DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. 1987F–0179]

Food Additives Permitted for Direct Addition to Food for Human Consumption; Olestra

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; denial of requests for a hearing and response to objections.

SUMMARY: The Food and Drug Administration (FDA) is denying the requests for a hearing it has received on the final rule that amended the food additive regulations to provide for the safe use of sucrose esterified with medium and long chain fatty acids (olestra) as a replacement for fats and oils in savory snacks. After reviewing the objections to the final rule and the requests for a hearing, FDA has concluded that the objections do not raise any issue of material fact that justifies a hearing or otherwise provides a basis for revoking the regulation.

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SUPPLEMENTARY INFORMATION:

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I. Background and Procedural History

In a notice published in the **Federal Register** of June 23, 1987 (52 FR 23606), FDA announced that a food additive petition (FAP 7A3997) had been filed by the Procter & Gamble Co., 6071 Center Hill Rd., Cincinnati, OH 45224–1703 (P&G, the petitioner), proposing the issuance of a food additive regulation providing for the safe use of sucrose esterified with medium and long chain fatty acids as a replacement for fats and oils. The common name for this additive is olestra. Subsequently, the petitioner amended the petition to limit the intended use of the additive to a 100 percent replacement for conventional fats in the preparation of savory snacks (i.e., snacks that are salty or piquant but not sweet, such as potato chips, cheese puffs, and crackers).

FDA reviewed the data and information in the olestra food additive petition to determine whether the additive is safe (see section 409(c)(3) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(c)(3)), for use in savory snacks. As part of this review process, FDA held public meetings of the agency's Food Advisory Committee (the FAC) and a working group of the FAC, the Olestra Working Group (the OWG) to provide for a scientific discussion of FDA's evaluation of the safety data in the petition.

On January 30, 1996, FDA issued a final rule in the **Federal Register** authorizing the use of olestra in place of fats and oils in prepackaged ready-to-eat savory snacks (61 FR 3118, January 30, 1996) (§ 172.867 (21 CFR 172.867)). In the preamble to the final rule, FDA concluded that all safety issues regarding olestra had been addressed adequately and that there is a reasonable certainty that no harm will result from the use of olestra in savory snacks. The 1996 olestra regulation requires that the fat-soluble vitamins A, D, E, and K be added to olestra-containing foods to compensate for any inhibition of absorption of these vitamins caused by olestra. The 1996 regulation also requires that foods containing olestra be labeled with the following information statement:

THIS PRODUCT CONTAINS OLESTRA. Olestra may cause abdominal cramping and loose stools. Olestra inhibits the absorption of some vitamins and other nutrients. Vitamins A, D, E, and K have been added. (§ 172.867(e)(1)).

Consistent with section 409(f) of the act (21 U.S.C. 348(f)), the preamble to the final rule advised that objections to the final rule and requests for a hearing were due within 30 days of the publication date (i.e., by February 29, 1996)[1] (§ 171.110 (21 CFR 171.110) and 21 CFR 12.22(a).) On February 29, 1996, CSPI filed six objections to the final rule and requested a hearing on all six objections.[2] CSPI had substantially participated in the November 1995 OWG/FAC meeting and had also filed multiple sets of comments with FDA prior to issuance of the final rule.

In the preamble to the 1996 final rule (61 FR 3118 at 3169), FDA advised that it would publish in the **Federal Register** notice of the objections that it received or lack thereof.[3] This document fulfills the agency's obligation to publish such a notice. The only timely, substantive objections FDA received were from CSPI.

II. Standard for Granting a Hearing

Under § 171.110 of the food additive regulations, objections and requests for a hearing are governed by part 12 (21 CFR part 12) of FDA's regulations. Specific criteria for determining whether a hearing has been justified are set forth in § 12.24(b). Under the regulation, a hearing will be granted if the material submitted by the requester shows, among other things, that: (1) There is a genuine and substantial issue of fact for resolution at a hearing; a hearing will not be granted on issues of policy or law; (2) the factual issue can be resolved by available and specifically identified reliable evidence; a hearing will not be granted on the basis of mere allegations or denials or general descriptions of positions and contentions; (3) the data and information submitted, if established at a hearing, would be adequate to justify resolution of the factual issue in the way sought by the requestor; a hearing will be denied if the data and information

