract	$359,648	$370,138	$370,942
Commodity Credit Corporation	Contract	$1,746,126	$1,701,148	$1,800,830
Forest Service	Contract	$4,637,611	$3,803,974	$3,918,093
Rural Development*	**In-House**	$909,762	$864,461	$890,400
Natural Resources Conservation Service	Contract	$2,018,537	$1,868,302	$2,315,741
TOTAL		$9,671,684	$8,608,023	$9,296,006
OIG Financial Information System	**Method of Performance**	**FY 2009 Actual Cost**	**FY 2010 Actual Cost**	**FY 2011 Estimate**
Financial Management Modernization Initiative	Contract	$99,982	N/A	N/A

* Credit Reform section of audit is contracted

Notes: Financial Statements Audit contracts are funded by the audited agency.

(32) **Mr. Kingston**: Please update the Committee on all of the audit and investigation work OIG is conducting on the WIC Program, including vendor monitoring.

Response: We are currently conducting our audit of vendor management and participant eligibility in WIC. The overall objective of this audit is to evaluate implementation of food delivery regulations intended to improve the integrity of vendor management, and assess the eligibility of participants. Specifically, we will assess (1) implementation of compliance investigations; (2) accountability, control, and security of food instruments; and (3) determinations of participant eligibility.

Investigations relating to the WIC program have shown similar results to that of SNAP in that some vendors/retailers, recipients, and public employees are engaged in misusing the WIC program for personal financial gain. For this program area in FY 2010, OIG opened 16 criminal investigations and obtained 14 indictments, 22 convictions, and $278,364 in monetary results.

(33) **Mr. Kingston:** What was OIG's cost of performing audits of Commodity Credit Corporation (CCC) financial statements in fiscal year 2010? What was the reimbursement from CCC?

Response: CCC's financial statement audit is contracted out. However, OIG monitors the audit to ensure that it performed by an audit firm that is independent, objective, and possesses the required qualifications, and that the audit is performed in accordance with generally accepted auditing standards in the United States. OIG's cost of performing the monitoring for FY 2010 was $41,900. OIG did not receive reimbursement from CCC for this service. CCC paid the contract cost of $1,701,148 for FY 2010.

(34) **Mr. Kingston:** Please provide a list of all USDA financial statements OIG audits along with the opinions you provided on those financial statements. Include a brief description of each audit opinion and the reasons these opinions were rendered.

Response: The USDA Consolidated, Rural Development (RD), Commodity Credit Corporation (CCC), Forest Service (FS), Food and Nutrition Service (FNS), and Risk Management Agency (RMA)/Federal Crop Insurance Corporation (FCIC) Financial Statement audit reports disclosed that the financial statements were presented fairly and conformed to generally accepted accounting principles resulting in unqualified opinions for FY 2010. NRCS' last three Financial Statement audits (fiscal years 2008, 2009, and 2010) resulted in a disclaimer of opinion; however, the errors were determined not to be material to the USDA consolidated financial statements, taken as a whole.

The NRCS disclaimer of opinion was the result of NRCS management's inability to provide sufficient evidential matter in support of transactions and account balances, as presented in the NRCS consolidated financial statements as of and for the year ended September 30, 2010. In addition, the independent public accountant identified seven material weaknesses in NRCS' accounting and controls over undelivered orders; revenue and unfilled customer orders process; accrued expenses; financial reporting; property, plant, and equipment; purchase and fleet card transactions; and general and application controls environment.

(35) **Mr. Kingston:** Please provide a status report on all current and previous findings of material weakness since 2008. Specifically, please list the finding, OIG's recommendation and the current status.

Response: The information follows:

FY 2008 through FY 2010 Material Weaknesses Findings and Recommendations	**Status (Reached Management Decision)**
FY 2008 Consolidated Financial Statements Audit, Assignment No. 50401-65-FM	
Finding 1: Improvements are needed in overall financial management. **Recommendation:** Provide additional oversight to ensure that general ledgers reflect valid obligations and that agencies perform the required reviews timely and effectively.	Yes
Finding 2: Improvements are needed in Information Technology, Security and Controls. **Recommendation:** The Department and its agencies are in the process of addressing the weaknesses; therefore, no recommendations were made in the	N/A

FY 2008 through FY 2010 Material Weaknesses Findings and Recommendations	Status (Reached Management Decision)
report.	
FY 2009 Consolidated Financial Statements Audit, Assignment No. 50401-67-FM	
Finding 1: Improvements are needed in overall financial management. **Recommendation:** Provide additional oversight to ensure agencies (1) properly monitor and review obligation balances, (2) provide valid certifications based on complete and accurate reviews as required by Departmental Regulation 2230-001, and (3) understand the importance of responding to requests for bills or additional information in a timely manner.	Yes
Finding 2: Improvements are needed in Information Technology, Security and Controls. **Recommendation:** (1) Create a plan of action and milestones to correct deficiencies in both System Security Plans and Contingency and Disaster Recovery Plans, (2) revise Cyber Security Assessment and Management and/or system documentation to reflect consistent and accurate information, and (3) institute policy and procedures to ensure review and signature of all parties bound by Interconnection Security Agreements.	Yes
FY 2010 Consolidated Financial Statements Audit, Assignment No. 50401-70-FM	
Finding 1: Improvements are needed in overall financial management. **Recommendation:** Provide additional oversight to ensure that agencies are properly reviewing, researching, and timely implementing action to correct abnormal balances.	Yes
Finding 2: Improvements are needed in Information Technology, Security and Controls. **Recommendation:** Because of actions planned by the Department and recommendations made in other audits, no recommendation was made.	N/A
FY 2008 CCC Financial Statements Audit, Assignment No. 06401-23-FM	
Finding 1: Improvements needed in Financial System Functionality and Fund Control. **Recommendation:** CCC is addressing the weakness; therefore, no recommendations were made in the report.	N/A
Finding 2: Improvements needed in management's review procedures over its cash flow models. **Recommendation:** The Office of Budget and Finance (OBF) perform a more thorough and in-depth review of the models prior to submitting them for auditor review. In addition, OBF should begin making any necessary revisions to the model earlier in the fiscal year.	Yes
Finding 3: Improvements needed in management's analysis of obligations and liabilities for the Direct and Countercyclical Payment Programs. **Recommendation:** The formalized policies and procedures specific to the Countercyclical Payment and Direct Payment program specifically describe: (i) a process to perform a reasonableness analysis on the prior program year accruals and obligations carried forward to the current period; (ii) actions that	Yes

FY 2008 through FY 2010 Material Weaknesses Findings and Recommendations	Status (Reached Management Decision)
should be taken based on this analysis; and (iii) procedures that should be followed to update the recorded amounts based on information that comes to management's attention subsequent to fiscal year end that is relevant to current year recorded amounts.	
FY 2009 CCC Financial Statements Audit, Assignment No. 06401-24-FM	
Finding 1: Improvements are needed in financial management system's functionality. **Recommendation:** Because of actions planned by the Department and recommendations made in other audits, no recommendation was made.	N/A
FY 2010 CCC Financial Statements Audit, Assignment No. 06401-25-FM	
Finding 1: Improvements are needed in financial management system's functionality. **Recommendation:** Because of actions planned by the Department and recommendations made in other audits, no recommendation was made.	N/A
FY 2009 Rural Development Financial Statements Audit, Assignment No. 85401-17-FM	
Finding 1: Improvements needed in controls over cash flow assumptions. **Recommendation:** Design and implement controls over the development, validation, and approval of assumption curves used in the cash flow models.	Yes
FY 2008 NRCS Financial Statements Audit, Assignment No. 10401-02-FM	
Finding 1: Improved accounting and controls needed over undelivered orders. **Recommendation:** Ensure undelivered orders balances are valid at period end.	Yes
Finding 2: Improved accounting and controls needed for unfilled customer orders. **Recommendation:** Ensure unfilled customer orders are complete and valid at period end.	Yes
Finding 3: Improved accounting and controls needed for accrued expenses. **Recommendation:** Develop and provide guidance and training regarding policy and procedures over preparing, reviewing, and recording accruals.	Yes
Finding 4: Improved accounting and controls needed for property, plant, and equipment. **Recommendation:** Ensure capital leases are identified and accounted for as required.	Yes
Finding 5: Improved controls are needed over financial reporting. **Recommendation:** Ensure employees preparing the financial statements have the appropriate training and that financial statements are reviewed and approved by management to ensure compliance with generally accepted accounting principles.	Yes
FY 2009 NRCS Financial Statements Audit, Assignment No. 10401-03-FM	
Finding 1: Improved accounting and controls needed over undelivered orders.	Yes