[1] In addition to notifying the public of the opportunity to submit objections and hearing requests, FDA requested comments on the olestra label requirement on such issues as the need for such a label, the adequacy of its content, the agency's word choice, and the configuration of the label. In the **Federal Register** of March 3, 2000 (65 FR 11585), FDA announced that a food additive petition (FAP 0A4708) had been filed by P&G proposing to amend § 172.867 by removing the requirement for the label statement prescribed in § 172.867(e). Elsewhere in this issue of the **Federal Register**, FDA is issuing a final rule that responds to FAP 0A4708. In that final rule, the agency responds to comments received regarding the label statement.

[2] In addition, FDA received several letters within the 30 day objection period, all of which expressed general opposition to olestra, identified no substantive question to which the agency can respond, and did not request a hearing. These letters will not be discussed further.

[3] The January 30, 1996, final rule includes a more detailed background statement.

submitted are insufficient to justify the factual determination urged, even if accurate; and (4) resolution of the factual issue in the way sought by the requestor is adequate to justify the action requested; a hearing will not be granted on factual issues that are not determinative with respect to the action requested, (e.g., if the action would be the same even if the factual issue were resolved in the way sought).

A party seeking a hearing is required to meet a ''threshold burden of tendering evidence suggesting the need for a hearing.'' (See *Costle* v. *Pacific Legal Foundation*, 445 U.S. 198, 214–215 (1980), *reh. den.*, 446 U.S. 947 (1980), citing *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 620–621 (1973).) An allegation that a hearing is necessary to ''sharpen the issues'' or to ''fully develop the facts'' does not meet this test. (See *Georgia-Pacific Corp.* v. *U.S. EPA*, 671 F.2d 1235, 1241 (9th Cir. 1982).) If a hearing request fails to identify any evidence that would be the subject of a hearing, there is no point in holding one. In judicial proceedings, a court is authorized to issue summary judgment without an evidentiary hearing whenever it finds that there is no genuine issue of material fact, and a party is entitled to judgment as a matter of law (see Rule 56, Federal Rules of Civil Procedure). The same principle applies in administrative proceedings (§ 12.28).

A hearing request must not only contain evidence, but that evidence must raise a material issue of fact concerning which a meaningful hearing might be held. (See *Pineapple Growers Association* v. *FDA*, 673 F.2d 1083, 1085 (9th Cir. 1982).) Where the issues raised in the objection are, even if true, legally insufficient to alter the decision, the agency need not grant a hearing. (See *Dyestuffs and Chemicals, Inc.* v. *Flemming*, 271 F.2d 281 (8th Cir. 1959), *cert. denied*, 362 U.S. 911 (1960).) FDA need not grant a hearing in each case where an objector submits additional information or posits a novel interpretation of existing information. (See *United States* v. *Consolidated Mines* & *Smelting Co.*, 455 F.2d 432 (9th Cir. 1971).) In other words, a hearing is justified only if the objections are made in good faith, and if they ''draw in question in a material way the underpinnings of the regulation at issue.'' (See *Pactra Industries* v. *CPSC*, 555 F.2d 677 (9th Cir. 1977).) Finally, courts have uniformly recognized that a hearing need not be held to resolve questions of law or policy. (See *Citizens for Allegan County, Inc.* v. *FPC*, 414 F.2d 1125 (D.C. Cir. 1969); *Sun Oil Co.* v. *FPC*, 256 F.2d 233, 240 (5th Cir.), *cert. denied*, 358 U.S. 872 (1958).)

Even if the objections raise material issues of fact, FDA need not grant a hearing if those same issues were adequately raised and considered in an earlier proceeding. Once an issue has been so raised and considered, a party is estopped from raising that same issue in a later proceeding without new evidence. The various judicial doctrines dealing with finality can be validly applied to the administrative process. In explaining why these principles ''self-evidently'' ought to apply to an agency proceeding, the D.C. Circuit wrote:

> The underlying concept is as simple as this: justice requires that a party have a fair chance to present his position. But overall interests of administration do not require or generally contemplate that he will be given more than a fair opportunity.

(*Retail Clerks Union, Local 1401, RCIA* v. *NLRB*, 463 F.2d 316, 322 (D.C. Cir. 1972).) (See also *Costle* v. *Pacific Legal Foundation*, *supra* at 1106, and *Pacific Seafarers, Inc.* v. *Pacific Far East Line, Inc.* 404 F.2d 804 (D.C. Cir. 1968).)

In summary, a hearing request must present sufficient credible evidence to raise a material issue of fact and the evidence presented must be adequate to resolve the issue as requested and to justify the action requested.

III. Objections and Supporting Documents Submitted by CSPI

In a document dated February 29, 1996, entitled ''Objections and Request for Hearing'' (CSPI obj.), CSPI submitted to the Division of Dockets Management, its objections to the approval of the use of olestra as a food additive in savory snacks. CSPI submitted six objections to the 1996 final rule, and requested a hearing on issues raised by each objection. CSPI raised one general objection to the 1996 final rule, asserting that FDA improperly concluded that the use of olestra in savory snacks meets the safety standard of reasonable certainty of no harm. CSPI also raised five specific objections, asserting that: (1) Olestra's potential to deplete carotenoids may present a risk of harm to health, which precludes a finding of reasonable certainty of no harm; (2) FDA's decision to require compensation with vitamin K may not solve health problems that depletion of vitamin K may cause; (3) the potential GI disturbances that olestra may cause are adverse health effects that preclude a finding of reasonable certainty of no harm; (4) the label statement required on an interim basis by the 1996 final rule is insufficient to protect the public against adverse effects associated with consumption of olestra; and (5) problems with procedure and process tainted FDA's review of, and decision-making process for, the food additive petition for olestra to the detriment of FDA's consideration of the public health concerns raised by CSPI and others. In support of its objections and hearing requests, CSPI filed 18 exhibits (CSPI exh. 1 through 18.)[4]

IV. Analysis of Objections and Response to Hearing Requests

As noted in section III of this document, CSPI raised one general objection and five specific objections to the 1996 final rule. In this document, FDA addresses each of CSPI's objections, as well as the data and information filed in support of each, comparing each to the standards for granting a hearing in § 12.24(b). Because several of the issues in the general objection overlap with the five more specific objections, FDA addresses CSPI's five specific objections first (CSPI obj. 2 through 6), followed by the general objection (CSPI obj. 1).

A. Carotenoids

In its second objection and request for a hearing, CSPI states that there are two questions central to a discussion of the depletion of carotenoids by consumption of olestra. First, are carotenoids beneficial to health? Second, if carotenoids are beneficial to health, does consumption of olestra cause depletion of carotenoids such that there would be an absence of a reasonable certainty of no harm? CSPI claims that FDA did not answer either of these questions accurately and requests a hearing on both factual issues.

1. Are Carotenoids Beneficial to Health?

In its objection and request for a hearing, CSPI asserts that FDA erroneously concluded that there is no demonstrated health benefit of carotenoids except the provitamin A function of beta-carotene.

In analyzing this objection, it is important to recognize that FDA's position on carotenoids (as articulated in the 1996 final rule) has two parts. First, although FDA concluded that there is no demonstrated association between carotenoids per se and health

[4] In a letter dated August 26, 1996 (Docket No. 1987F–0179), CSPI requested that certain documents submitted to the agency after February 29, 1996, be considered part of their objections. As noted previously, February 29, 1996, was the final day allowed under section 409(f)(1) of the act for submission of objections and hearing requests, including supporting material. Accordingly, the material submitted in August 1996 was not timely filed and thus, has not been considered in evaluating the CSPI objections and hearing requests.

benefits, the agency agrees that epidemiological studies show an association between diets rich in fruits and vegetables and decreased cancer risk (61 FR 3118 at 3149).[5] As shown in this section, all of the evidence and opinions cited by CSPI to support this objection is consistent with an association between fruit and vegetable consumption and health benefits. Second, FDA concluded that the variation in serum levels of carotenoids associated with olestra consumption is within the normal range, given diet variations and the bioavailability of carotenoids. CSPI's objection does not directly address this second issue.[6]