FY 2008 through FY 2010 Material Weaknesses Findings and Recommendations	Status (Reached Management Decision)
Recommendation: Continue to train budget and program personnel to review open obligation balances and monitor compliance.	
Finding 2: Improved accounting and controls needed over the revenue and unfilled customer order process. **Recommendation:** Develop and implement policies and procedures for reimbursable agreements, accounts receivable, and unfilled customer orders.	Yes
Finding 3: Improved accounting and controls needed over accrued expenses. **Recommendation:** Provide additional training to field personnel regarding the policy and procedures for recording accruals.	Yes
Finding 4: Improved controls needed over financial reporting. **Recommendation:** Obtain and use the United States Government Standard General Ledger posting models for conservation easements, travel advances to others, cumulative results of operations for non-appropriated funds, recoveries of prior year obligations, and accounts receivable with the public.	Yes
Finding 5: Improved accounting and controls needed for property, plant, and equipment. **Recommendation:** Establish a policy that outlines the proper procedures for identifying and tracking the appropriate costs related to the development of new applications through the various stages of the development process.	Yes
FY 2010 NRCS Financial Statements Audit, Assignment No. 10401-03-FM	
Finding 1: Improved accounting and controls needed over undelivered orders. **Recommendation:** Review and ensure that the current policies are compliant with Title 31 U.S. Code and GAO's Redbook, The Principles of Federal Appropriations Law.	Yes
Finding 2: Improved accounting and controls needed over the revenue and unfilled customer order process. **Recommendation:** Develop a systematic methodology for calculating the allowance for uncollectible accounts which considers historical data, estimates losses on an individual and aggregate account basis, and considers other risk factors that may have an impact on NRCS' ability to collect amounts due.	Yes
Finding 3: Improved accounting and controls needed over accrued expenses. **Recommendation:** Perform quality assurance procedures to determine if accrued expenses are complete, accurate, and exist at quarter and year end.	Yes
Finding 4: Improved controls needed over financial reporting. **Recommendation:** Establish a more robust internal control identification and evaluation process to identify all significant control deficiencies.	Yes
Finding 5: Improved accounting and controls needed for property, plant, and equipment. **Recommendation:** Reinforce segregation of duties responsibilities for inventory taking, reminding Accountable Property Officers that the inventory taker should not also have the authority to purchase property, plant and	No

FY 2008 through FY 2010 Material Weaknesses Findings and Recommendations	Status (Reached Management Decision)
equipment.	
Finding 6: Improved general and application access controls needed. **Recommendation:** Establish a process to actively review and document its review of application, active directory, and Virtual Private Network access to determine whether it is appropriate based on the employee's role.	Yes
Finding 7: Improved controls needed over purchase and fleet card transactions. **Recommendation:** NRCS management should immediately review all cardholders to determine whether they are current NRCS employees and should have access to a purchase card.	Yes
Notes: • OIG tracks recommendations to management decision (agreement by agency officials). OCFO tracks recommendations until final action has been implemented. • Additional recommendations related to NRCS' financial statements can be provided upon request.	

(36) **Mr. Kingston:** Please provide a table showing the amount spent for confidential operational activities for fiscal years 2009 (actual), 2010 (actual) and 2011 (estimate).

Response: The information is as follows:

Fiscal Year	Available	Spent
2009	$125,000	$ 77,654
2010	$125,000	$ 88,451
2011	$125,000	$125,000*

* Estimated use through the end of the fiscal year based on current investigative activity.

(37) **Mr. Kingston:** Please provide a summary of complaints from OIG Hotline for Fiscal Year 2010.

Response: The information is as follows:

During FY 2010, USDA received 2,936 complaints over the Hotline:

From the public	2870
From USDA employees	207
From duplicate sources	-141*
TOTAL	**2936**

How the Hotline was contacted:

Telephone	1667
Mail	416
Walk-in	1
E-Mail	761
Fax	91

Type of Allegation:

Program participation fraud	1870
Employee misconduct	387
Waste/mismanagement	273
Health/safety	76
Opinion/information	325
Bribery	2
Reprisal	3

Disposition of the contacts:

USDA agencies for response	991
Food stamp recipient fraud complaints tracked by FNS	1152
USDA agencies for information	361
OIG-Audit/Investigations	232
Other law enforcement agencies	9
Insufficient information	171
Complainant referred to State agency	20

During FY 2010, 1,310 Hotline complaint files were closed:

Substantiated	101
Unsubstantiated	604
Partially substantiated	92
Referred to other law enforcement agencies	16
Other (declined)	497

*141 Hotline contacts were duplicate sources and did not require processing as a separate file.

(38) **Mr. Kingston:** Please provide a table showing the number of audit reports, investigative reports, indictments, convictions, and lawsuits filed for fiscal year 2010.

Response: The information is as follows:

FY 2010 Results in Key Categories—OCTOBER 2009–SEPTEMBER 2010

Audit Reports Issued	65
Investigative Reports Issued	247
Impact of Investigations*	
Indictments	356
Convictions	459
Arrests	992
Lawsuits	8

*The period of time to obtain court action on an indictment varies widely; therefore, the 459 convictions do not necessarily relate to the 356 indictments.

(39) **Mr. Kingston:** How were the indictments resolved, and what percent led to convictions? Please report for the latest data available.

Response: We would like to note that indictments may be obtained in one FY, but the trial or conviction may not occur in that same FY. Therefore, at this time we cannot say how each indictment obtained in FY 2010 will be resolved. However, based upon an analysis of the cases closed in FY 2010, 96% of all investigations that resulted in indictment ultimately led to conviction.

(40) **Mr. Kingston:** Provide a table showing the allocation of OIG's resources and the percent of each that went towards investigations and audits of each USDA agency for fiscal year 2010.

Response: The information is as follows:

Investigations

	Total OIG Dollars (dollars are in millions)	OIG Staff Years	Investigation Dollars (dollars are in millions)	Percentage of OIG Dollars per Agency	Investigations Staff Years	Percentage of OIG Staff Years per Agency
RMA	$4,326	29	2,748	3	18	3
FSA	10,045	67	6,240	7	40	7
FAS	514	3	500	1	3	1
FNS	27,369	179	21,995	24	141	24
AMS	1,649	11	792	1	5	1
APHIS	4,231	28	3,449	4	22	4
GIPSA	38	0	36	0	0	0
FSIS	3,981	27	2,225	3	15	3
ARS	559	5	526	1	4	1
NIFA	64	0	30	0	0	0
RD	1,207	8	0	0	0	0
RBS	1,718	12	108	0	1	0
RHS	6,851	47	2,127	2	14	2
RUS	1,285	9	289	0	2	0
FS	8,755	60	1,953	2	13	2
NRCS	3,050	21	980	1	6	1
OO	43	0	43	0	0	0
OCFO	808	6	105	0	2	0
OCIO	494	3	33	0	0	0
OIG (internal)	6,396	44	658	1	4	1
Multi-Agency	4,808	34	58	0	0	0
OCRE	76	0	76	0	0	0
SEC	30	0	30	0	0	0
Total*	**$88,297**	**593**	**$45,031**	**50**	**290**	**49**

- Please note that the numbers may not add due to rounding.