CSPI offers essentially two arguments to support its view that FDA erroneously concluded that there is no demonstrated health benefit of carotenoids except the provitamin A function of beta-carotene. First, CSPI asserts that FDA's position on carotenoids is a minority view.[7] To support this challenge, CSPI relies on statements of Drs. Regina Ziegler (CSPI exh. 10), Walter Willet (CSPI exh. 13), and Jerianne Heimendinger (CSPI exh. 8) to demonstrate that FDA's position is not well-founded. Importantly, Drs. Ziegler and Willet both state that fruits and vegetables, not carotenoids per se, are associated with reduction of the risk of cancer. (CSPI exh. 13, p. 1; CSPI exh. 10, letter dated October 23, 1995, p. 1, and letter dated January 21, 1996, p. 2.) Similarly, Dr. Heimendinger asserts merely that evidence is ''increasing that * * * carotenoids *may* play important roles'' in reducing cancer risk (emphasis added). (CSPI exh. 8, Heimendinger letter, p. 2). Thus, none of these statements support CSPI's claim that carotenoids have been demonstrated to have a significant beneficial health role.[8] Accordingly, FDA is denying CSPI's request for a hearing on this issue because the information identified in the objection is insufficient to justify the factual determination urged by CSPI (§ 12.24(b)(3)).[9]

CSPI also relies on the dietary guidelines issued by the Department of Health and Human Services (DHHS), 4th edition, to support its assertion that FDA's position on carotenoids is a minority view. Careful reading of the guidelines establishes that, once again, the evidence identified in the objection does not support the position urged by CSPI because the guidelines do not identify carotenoids per se as beneficial to human health.

> Consumption of these foods [fruits and vegetables] is associated with a substantially lower risk of many chronic diseases, including certain types of cancers. (CSPI exh. 11, p. 13.)[10]

Elsewhere the guidelines describe the role of carotenoids in health as yet-to-be established.

> The antioxidant nutrients found in plant foods (e.g., vitamin C, carotenoids, vitamin E, and certain minerals) are presently of great interest to scientists and the public because of their *potentially beneficial* role in reducing the risk for cancer and certain other chronic diseases. Scientists are also trying to determine if other substances in plant foods protect against cancer. (CSPI exh. 11, p. 13, emphasis added.)

Because the information regarding the DHHS dietary guidelines is insufficient to establish CSPI's claim regarding the role of carotenoids in human health, FDA is denying a hearing on this issue (§ 12.24(b)(3)).

As a third basis to show that FDA's position regarding carotenoids is a minority view, CSPI cites correspondence between FDA and two different institutes of the National Institutes of Health (NIH).[11] CSPI challenges FDA's reliance on the letter from the NEI because it only addresses the role of beta-carotene, not lutein or lycopene. Even if CSPI's claims on this issue are correct, FDA is denying its request for a hearing because the assertion that lutein and lycopene have a beneficial role in eye health is not supported by specifically identified factual evidence. Accordingly, CSPI's allegations are mere speculation, which is not an adequate basis for a hearing request (§ 12.24(b)(2)).

With respect to the NCI, CSPI claims that there are conflicting views in the record from NCI and that FDA should determine, on the record, the ''official'' NIH position. Specifically, CSPI believes that Dr. Ziegler's views are significantly different from the views expressed by the then Director of the Division of Cancer Prevention and Control, NCI, NIH, Dr. Peter Greenwald.[12] CSPI does not demonstrate why such a determination is necessary, the authority under which it would be done, or how it would alter the outcome of this proceeding. Accordingly, FDA is denying CSPI's request for a hearing on this issue (§ 12.24(b)(2) and (b)(4)).

Finally, CSPI asserts that FDA staff, the OWG, and the FAC failed to acknowledge and accept data from in vitro, animal, and epidemiologic studies that all point to a protective role for carotenoids. In support of this portion of its second objection, CSPI cites two articles (CSPI obj. at p. 20, footnote 19).[13] This portion of CSPI's objection is without foundation because the information specifically cited is not adequate to establish the factual issue urged by CSPI[14] (§ 12.24(b)(3)). In particular, the first article cited (Garewal, H., ''Antioxidants in Oral Cancer Prevention,'' *American Journal of Clinical Nutrition*, 62:1410S–1416S, 1995, at 1413S.) concludes that the reported results do not themselves demonstrate a reduction in human

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[5] Indeed, CSPI itself concedes that there may be ''substances in fruits and vegetables for which carotenoids are markers'' that are beneficial to health (CSPI obj. at 19).

[6] Although not strictly relevant to the objections lodged by CSPI, it is important to note that in its 1996 final rule, FDA acknowledged the growing body of data and information regarding carotenoids and committed to reviewing such information within 30 months of olestra's initial approval (61 FR 3118 at 3168 and footnote 94). In June 1998, FDA presented the accumulated data and information to the FAC.

[7] Although CSPI asserts that FDA's view is a minority view, the final rule noted that five different conferences or reviewing groups have examined the relationship between carotenoids and disease and concluded that there was insufficient evidence to recommend specifically the consumption of carotenoids, except to encourage the consumption of fruits and vegetables (61 FR 3118 at 3148). CSPI does not challenge this fact.

[8] CSPI's objection and hearing request on this point also refer to an article published by Dr. Edward Giovannucci addressing the association between high intake of tomato products and reduced incidence of prostate cancer and claims that Dr. Giovannucci opposes the approval of olestra because of the additive's potential to deplete carotenoids, citing CSPI exh. 8. Although CSPI exh. 8 contains numerous letters from individuals opposing olestra's approval, there is no identifiable communication from Dr. Giovannucci in that exhibit. In the absence of specifically identified evidence demonstrating Dr. Giovannucci's position, FDA is denying CSPI's objection and hearing on this point (§ 12.24 (b)(2)). In addition, CSPI's reliance on the Giovannucci article is misplaced because, even as described by CSPI, the paper does not support CSPI's claim that carotenoids themselves have been shown to have distinct health benefits. Accordingly, FDA is denying CSPI's claim on this point (§ 12.24(b)(2) and (b)(4)).

[9] CSPI also relies on its White Paper (CSPI exh. 1) and exhibits 3 through 7 to the White Paper. examined the relationship between carotenoids and disease and concluded that there was insufficient evidence to recommend specifically the consumption of carotenoids, except to encourage the consumption of fruits and vegetables (61 FR 3118 at 3148). CSPI does not challenge this fact.

[10] CSPI's objection and hearing request on this point also refer to an article published by Dr. Edward Giovannucci addressing the association

[11] In fact, CSPI's own documents demonstrate that there is no conflict as to the official statements of the NCI regarding carotenoids because Dr. Ziegler acknowledges that she does not speak on behalf of the NCI (even though her two letters are written on NCI letterhead). (CSPI exh. 10, letter dated January 21, 1996, p. 1).

[12] These articles are the only specific data identified by CSPI to support its second objection.

[13] CSPI claims that FDA, the OWG, and the FAC ignored certain data on carotenoids. Importantly, however, the two journal articles cited by CSPI were published in a supplement to the December 1, 1995, issue of the *American Journal of Clinical Nutrition*. The FAC/OWG meeting was held November 14 through 17, 1995, and CSPI presents no evidence that these articles were even available at the time of the meeting. In fact, these two articles were not submitted to FDA until December 22, 1995.

cancer risk,[15] and CSPI does not identify any other potential health benefit of carotenoids established by this article. Similarly, the second publication (Bertram, J. S. and H. Bortkiewicz, ''Dietary Carotenoids Inhibit Neoplastic Transformation and Modulate Gene Expression in Mouse and Human Cells,'' *American Journal of Clinical Nutrition*, 62:1327S–1336S, 1995, at 1328S.), notes that the investigators' results simply provide ''a *possible* mechanistic basis for the activity of carotenoids as chemopreventive agents (emphasis added).'' Moreover, citing this second publication, CSPI asserts that ''carotenoids affect intercellular communications'' (CSPI obj. at p. 20, footnote 19). However, CSPI does not demonstrate how the effect of carotenoids on intercellular communications supports its assertion that carotenoids are beneficial to health.[16] Accordingly, FDA is denying CSPI's hearing request on this issue (§ 12.24(b)(3)).[17]

CSPI's second argument to support its position that FDA erroneously concluded that there is no demonstrated health benefit of carotenoids, except the provitamin A function of beta-carotene, is that the agency wrongly insisted on randomized trials to establish the role of carotenoids in health. CSPI bases this allegation on the fact that FDA quoted Dr. Alvan Feinstein in the preamble to the 1996 final rule. CSPI implies that FDA relied on Dr. Feinstein and thus, ignored evidence in the record that establishes a beneficial role of carotenoids in human health. In addition, CSPI claims that Dr. Feinstein is a ''debunker'' and he, and his views, lack credibility.