Audit

Total OIG Dollars (dollars in millions)		OIG Staff Years	Audit Dollars (dollars are in millions)	Percentage of OIG Dollars per Agency	Audit Staff Years	Percentage of OIG Staff Years per Agency
RMA	$4,326	29	1,578	5	11	2
FSA	10,045	67	3,805	4	27	5
FAS	514	3	14	0	0	0
FNS	27,369	179	5,374	6	38	6
AMS	1,649	11	857	1	6	1
APHIS	4,231	28	783	1	5	1
GIPSA	38	0	2	0	0	0
FSIS	3,981	27	1,726	2	12	2
ARS	559	5	32	0	0	0
NIFA	64	0	35	0	0	0
RD	1,207	8	1,207	1	8	1
RBS	1,718	12	1,610	2	11	2
RHS	6,851	47	4,724	5	33	6
RUS	1,285	9	994	1	7	1
FS	8,755	60	6,802	8	48	8
NRCS	3,050	21	2,071	2	15	3
OO	43	0	0	0	0	0
OCFO	808	6	703	1	6	1
OCIO	494	3	461	1	3	1
OIG (internal)	6,396	44	5,739	6	40	7
Multi-Agency	4,808	34	4,749	5	33	6
OCRE	76	0	0	0	0	0
SEC	30	0	0	0	0	0
Total*	**$88,297**	**593**	**$43,266**	**52**	**303**	**51**

- Please note that the numbers may not add due to rounding.

(41) **Mr. Kingston:** Please provide for the record the amounts transferred to OIG from the Department of Justice Assets Forfeiture fund for fiscal years 2008 through 2011. Provide an explanation of the use of these funds by OIG.

Response: The information is as follows:

Fiscal Year	Amount transferred from DOJ-AFF
2008	$1,155,936
2009	$1,750,055
2010	$1,597,790
2011*	$986,636

*Current Authorizations for FY 2011 as of March 31, 2011.

As a participating member of the DOJ Assets Forfeiture Fund, USDA OIG requests monies under DOJ's Annual Allocation program. These allocations are usually requested for use in two categories of the fund, including program operations expenses and investigative expenses.

Program operations expenses include case related expenses, joint law enforcement operations (conducted with various State and local law enforcement entities), and training. Investigative expenses include such items as the purchase of evidence and the equipping of conveyances.

For FY 2011 OIG was authorized $1,683,000 from the DOJ Assets Forfeiture Fund however, we have only expended $986,636 during the first half of fiscal year 2011.

(42) **Mr. Kingston**: Please provide for the record amounts transferred to OIG from the Department of Treasury Forfeiture Fund for fiscal years 2008 through 2011. Provide an explanation of the use of these funds by OIG.

Response: The information is as follows:

Fiscal Year	Amount transferred from TFF
2008	$210,421
2009	$485,279
2010	$1,400,501*
2011**	$0

*The spike in the FY 10 amount is from an isolated event from an aged investigation, where funds were recovered and transferred to USDA OIG in FY 10.

**Current Authorizations for FY 2011 as of March 31, 2011.

Amounts transferred to USDA-OIG are utilized in accordance with TFF requirements and are used to support program operations and investigative case related expenses, such as law enforcement equipment and investigative/law enforcement supplies.

(43) **Mr. Kingston**: Please provide for the record amounts transferred to OIG through the granting of a Petition for Remission or Mitigation for fiscal years 2008 through 2011.

Response: The information is as follows:

Fiscal Year	Amount transferred through the Granting of a Petition for Remission or Mitigation
2008	$874,071
2009	$608,320
2010	$1,546,212
2011*	$0

*Current Authorizations for FY 2011 as of March 31, 2011.

(44) **Mr. Kingston**: How many OIG employees are entitled to special pay rates? What is OIG's pay scale?

Response: The Office of Inspector General (OIG) does not have any employees on a special rate pay scale. OIG employees are either on the GS or ES pay scale. However, OIG's 223 Criminal Investigators (GS 1811) are entitled to Law Enforcement Officer Pay. In addition, investigators who meet the requirements for Law Enforcement Availability Pay are entitled to an additional 25%, pursuant to law and OPM regulations.

OIG uses the Federal locality pay scale authorized by OPM for all other employees within the Federal Government.

(45) **Mr. Kingston**: Please provide for the record a table showing OIG-owned firearms.

Response: The information is as follows:

OIG Owned Firearms *(Inventory as of March 31, 2011)*	
Type of Firearms	**Number**
9mm semiautomatic pistols	87*
.40 cal. semiautomatic pistols	319
MP-5s	82
M4 carbines	48
.357 cal. revolvers	6
.38 cal. revolvers	23
12-gauge shotguns	108
Miscellaneous weapons maintained for training purposes	70
Total	**743**

*USDA OIG is currently transitioning to the Glock .40 caliber semiautomatic pistol. Upon completion of this transition, 295 9mm weapons will be shipped to Glock, Inc. as a part of the trade-in program which kept overall costs lower. To date, 208 pistols have been sent to Glock, Inc.

(46) **Mr. Kingston**: Please provide a description of the work the IG is doing in regard to federal, state or industry employee whistleblowers.

Response: Whistleblower complaints are received from both Federal employees and the general public. In instances where criminal activity or severe USDA program abuse is alleged, OIG performs a preliminary investigation to determine if further criminal investigation or OIG audit is warranted. If it is determined the complaint should be handled administratively, it is referred to the USDA agency for investigation. Previous experience has shown most complaints are more effectively examined through administrative or regulatory investigations. When complaints are sent to the USDA agency for investigation, OIG monitors the progress and reviews all responses received from the USDA agency to ensure all allegations were sufficiently investigated and addressed.

The Recovery Act provides whistleblower protections to non-Federal employees who reasonably believe they are being retaliated against for reporting misuse of funds received by their non-Federal employer under the Recovery Act. The Recovery Act requires OIGs to review any such Recovery Act reprisal complaints and determine whether an investigation will be conducted. Within 180 days of receiving a complaint, OIGs must investigate the complaints and issue a report of the findings.

To date, we have received 4 non-Federal employee Recovery Act whistleblower reprisal complaints and have handled them in accordance with these provisions.

(47) **Mr. Kingston**: How many open investigations and reviews are related to whistleblower complaints?

Response: For FY 2010, there were a total of 28 open investigations and 8 open reviews or audits in OIG that were initiated as a result of whistleblower complaints reported to our Hotline. For FY 2011, there were a total of 33 investigations and 12 audits or reviews that were initiated as a result of whistleblower complaints received via the Hotline as of April 21, 2011.

(48) **Mr. Kingston:** Please update the list of ongoing, completed and planned work on USDA's homeland security activities.

Response: The requested information about OIG audits of USDA homeland security activities follows. This information is current as of March 31, 2011.

WORK CURRENTLY IN PROCESS (sorted by audit number)	
Audit No.	**Audit Title/Description**
24601-08-At	FSIS In-Commerce Surveillance Activities
24701-01-Te	FSIS Food Defense Verification Procedures
33601-12-Ch	Effectiveness of the Smuggling, Interdiction, and Trade Compliance Unit, APHIS
33701-01-At	Follow up on APHIS Select Agent Program

AUDIT REPORTS ISSUED SINCE MARCH 2010 (sorted by issued date)		
Audit No.	**Audit Title/Description**	**Issued**
33601-11-Ch	USDA's Controls Over Animal Import Centers	08/13/10
42099-04-HQ	Assessment of the U.S. Department of Agriculture's Disaster Response Capabilities	08/30/10
50501-02-IT	United States Department of Agriculture, Office of the Chief Information Officer, Fiscal Year 2010 Federal Information Security Management Act	11/15/10
24601-06-At	Food Emergency Response Network	3/22/11

WORK CURRENTLY PLANNED
USDA's Ability to Respond to Agricultural Emergencies
USDA, Office of the Chief Information Officer, Fiscal Year 2011 Federal Information Security Management Act

Several years ago, OIG established an Emergency Response Team (ERT) comprised of investigators trained to respond to threats against the agriculture infrastructure. Over the last fiscal year, the ERT worked closely with APHIS and FSIS on matters pertaining to homeland security. They have participated in numerous working groups and tabletop exercises at the Federal, state and local levels to ensure interagency cooperation in the event of a homeland security related crisis. Within the next year, the ERT will continue to serve as a resource for USDA and will enhance its knowledge and capabilities through additional training and tabletop exercises.