These allegations are not adequate to justify a hearing on this issue for three reasons. First, CSPI quotes Dr. Feinstein out of context. Contrary to CSPI's claim, Dr. Feinstein did not ''insist'' on randomized trials. Instead, Dr. Feinstein described certain limitations of epidemiologic studies (studies such as those cited by another witness, Dr. Meir Stampfer), including the fact that it is difficult to draw conclusions about cause and effect relationships from such studies (61 FR 3118 at 3147 to 3148), a conclusion not directly challenged by CSPI. Thus, FDA is denying CSPI's hearing request on this point because a hearing will not be granted where the information to support the factual conclusion urged is unreliable (§ 12.24(b)(2)). Second, CSPI asserts that Dr. Feinstein failed to acknowledge that the test methods he advocated might not be meaningful for dietary carotenoids. Because CSPI offers no evidence to suggest that these methods are not appropriate and does not show how, if at all, prevailing on this factual issue would change the outcome of the rulemaking, FDA is denying a hearing on this issue (§ 12.24(b)(2) and (b)(4)). Finally, in reaching its position on carotenoids, FDA considered all the comments, data, and information that the agency had received on carotenoids, including information from epidemiological studies (61 FR 3118 at 3149). FDA's position on the carotenoids issue is not inconsistent with the findings of the epidemiological studies relied upon by CSPI (61 FR 3118 at 3149). Thus, even if Dr. Feinstein's views were shown to be incorrect and CSPI prevailed on this issue, the outcome of the ruling would not be altered. Therefore, FDA is denying CSPI's request for a hearing on this issue (§ 12.24(b)(4)).

2. Does Consumption of Olestra Cause a Harmful Depletion of Carotenoids?

In its second objection and request for a hearing, CSPI asserts that consumption of olestra likely would cause major depletions of serum levels of carotenoids and that this depletion could be harmful because carotenoids have beneficial properties.[18] CSPI also asserts that even a 5 to 10 percent reduction in serum levels of carotenoids could be harmful. CSPI offers several arguments to support this portion of its objection.[19]

First, CSPI asserts generally that the amounts of olestra consumed are sufficient to cause major depletions of carotenoids, referring to ''the section [above] on consumption estimates.'' (CSPI obj. at p. 24.) However, there is no such section in CSPI's submission.[20] Moreover, CSPI's objection did not offer any facts to contradict FDA's conclusion in the final rule that the magnitude of olestra's effects on carotenoid absorption are likely to be within the range of normal variation (61 FR 3118 at 3149). Accordingly, FDA is denying CSPI's challenge to the agency's determination that any depletion of carotenoids by olestra consumption would be minor because a hearing on a factual issue will not be granted in the absence of specifically identified, available evidence to support the requestor's position (§ 12.24(b)(2)).

CSPI also challenges FDA's conclusion on the magnitude of carotenoid depletion by asserting that patterns of consumption of olestra will not prevent such depletion. In particular, CSPI asserts that P&G's depletion studies only measured the status of beta-carotene and thus, the full impact of olestra consumption on carotenoids was not assessed. However, CSPI did not submit or otherwise specifically identify evidence to establish that olestra's effect on beta-carotene was not representative of the additive's effect on carotenoids generally. Moreover, CSPI does not demonstrate how resolving this particular issue in its favor will alter the outcome of this proceeding. Accordingly, FDA is denying CSPI's objection and hearing request (§ 12.24(b)(2) and (b)(4)).

CSPI also claims that FDA erroneously relied on data presented by P&G on patterns of consumption when the agency concluded that olestra's effects on carotenoid absorption would not be harmful. CSPI did not present

[15] CSPI states that ''carotenoids reverse oral leukoplakia in rats.'' (CSPI obj. at p. 20, footnote 19.) However, the Garewal article cited by CSPI in support of this statement presents no data on the reversal of oral leukoplakia in rats.

[16] As noted previously, in the 1996 final rule, FDA concluded that the variation in serum levels of carotenoids associated with olestra consumption is within the normal range, given diet variations and the bioavailability of carotenoids, a conclusion not addressed directly by CSPI. In view of this unchallenged conclusion, the Bertram and Bortkiewicz paper, id. at 1333S–1334S, appears to support a finding of no harm from olestra's effects on carotenoid levels of consumers of olestra-containing food. ''Our demonstration that dietary carotenoids can inhibit neoplastic transformation and modulate the expression of gene products in both human and mouse cells implies that these ubiquitous compounds have hitherto unknown properties. Moreover, these effects were produced at micromolar concentrations that are within the physiologic range * * * ''

[17] Indeed, the paper by Bertram and Bortkiewicz is consistent with FDA's conclusion that the available evidence demonstrates an association between a diet rich in fruits and vegetables and reduction in the risk of certain diseases. ''Many epidemiologic studies have shown a consistent inverse correlation between consumption of foods rich in carotenoids * * * and future risk of cancer.'' (Id. at 1327S.)

[18] To the extent that CSPI contends that there is a lack of reasonable certainty of no harm from olestra's depletion effect on carotenoids, CSPI's hearing request is denied because whether a food additive is safe for its intended use (i.e., whether there is a reasonable certainty of no harm) is a question of law to be decided based on the facts established in the record. Under § 12.24(b)(1), a hearing will not be granted on issues of policy or law.

[19] It is important to note that depletion of serum carotenoid levels is relevant only if carotenoids themselves are shown to have human health benefits. As discussed in the previous section, CSPI's objection and hearing request fails to establish any genuine issue of material fact regarding FDA's conclusion that there is no demonstrated health benefit of any carotenoid except the provitamin A function of beta-carotene. Thus, this portion of CSPI's objection and hearing request is also denied because resolution of this issue in CSPI's favor would not alter the outcome of this proceeding (§ 12.24(b)(4)).

[20] It is possible that CSPI intended to reference the discussion in its White Paper (CSPI exh. 1) on consumption estimates, but no such reference was given (§ 12.24(b)(2)).

any specific information to dispute P&G's consumption pattern data; instead, CSPI simply asserted that other consumption patterns were likely.[21] Mere allegations of this type do not require that a hearing request be granted (§ 12.24(b)(2)). Moreover, although the petitioner did present information on snack consumption patterns and their effects on carotenoid depletion, FDA did not rely on this information in its safety determination (61 FR 3118 at 3149 at footnote 51). Accordingly, even if CSPI were to prevail on this factual issue, the outcome of this rulemaking would not be altered and thus, FDA is denying this portion of CSPI's objection and hearing request (§ 12.24(b)(4)).[22]

Finally, CSPI relies on the proceedings of a January 1996 workshop at the Harvard School of Public Health to support its view that olestra's depletion of carotenoids will be harmful.[23] In particular, CSPI cites estimates of the possible impact on the public health that would allegedly result from the wide-spread use of olestra in snack foods, which estimates were presented at the Harvard meeting (CSPI exh. 13). CSPI contends that if FDA had correctly understood the Harvard meeting estimates regarding carotenoid depletion, it is doubtful that olestra would have been approved[24] (CSPI obj. at 28).

FDA is denying CSPI's request for a hearing on this point because the data and information submitted are insufficient to establish that olestra's depletion of carotenoids will be harmful (§ 12.24(b)(3)). First, the comments of those preparing the estimates undermine their validity. In particular, in their letter transmitting the estimates, Drs. Willett and Stampfer readily acknowledge that the estimates are not based on an established cause and effect relationship and are speculative in that they are based on a number of assumptions (CSPI exh. 13, pp. 1, 3, and 4). Moreover, in the preamble to the final rule, FDA outlined several considerations to be addressed in determining whether olestra's effect on carotenoids will be harmful, including the other factors that influence carotenoid utilization (carotenoid stability, bioavailability, and absorption) and whether serum carotenoid levels are an adequate indicator of carotenoid availability (61 FR 3118 at 3148 to 3149). Neither CSPI nor the scientists who prepared the Harvard estimates addressed these considerations. Accordingly, the Harvard estimates in and of themselves are not adequate to demonstrate that olestra's effect on carotenoid levels will be harmful.