(49) **Mr. Kingston:** How does OIG coordinating with the Office of the Chief Information Officer regarding its lead role in assuring security over IT resources?

Response: The Office of the Chief Information Officer (OCIO) has several ongoing Department-wide IT security projects. OIG coordinates with OCIO by attending bi-weekly meetings on the new access control framework the Department is building, and on the data consolidation project being undertaken by the three farm service-related agencies. In addition, we participate in the monthly Departmentwide security call where the agency responsible officials discuss projects, training, and new ideas. OIG's participation in these activities is for

purposes of obtaining information and keeping apprised of USDA activities in order for OIG to carry out its oversight duties.

OIG also coordinates with the agencies during the annual FISMA review. Both the Department and OIG are required to coordinate the responses back to the Department of Homeland Security (DHS) and work closely during the entire process. OIG has a close working relationship with OCIO and OCIO is briefed regularly on ongoing OIG projects.

While the OCIO is the lead for USDA on IT, OIG's National Computer Forensic Division (NCFD) provides technical assistance as needed to OCIO. In accordance with OCIO's Agricultural Security Operations Center and National Information Technology Center intrusion response protocols, NCFD will provide forensic expertise in the event of an intrusion by an outside entity into USDA IT systems.

(50) **Mr. Kingston**: Please provide for the record a description of the latest OIG work relating to APHIS.

Response: The requested information about OIG audits relating to Animal and Plant Health Inspection Service (APHIS) activities follows. This information is current as of March 31, 2011.

AUDIT REPORTS ISSUED SINCE MARCH 2010 (sorted by issued date)		
Audit No.	**Audit Title**	**Issued**
33002-4-SF	Animal Care Program – Inspection of Problematic Dealers	05/14/10
33601-10-Ch	Controls Over Licensing of Animal Exhibitors	06/29/10
33601-11-Ch	Controls Over Animal Import Centers	08/13/10
33601-2-KC	Administration of the Horse Protection Program and Slaughter Horse Transportation Program	09/30/10

WORK CURRENTLY IN PROCESS (sorted by audit number)	
Audit No.	**Audit Title/Description**
33601-12-Ch	Effectiveness of the Smuggling, Interdiction, and Trade Compliance Unit
33701-1-At	Follow up on APHIS' Implementation of the Select Agent or Toxin Regulations
50601-1-23	USDA Controls Over Shell Egg Inspections
50601-16-Te	Controls Over Genetically Engineered Animal and Insect Research
50099-46-At	USDA Payments for 2005 Citrus Canker Losses
50099-84-Hy	USDA's Response to Colony Collapse Disorder (CCD)

During FY 2010, OIG conducted successful APHIS related investigations that led to 87 indictments, 129 convictions, and over $3.5 million in recoveries and restitution. OIG's most significant APHIS investigations involved animal fighting, which became a felony in 2007 and is often associated with other kinds of crimes such as assaults, gambling, illegal drug possession,

and illegal gun possession. Other APHIS related work includes protecting America's animal and plant resources and safeguarding them from exotic invasive pests by investigating import/export violations. Lastly, OIG investigates instances of workplace violence and employee misconduct.

(51) **Mr. Kingston**: Please provide for the record a description of the latest OIG work relating to FSIS.

Response: The requested information about OIG audits relating to Food Safety and Inspection Service (FSIS) activities follows. This information is current as of March 31, 2011.

AUDIT REPORTS ISSUED SINCE MARCH 2010 (sorted by issued date)		
Audit No.	**Audit Title/Description**	**Issued**
24601-9-KC	FSIS Sampling Protocol for Testing Beef Trim for *E.coli* O157:H7	02/24/11
24601-6-At	Food Emergency Response Network	03/22/11

WORK CURRENTLY IN PROCESS (sorted by audit number)	
Audit No.	**Audit Title/Description**
24601-1-31	FSIS N-60 Testing Protocol on Beef Trim for *E.Coli* O157:H7 – Phase II
24601-2-31	Review of Appeals of Humane Handling Non-compliance Records
24701-1-Te	FSIS Food Defense Verification Procedures
24601-8-At	FSIS In-Commerce Surveillance Activities
24601-11-Hy	Assessment of FSIS Inspection Personnel Shortages in Processing Establishments
50601-1-23	USDA Controls Over Shell Egg Inspections

During FY 2010, OIG successfully conducted FSIS related investigations that led to 6 indictments, 6 convictions, and nearly $1.2 million in monetary recoveries and restitution. These investigations included instances of smuggled meat product from a foreign country, mislabeled meat products, product tampering, and employee misconduct.

(52) **Mr. Kingston:** Please provide for the record a description of the latest OIG work relating to FSA.

Response: The requested information about OIG audits relating to Farm Service Agency (FSA) activities follows. This information is current as of March 31, 2011.

AUDIT REPORTS ISSUED SINCE MARCH 2010 (sorted by issued date)		
Audit No.	**Audit Title**	**Issued**
50703-1-DA	Recovery Act Review of the Effectiveness of Departmental/Agency Data Quality Review Processes	06/23/10

AUDIT REPORTS ISSUED SINCE MARCH 2010 (sorted by issued date)		
Audit No.	**Audit Title**	**Issued**
03601-18-Ch	FSA Farm Loan Security	08/10/10
03702-1-Te	Emergency Disaster Assistance for the 2008 Natural Disasters Emergency Conservation Program (ECP)	09/30/10
03099-199-KC	FSA Average Crop Revenue Election Program, Sheridan County, Montana	12/10/10
03703-2-Te	Recovery Act – Direct Farm Operating Loans (Phase 2)	01/13/11
03703-1-IT	Recovery Act Spending for FSA IT Issues	3/31/11
50601-16-KC	2008 Emergency Disaster Assistance Emergency Conservation Program (ECP)	3/31/11

AUDIT WORK CURRENTLY IN PROCESS (sorted by audit number)	
Audit No.	**Audit Title**
03024-1-11	FSA Farm Assistance Program Payments for Fiscal Year 2010
03024-1-22	Review of FSA's Error Rate Determinations for Payments Made to Estates and Deceased Individuals
03401-1-11	Review of FSA Accounting for Fiscal Year 2011
03601-1-32	Farm Storage Facility Loan Program
03601-19-Ch	Verification of Income Eligibility for Program Payments
03601-28-KC	Biomass Crop Assistance Program Collection, Harvest, Storage, and Transportation Matching Payments Program
03601-50-Te	2008 Farm Bill Changes to Payment Limitation
03601-51-Te	Conservation Reserve Program Soil Rental Rates
03703-2-Ch	Controls over Aquaculture Grant Recovery Act Funds (Phase 2)
50099-84-Hy	USDA's Response to Colony Collapse Disorder (CCD)
50601-15-KC	NASS Establishments of Average Yields

During FY 2010, OIG conducted successful FSA related investigations that led to 14 indictments, 34 convictions, and nearly $43 million in monetary recoveries and restitution. OIG continues to direct a significant percent of our investigative resources to farm program cases. These cases not only involve direct or indirect subsidy payments but include conversion, loan fraud, guaranteed loan fraud, disaster payments, Noninsured Crop Disaster Assistance Program, and payment limitation fraud.

(53) **Mr. Kingston:** Please provide for the record a description of the latest OIG work relating to GIPSA.

Response: We have not issued any audits on the Grain Inspection Packers and Stockyards Administration (GIPSA) since our last testimony given in March 2010. We currently do not have any active audits in this area.

In FY 2010, we opened two GIPSA investigations, one of which involves employee misconduct violations. During FY 2010, our investigative results in GIPSA related investigations included 3 indictments and 1 conviction.

(54) **Mr. Kingston:** Please provide for the record a description of the latest OIG work relating to ARS.

Response: The requested information about OIG audits relating to Agricultural Research Service (ARS) activities follows. This information is current as of March 31, 2011.

AUDIT REPORTS ISSUED SINCE MARCH 2010 (sorted by issued date)		
Audit No.	**Audit Title**	**Issued**
02703-01-HQ	General Procurement Oversight Audit of Beltsville's Agriculture and Research Center Steam Study Task Order Awarded to Perkins + Will, Inc.	9/15/10
02703-02-HQ	General Procurement Oversight Audit of Architectural and Engineering Services Contracts Awarded by Agricultural Research Service to RMF Engineering, Inc	9/15/10

AUDIT WORK CURRENTLY IN PROCESS (sorted by audit number)	
Audit No.	**Audit Title**
02703-01-10	Procurement Oversight Audit of the Invasive Plant Research Laboratory Contract, Awarded by Agricultural Research Service, South Atlantic Area Office, to SheltonDean, Inc.
02703-02-10	Procurement Oversight Audit of Red River Valley Agricultural Research Center Contract Awarded to Pro-Mark Services, Inc.
02703-03-HQ	General Procurement Oversight Audit of Beltsville's Agricultural Research Service National Agricultural Library Bricks Repair Contract Awarded to Vigil Contracting, Inc.
02703-04-HQ	Procurement Oversight Audit of Southeast Poultry Research Laboratory – Replacement of Critical Mechanical Systems Serving Buildings 1, 4, and 34 Contract Awarded to Peachtree Mechanical, Inc.
02703-05-HQ	Procurement Oversight Audit of Architectural-Engineering Services Contract Awarded to Delta Engineers & Architects, P.C.
02703-06-HQ	Procurement Oversight Audit of Agricultural Research Service's Facilities Repairs Contract Awarded to Veteran Construction, LLC.
02703-07-HQ	Procurement Oversight Audit of National Center for Agricultural

AUDIT WORK CURRENTLY IN PROCESS (sorted by audit number)	
Audit No.	**Audit Title**
	Utilization Research Contract Awarded to Bernard Johnson Corporation.
02703-08-HQ	Procurement Oversight Audit of National Center for Agricultural Utilization Research Contract Awarded to Core Construction Services.
02703-09-HQ	Procurement Oversight Audit of Western Regional Research Facility contract Awarded to Abide International, Inc.
50099-84-Hy	USDA's Response to Colony Collapse Disorder

During FY 2010, OIG conducted successful ARS related investigations that led to 1 indictment, 2 convictions, and over $4.5 million in monetary recoveries and restitution. The monetary recoveries and restitution are a result of a contract fraud investigation that resulted in a significant civil settlement. In FY 2010, we opened four ARS investigations, which included allegations of employee misconduct violations, contract fraud, and false claims.

(55) **Mr. Kingston:** Please provide for the record a description of the latest OIG work relating to NIFA.

Response: National Institute of Food and Agriculture (NIFA) activities are currently being reviewed as part of a multi-agency OIG audit looking at USDA's response to Colony Collapse Disorder (Audit 50099-84-Hy). We have not issued any audits on NIFA activities since our March 2010 hearing.

In FY 2010, we opened one NIFA investigation that remains ongoing.

(56) **Mr. Kingston:** Please provide for the record a description of the latest OIG work relating to the Biomass Crop Assistance Program.

Response: Currently, we are concluding our audit of the Collection, Harvest, Storage and Transportation (CHST) portion of the Biomass Crop Assistance Program (BCAP). Our review identified wide-ranging problems in the program's operation. We issued two Fast Reports to quickly alert Farm Service Agency's (FSA) management to the issues we identified during our review. These issues included inconsistent application of program provisions across State and county offices, varying methods for measuring biomass moisture levels, inconsistent use of program forms, and data errors. Our review also identified potential schemes or devices aimed at circumventing the intent of CHST program agreement terms and guidelines. These problems occurred because FSA, in an effort to quickly implement the program to comply with a Presidential Directive, did not develop a handbook, specialized forms, or a computer support system that was suited to the specific requirements of the CHST program. FSA also left its field personnel without adequate guidance and oversight controls to detect, identify, and take action against potential schemes or devices. The program's agreement terms also lacked a sufficient definition of prohibited practices or activities. Due to these problems, FSA implemented a program that encumbered the efforts of its field-level personnel and resulted in inequitable

treatment of program participants, improper payments, and reduced scope for oversight and accountability.

We recommended that the agency develop a program handbook, forms, and a data system; evaluate the three circumstances we identified to determine if they constitute a scheme or device; specifically prohibit schemes or devices of this nature; create new terms of agreement and/or guidance that address schemes or devices comprehensively; and create controls and compliance review procedures at the county office level to detect and identify potential schemes or devices. The agency has generally agreed with our recommendations and has begun corrective action. On October 27, 2010, FSA issued its final rule on this program; the final rule addressed some of the concerns we have discussed or reported to FSA.

Later this fiscal year we will begin our review of the Project Areas portion of BCAP. Under this portion of BCAP, FSA is authorized to approve BCAP project areas, which are distinct geographic regions in which participants can enroll into BCAP contracts and produce (and be reimbursed for growing) eligible crops. We will evaluate FSA's management controls over the establishment of project areas, approval of individual contracts, and propriety of establishment and annual payments.

Because BCAP is a relatively new program, OIG currently does not have any open investigations in this area. We will monitor incoming complaints and work closely with FSA officials concerning any potential criminal violations of the program in anticipation of future work in this area.

(57) **Mr. Kingston**: Has the Secretary requested OIG undertake any audits or investigations?

Response: Yes. In response to a request from the Secretary, OIG initiated an audit in February 2011 of the Office of the Assistant Secretary for Civil Right's oversight of agreements reached in program complaints. The Secretary has also requested that we determine if Food Service Management Companies are retaining discounts and rebates received on behalf of purchases made for school districts. We plan to initiate the requested audit in the summer.

Within the last fiscal year, the Deputy Secretary requested that OIG review a matter involving a former FS employee for potential ethics violations. Based on the investigation, it was determined that no criminal activity or ethics violations had occurred.

Questions for the Record from Rep. Rosa DeLauro
House Agriculture-FDA Appropriations Subcommittee
Hearing on USDA OIG
March 2, 2011

Supplemental Nutrition Assistance Program (SNAP)

(Q) **Ms. DeLauro:** In evaluating FNS' State-level controls to mitigate SNAP fraud related to increased ARRA funding, OIG determined that, while FNS performed reviews to evaluate how States manage SNAP, the agency did not target State fraud detection units. They argued that state annual activity reports were adequate to oversee State fraud detection, which OIG determined to contain unreliable and unverifiable data.

Can you help clarify this, so the States were providing FNS unreliable and unverifiable data, is that correct?

Response: OIG reviewed two States: New Jersey and Florida. There were instances in New Jersey where we could not verify or validate the accuracy of the information reported since there was not always supporting documentation. We found that Florida had incorrectly included non-SNAP cash benefits in its SNAP budget statement, due to a continued use of outdated guidance.

(Q) **Ms. DeLauro:** Have you been able to calculate an error rate for SNAP ARRA funds based on OIG's findings?

Response: The purpose of the audit did not involve calculating an error rate for SNAP Recovery Act funds. The objective for this audit was to evaluate FNS' efforts in monitoring the States' fraud detection units to ensure their effectiveness. SNAP benefits vary by income and household and the benefits are redeemed daily by households with varying benefit allotments. Therefore, instead of reporting Recovery benefits separately, FNS computed a weighted average to disaggregate the Recovery portion of benefits. The error rate calculated by FNS does not differentiate between regular and Recovery Act SNAP benefits.

(Q) **Ms. DeLauro:** During the hearing with Secretary Vilsack, there was a discussion about SNAP error rates. Based on department data, error rates for SNAP for the past several years are as follows:

FY 2007: 5.64 percent
FY 2008: 5.01 percent
FY 2009: 4.35 percent
FY 2010: 4.40 percent (estimate)
FY 2011: 4.40 percent (estimate)

Just to provide some context on how much the SNAP error rate has improved for the better, in FY 1998, the error rate for food stamps was over 10 percent.

Clearly FNS is doing something right to have such a low error rate, especially considering the dramatic increase in participation rates during the most recent recession.

Is there a difference between what FNS has been doing to successfully reduce payment errors compared to how they are monitoring ARRA funds?

Response: Based on the information provided by FNS, the agency is not doing anything differently with respect to monitoring Recovery Act funds. SNAP is not a new program and FNS has not made any changes other than to keep doing what it has been doing for many years. The Quality Control Process in existence, which samples and reviews the eligibility determinations and benefit amounts of SNAP recipients, was not changed due to the Recovery Act. FNS has been working with States to reduce error rates for several years and, as agency officials have advised, they will continue to do this after the Recovery Act.

(Q) **Ms. DeLauro:** Your testimony notes that FNS agreed to review the electronic benefit reports and to encourage States to use them to identify SNAP fraud. Have you been able to follow up with FNS to see if this was done?

Response: We have not yet followed up with FNS to review the corrective actions taken.

(Q) **Ms. DeLauro**: Do you know how the SNAP error rate of approximately 4.40 percent ranks in comparison to other government programs such as direct payment to farmers, oil subsidies or mineral subsidies?

Response: Below are two tables comparing SNAP to other Government programs:

Table 1 compares SNAP error rate, specifically, to direct payments to farmers, oil subsidies, and mineral subsidies.

Program	FY 2010 Error rate (rounded)
SNAP	4.4%
Direct payments to farmers (Farm Service Agency Conservation Reserve Program – paying farmers not to farm)	1.2%
Oil subsidies	Not accessible*
Mineral subsidies	Not accessible*

*According to Department of Interior's (DOI) FY 2010 Performance and Accountability Report, DOI does not have any programs susceptible to improper payments. Therefore, they are not required to list the error rate for their programs that do not meet OMB's guidance for high risk programs.

Table 2 compares SNAP to other Office of Management and Budget-designated high-error programs that accounted for over 81 percent of the $125 billion Government-wide improper payments reported for FY 2010. As shown below, SNAP had the 7th highest error rate of the top 14 high-error programs. (NR= no reporting data provided)

Program	Agency	Total Payments (outlays)	Improper Payment Amounts	Improper Payment Rates
National School Lunch Program (NSLP)	Department of Agriculture	$8.9B	$1.5B	16.30%
Medicare Advantage (Part C)	Department of Health and Human Services	$96.4B	$13.6B	14.10%
Unemployment Insurance (UI)	Department of Labor	$156.0B	$17.5B	11.20%
Medicare Fee-for-Service	Department of Health and Human Services	$326.4B	$34.3B	10.50%
Supplemental Security Income (SSI)	Social Security Administration	$48.3B	$4.8B	10.00%
Medicaid	Department of Health and Human Services	$239.0B	$22.5B	9.40%
Supplemental Nutrition Assistance Program (SNAP)	Department of Agriculture	$50.4B	$2.2B	4.40%
Rental Housing Assistance Programs	Department of Housing and Urban Development	$30.0B	$0.9B	3.10%
Federal-Aid Highway Program, Highway Planning and Construction	Department of Transportation	$44.2B	$0.6B	1.40%
Retirement, Survivors, and Disability Insurance (RSDI)	Social Security Administration	$659.6B	$3.2B	0.50%
Children's Health Insurance Program (CHIP)	Department of Health and Human Services	$8.9B	NR	NR
Earned Income Tax Credit (EITC)	Department of the Treasury	$64.2B	NR	NR
High Cost Program of the Universal Service Fund	Federal Communications Commission	$4.6B	NR	NR
Medicare Prescription Drug Benefit (Part D)	Department of Health and Human Services	$58.8B	NR	NR

Source: www.paymentaccuracy.gov

N-60 Testing

Thank you very much for completing the audit on the N-60 testing protocol, which is how FSIS samples beef trim for *E. coli* – taking 60 samples from large lots of beef trim to test. As you recall, this was an audit that I requested in November 2009.

The OIG finding that this procedure "does not yield a statistical precision that is reasonable for food safety" is astounding because it confirms the concerns that have been expressed in that the sampling system is flawed.

By recommending that FSIS redesign its sampling methodology to account for varying levels of contamination – makes you wonder if it undercuts everything that they are working on now since it seems like they have to start over.

(Q) **Ms. DeLauro:** Is there an estimate of how much the *E. coli* 0157:H7 levels in the FSIS regulatory sampling program have been understated by using the N-60 sampling technique?

Response: Neither FSIS nor OIG are currently able to provide a sound estimate of whether or not the *E. coli* O157:H7 levels may be understated or overstated because, as our report points out, FSIS has not performed the baseline studies necessary to determine the estimated prevalence rate of *E. coli* O157:H7 in a sampled lot of beef trim. In January 2011, FSIS released a prevalence study that indicates a very low occurrence rate of 0.39 percent. (See U.S. Dep't Agric., Food Safety & Inspection Serv., National Prevalence Estimate of Pathogens in Domestic Beef Manufacturing Trimmings (Trim) Dec. 2005 – Jan. 2007 (2011), http://www.fsis.usda.gov/PDF/Baseline_Data_Domestic_Beef_Trimmings_Rev.pdf.) However, this was based on the N-60 method that we reported has a low probability of detecting *E. coli* O157:H7 even if it is present. Therefore, in our opinion, the present N-60 testing method FSIS used is not sufficient to establish this level. We recommended that FSIS "perform necessary baseline studies of beef trim and ground beef to determine the estimated prevalence rate of *E. coli* O157:H7 for redesigning FSIS' sampling program." This prevalence rate should provide the statistical data needed for FSIS to better estimate the expected levels of *E. coli* O157:H7 in a sampled lot, but will not be useful in determining the past history of errors in its sampling program results to date.

(Q) **Ms. DeLauro:** What would be a better sample to capture a more accurate picture of the levels of *E. coli* 0157:H7 in a bin of trim?

Response: Until a reliable prevalence rate is established, statistical theory cannot adequately be applied to determine a precise sample size to test for *E. coli* O157:H7 in a sampled lot of beef trim. As we reported, however, to maintain a high probability of detecting a pathogen with presumably as low a level of contamination as *E. coli* O157:H7, FSIS' sample size must increase. Since more sample units require more of FSIS' limited resources, we recommended that FSIS "develop a detailed operational plan with specific timeframes and milestones to implement an inspection system that focuses *E. coli* O157:H7 sampling and testing resources primarily at plants that are likely to be of higher risk, and consider the use of specialized sample collection teams." However, we also cautioned in our report that the inherent nature of the *E.*

coli O157:H7 pathogen makes the probability of detecting it, even if it is present, very low. As more effective control measures are adopted by the industry, the prevalence of *E. coli* O157:H7 contamination should continually decrease; therefore, additional testing may not be the optimal solution over time. Based on these premises, FSIS may need to consider a fundamental redesign of its approach to ensuring food safety by relying less on its testing program and more on the verification and validation of industry control processes and consider the use of specialized sample collection teams.

(Q) **Ms. DeLauro:** FSIS adopted an industry sampling technique when it started to use N-60. Industry has made claims that the levels of E. coli 0157:H7 has been declining in beef. What would you advise the industry based on your audit findings for the FSIS sampling program?

Response: Based on the frequency of testing performed, we believe industry may be in a better position than FSIS to use N-60 sample test results to detect an establishment's failure to execute effective interventions or process controls; thus, reducing the distribution of *E. coli* O157:H7 contaminated meat. Although our audit was "exclusively directed towards the FSIS N-60 sampling," we acknowledged in our report that both industry and FSIS conduct N-60 sampling of trim and ground beef product. FSIS and industry have distinct differences in their overall scheme of sampling. FSIS samples beef trimming infrequently at any given establishment, maybe as seldom as twice a year, which makes the results of their N-60 testing method insufficient for detecting an establishment's failure to execute effective interventions or process controls. OIG understands, however, that large plants which produce over approximately 75 percent of domestically produced ground beef, unlike FSIS, generally test the lots of beef trim frequently throughout each day and also test samples of their ground product at multiple intervals, some as often as every 15 minutes. The greater frequency of testing that industry performs may increase the reliance on the cumulative N-60 sampling results. We also believe that FSIS should take advantage of the fact that many plants, especially the larger and more sophisticated ones, are independently performing hundreds of their own *E. coli* O157:H7 tests daily, some more rigorously than others. If FSIS could assure itself these plants' samples and tests for *E. coli* O157:H7 at least met FSIS standards, or even more rigorous ones, then FSIS could utilize these plants' testing results to augment its own. Our Phase II audit efforts will focus more on FSIS and industry sampling at the plant level.

(Q) **Ms. DeLauro:** Was OIG able to provide more specific recommendations to FSIS beyond placing its testing process on sounder statistical ground by redesigning its sampling technology? Given that FSIS generally agreed with the recommendation, do you have a sense of how much time this process would take?

Response: Consistent with our first recommendation, we believe FSIS must complete its baseline studies to determine the estimated prevalence rate of *E. coli* O157:H7 in beef trim before making more specific recommendations for the redesign of its trim sampling program. In response to our report, FSIS stated that it plans to publish and finalize its plan to accomplish the baseline studies by December 2011. Therefore, FSIS needs to take the time necessary to thoroughly evaluate all of its options, sampling goals, and available technology in designing a proposed plan; and, as we further recommended, post the design as well as the support and rationale behind it for public comment.

Salmonella in Eggs

According to your testimony, your office has initiated an audit of USDA's system for detecting Salmonella in eggs. As you know, inspection of in-shell eggs is the responsibility of FDA although as everyone discovered from the Wright County Egg outbreak that Agricultural Marketing Service (AMS) has inspectors at the farm grading eggs.

The OIG looked at FSIS inspections of egg products in 2007 and other than a failure to integrate egg products into the agency's HACCP structure, found no significant deficiencies. I am assuming since you reference shell eggs that the focus of your audit this time is on AMS and its management of Shell Egg Surveillance Program.

(Q) **Ms. DeLauro:** Would you describe the audit in more detail and where you anticipate your inquiry leading?

Response: Our objectives are to evaluate USDA's controls over shell eggs to detect and report the presence of Salmonella or other contaminates and to evaluate the effectiveness of USDA's coordination efforts with FDA to ensure the safety and wholesomeness of shell eggs.

We will accomplish our objectives by interviewing agency officials from FSIS, AMS, and APHIS to determine their roles and responsibilities for shell egg inspection. We will evaluate the agencies' coordination and involvement before, during, and after the August 2010 shell egg recall. We will also follow up on recommendations from past OIG and GAO audits.

At this time, we cannot anticipate the findings that will come out of our review.

(Q) **Ms. DeLauro:** Are you going to examine the memorandum of understanding between FDA and AMS that sets out each agency's responsibilities and make recommendations for improving coordination between FDA and AMS on in-shell egg safety?

Response: We are examining the memorandum of understanding between FDA and AMS. Because there are three agencies within USDA that are involved with shell eggs (AMS, FSIS, and APHIS), we will be examining the agreements and coordination between all of these agencies and FDA. We have reached out to HHS OIG to facilitate this process. Although it is beyond our authority to make recommendations to FDA, we can make recommendations to USDA agencies to work with FDA to improve conditions noted.

Strengthening Program Integrity

OIG has determined that USDA should better protect its programs by debarring those individuals and entities that abuse them. Although the department has the authority to exclude those who commit crimes against its programs from doing business with the Government, you found that convicted violators were rarely suspended or debarred – only 38 of 1,073 individuals convicted of crimes against USDA programs were debarred (less than 4 percent).

(Q) **Ms. Delauro**: Can you give us some examples of the types of crimes that were committed by entities or individuals? What are some of the programs that are most affected?

Response: Typically the types of crimes we see in these investigations involve false statements or false certifications to obtain monies to which the company or individual would not otherwise have been entitled. For example, OIG investigations related to RMA are typically the result of companies and/or entities filing false crop insurance claims and receiving payments to which they were not entitled.

As to the second half of your question on programs that are most affected, below is an estimated breakdown—by USDA agency—where the 1,073 convictions occurred.

Agency	Percentage	Notes
FNS	70%	The majority of the convictions involved SNAP retailers and wholesalers.
FSA	14%	The majority of the convictions were for violations of Loan Programs.
APHIS	4%	
RHS	3%	The convictions involved entities in the Rural Rental Housing Program.
RMA	3%	
All others	6%	
TOTAL	100%	

Of the 38 entities that were suspended or debarred, 27 were from RMA; 1 was from RHS; 1 was from APHIS (pursued under the procurement regulations); and 9 were from ARS (pursued under the procurement regulations).

(Q) **Ms. DeLauro**: The department maintains that it is in the public's best interest that these suspensions and debarments do not occur. Have you received a more detailed explanation from the department about why it is in the public's best interest?

Response: Not yet. USDA's OCFO is in the process of obtaining this information and plans to have its review completed by July 2011. We will be involved in the assessment of the supporting documentation that USDA provides to justify its exclusions to the suspension and debarment requirements, including the documents that support the exclusions are in the best interest of the Government.

CR Cuts

Under the House CR passed in February 2011, funding for OIG's office is cut by $8.7 million from the FY 2010 level of $88.725 million to $80 million, a reduction of approximately 10 percent. It is my understanding that the USDA OIG's budget was cut more than any other IG offices in other departments. For instance, the IG offices for the Treasury and Interior Departments received cuts of one percent or less. The Defense Department IG received an increase of 17 percent.

(Q) **Ms. DeLauro:** Because a CR would be enacted so late in the fiscal year, what would be the impact of the cut to the USDA OIG's office? Would you have to furlough employees? If so, how many?

Response: Below is a breakdown of the impact on OIG if H.R. 1 were enacted:

OIG Overall Impact:

- OIG officials have analyzed our operating plan for FY2011 and taken steps to reduce our discretionary expenses to the maximum extent possible. Under H.R. 1, there would be a 16% (net impact of mid-year implementation) funding reduction for the remainder of FY2011. Consequently, we would likely need to impose six week furloughs for all of our auditor, investigator, information technology, and other OIG employees. This would have a severe impact on OIG's ability to fulfill our statutory mission.

Impact on OIG Audit Oversight

- In readjusting our audit oversight of USDA programs and operations to manage a 16% funding reduction and impose six week furloughs on all audit personnel, OIG audits related to public health and safety issues would be severely limited due to lack of resources. For example, OIG could not proactively evaluate USDA actions to improve its processes designed to protect the safety and wholesomeness of domestic and imported meat and poultry products.

- OIG efforts to protect and improve USDA's financial integrity would be greatly diminished. We would not have the audit resources necessary to make statistically valid projections of the level of improper payments in USDA programs (estimated to exceed $5 billion in FY2010), nor be able to follow up on our previous improper payment findings to assess whether USDA agencies have taken corrective actions. For example, if a 16% reduction and agency-wide furloughs are implemented in the remainder of FY2011, OIG would cancel its plan to follow up on USDA's actions regarding improper payments in the Conservation Stewardship Program. Our review of the Department's predecessor program found that 50% of the payments in our sample were made incorrectly.

- OIG would not be able to meet statutory deadlines for audits of USDA financial statements pursuant to the Chief Financial Officers Act and audits of agency information technology security required by the Federal Information Security Management Act. These audits involve detailed testing in the second half of the fiscal year when OIG audit staff would be furloughed.

Impact on OIG Investigations

- OIG would not have investigative resources to pursue numerous allegations of fraud involving USDA programs and operations. If a 16% half-year budget reduction and furloughs are implemented, OIG would shift almost all available investigative resources to address situations involving public health and safety concerns under USDA jurisdiction. OIG would therefore delay or decline numerous worthwhile investigations involving matters such as alleged fraud in USDA farm and nutrition programs and employee misconduct.

- OIG investigations have material and positive monetary impact for USDA and the Treasury. On average, over the last five years the recoveries, fines, and restitutions imposed by courts in successful OIG cases has exceeded OIG's total budget for the same.

(Q) **Ms. DeLauro:** How would this impact the work of the OIG? Would audits and investigations have to be delayed or suspended? Would the office miss statutory deadlines for audits?

Response: See response to question above.

(Q) **Ms. DeLauro:** How would your office have to reassess its priorities? Would your office have to shift away from investigating improper payments in order to focus on public health and safety priorities?

Response: Priorities would definitely need to be reassessed. Our primary focus would be on statutorily-mandated audits—such as the financial statements and FISMA—and on audits where our findings impact the health and safety of the public—such as food safety and IT security. Audits with identified improper payments and high dollar findings would follow. There would be a decrease in the number of other high priority audits performed and an even larger decrease in audits which are considered cyclical or exploratory. As a result, our efforts to identify and address ongoing problems in existing program areas would be further impeded. OIG would not have the resources to provide oversight and guidance during the development of agency programs—that is, offer up-front reporting on potential weaknesses before deployment of the program as we have done with the Recovery Act-funded programs.

Single Family Housing Guaranteed and Direct Loans

(Q) Ms. DeLauro: As noted in your testimony, the Recovery Act included $133 million to finance over $10 billion in single family housing loan guarantees in rural areas. You found borrowers who were ineligible for a variety of reason such as annual incomes that exceeded program limits or being able to secure credit without a Government loan guarantee

Do you have any statistics available on the income levels of the ineligible borrowers? Were these borrowers just above the income threshold or were they significantly above the income requirement?

Response: Of the 28 single family housing guaranteed loan borrowers that we reported as being ineligible, 12 of those earned income that exceeded agency maximum allowed limits for that county. Agency maximum income limits for this program vary depending on the rural county in which the guaranteed loan is being made. Agency income limits in those counties where we found the 12 ineligible borrowers ranged from approximately $50,000 to $80,000. The amount by which each of the 12 borrower incomes exceeded the agency's income limits ranged from $219 to $20,108, with an average of $5,344 over the agency income limits.

(Q) **Ms. DeLauro:** For the direct loan program, OIG found that the Rural Housing Service (RHS) did not ensure that calculations of borrower eligibility were current before closing loans. This increased the risk of making loans to ineligible borrowers if their circumstances changed. You also found that RHS reviewers also did not document the scope and timing of their second-party reviews, which reduced the effectiveness of the quality control process. OIG recommended that RHS ensure that supporting documents are updated before closing loans and that the scope and timing of reviews are specified.

What is the status of this recommendation to RHS? Have they implemented it?

Response: The agency has submitted plans to OIG to take corrective actions and we have concurred that the actions are adequate to resolve the reported deficiencies. The corrective actions are scheduled to be implemented by May 31, 2011.

(Q) **Ms. DeLauro:** You also recommended that State office reviews of loan-making and loan-servicing be aggregated into national, multi-year analyses, and that RHS train State staff to use the results to administer the program. What is the status of this recommendation to RHS?

Response: Rural Development's Financial Management Division (FMD) performed a multiple-year analysis of SIR (State Internal Review) weaknesses and issued the analysis to Rural Development National Office officials and State Directors on June 21, 2010. In addition, on August 12, 2010, FMD provided each Rural Development Administrator with the details of the SIR weaknesses including the specific states where the recurring weaknesses were reported. FMD also revised the RD Instruction to require multiple-year analyses of SIR weaknesses. This particular audit recommendation was closed as of November 2, 2010.

Ms. Kaptur Question For the Record
March 2nd, 2011
USDA OIG

Biomass Crop Assistance Program

(Q) **Ms. Kaptur**: "The Inspector General's Testimony describes implementation issues associated with the Biomass Crop Assistance Program. However, all of these issues are associated only with the Collection, Harvest, Storage, and Transportation Portion of the program (the "matching payments" portion, and not the Project Areas portion (the "annual payments" portion). Given that FSA has only recently issued a final rule for the entire program, will the implementation problems that OIG found still be relevant, or will the final rules and other steps that FSA has taken over the last few months help to address those issues?"

Response: The BCAP final rule was issued on October 27, 2010. We reviewed the final rule to determine if it addressed our formal comments provided in March 3110 and our informal concerns that we discussed with program managers and agency officials throughout the course of our review. We found that while the agency had addressed some of our concerns in the final rule, including the issues of a payment option and inconsistencies in reduction of annual payments, we continue to have concerns regarding Biomass Conversion Facility performance and additional concerns regarding overall management controls for the program. These concerns will be further detailed in our upcoming audit report.

Questions for the Record from Rep. Rosa DeLauro
House Agriculture-FDA Appropriations Subcommittee
Hearing on USDA OIG
March 2, 2011

Supplemental Nutrition Assistance Program (SNAP)

In evaluating FNS' State-level controls to mitigate SNAP fraud related to increased ARRA funding, OIG determined that, while FNS performed reviews to evaluate how States manage SNAP, the agency did not target State fraud detection units. They argued that state annual activity reports were adequate to oversee State fraud detection, which OIG determined to contain unreliable and unverifiable data.

- **Can you help clarify this, so the States were providing FNS unreliable and unverifiable data, is that correct?**

- **Have you been able to calculate an error rate for SNAP ARRA funds based on OIG's findings?**

During the hearing with Secretary Vilsack, there was a discussion about SNAP error rates. Based on department data, error rates for SNAP for the past several years are as follows:

FY 2007: 5.64 percent
FY 2008: 5.01 percent
FY 2009: 4.35 percent
FY 2010: 4.40 percent (estimate)
FY 2011: 4.40 percent (estimate)

Just to provide some context on how much the SNAP error rate has improved for the better, in FY 1998, the error rate for food stamps was over 10 percent.

Clearly FNS is doing something right to have such a low error rate, especially considering the dramatic increase in participation rates during the most recent recession.

- **Is there a difference between what FNS has been doing to successfully reduce payment errors compared to how they are monitoring ARRA funds?**

- **Your testimony notes that FNS agreed to review the electronic benefit reports and to encourage States to use them to identify SNAP fraud. Have you been able to follow up with FNS to see if this was done?**

- **Do you know how the SNAP error rate of approximately 4.40 percent ranks in comparison to other government programs such as direct payment to farmers, oil subsidies or mineral subsidies?**

N-60 Testing

Thank you very much for completing the audit on the N-60 testing protocol, which is how FSIS samples beef trim for *E. coli* – taking 60 samples from large lots of beef trim to test. As you recall, this was an audit that I requested in November 2009.

The OIG finding that this procedure "does not yield a statistical precision that is reasonable for food safety" is astounding because it confirms the concerns that has been expressed in that the sampling system is flawed.

By recommending that FSIS redesign its sampling methodology to account for varying levels of contamination – makes you wonder if it undercuts everything that they are working on now since it seems like they have to start over.

- **Is there an estimate of how much the *E. coli* 0157:H7 levels in the FSIS regulatory sampling program have been understated by using the N-60 sampling technique?**

- **What would be a better sample to capture a more accurate picture of the levels of *E. coli* 0157:H7 in a bin of trim?**

- **FSIS adopted an industry sampling technique when it started to use N-60. Industry has made claims that the levels of E. coli 0157:H7 has been declining in beef. What would you advise the industry based on your audit findings for the FSIS sampling program?**

- **Was OIG able to provide more specific recommendations to FSIS beyond placing its testing process on sounder statistical ground by redesigning its sampling technology? Given that FSIS generally agreed with the recommendation, do you have a sense of how much time this process would take?**

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WITNESSES