B. Vitamin K

In its third objection and request for a hearing, CSPI challenges FDA's conclusion that supplementation of olestra with vitamin K will offset the additive's effect on vitamin K and thereby prevent adverse health effects associated with vitamin K depletion in olestra consumers. CSPI claims that FDA's decision on this point is erroneous for two reasons. First, CSPI asserts that a decision on olestra's safety should not have been made in the absence of a study of the interaction between Coumadin (a widely used anti-coagulant) and olestra. Importantly, however, CSPI did not specifically identify any available data or information in the record to demonstrate why data from a study of olestra's effects on Coumadin therapy are necessary.[25] Accordingly, FDA is denying CSPI's request for a hearing on this question because it is merely an unsupported allegation (§ 12.24(b)(2)). Second, CSPI asserts that olestra supplemented with vitamin K may have adverse effects on bone formation. Once again, CSPI fails to specifically identify any data or information that could be used to resolve this question. Accordingly, FDA is denying CSPI's objection and hearing request on this point (§ 12.24(b)(2)).

C. GI Effects

In its fourth objection and request for a hearing, CSPI asserts that in a significant proportion of individuals olestra causes GI disturbances, including diarrhea, that these disturbances are adverse health effects, and that these GI disturbances are of sufficient concern to warrant a finding that there is no ''reasonable certainty of no harm.'' CSPI also asserts that FDA's analysis of the data from two 8-week studies obscured the detection of trends between olestra consumption and GI symptoms reported.

1. Are the Observed GI Symptoms Adverse Health Effects?

In its objection and request for a hearing, CSPI asserts that FDA erred by concluding that certain GI effects of olestra (such as anal leakage, underwear staining, and oil-in-the-toilet) are not relevant to the question of the safety of olestra.[26] In particular, CSPI asserts that these olestra-related effects can have an ''adverse effect on people's lives and interfere with their daily activities'' and thus implies that FDA should have considered them in determining olestra's safety. In support of this objection, CSPI relies heavily on the proceedings before the OWG and the FAC (such as the testimony of Dr. Ian Greaves and Ms. Rosie Schwartz.)[27]

At its core, CSPI's fourth objection concerns the meaning of the statutory standard of ''safe,'' section 409(c)(3)(A) of the act, and, specifically, what is

[21] For example, CSPI claims that the ''great popularity of tomato-based salsa in recent years suggests that many consumers would consume tortilla, corn, or potato chips with this carotenoid-rich dip, with or between meals.'' (CSPI obj. at p. 24.) Similarly, CSPI asserts that ''consumption of savory snacks is likely to increase if olestra snacks become generally available.'' (CSPI obj. at p. 25.) CSPI does not identify any particular information or evidence in the record to support either assertion (§ 12.24(b)(2)).

[22] In questioning the petitioner's evidence on consumption patterns, CSPI also challenges the hypothesis of Dr. Penny Kris-Etherton, a P&G consultant, that consumption of olestra-containing foods between meals has no effect on carotenoid depletion. Importantly, however, CSPI fails to identify any credible data or information to support its assertion that this hypothesis is ''unproven and doubtful.'' (CSPI obj. at p. 25.) Thus, FDA is denying CSPI's request for a hearing on this point (§ 12.24(b)(2)).

[23] CSPI raises two spurious arguments regarding carotenoids, neither of which is adequate to justify a hearing on this issue. Specifically, CSPI criticizes the agency because no one from FDA's ''senior level'' attended the meeting, and faults the summary prepared by the FDA staffer who did attend the meeting. In addition, CSPI claims that Dr. Stampfer was given only a limited period to speak during the November 1995 FAC meeting and that his schedule precluded him from staying for the afternoon session when he could have expanded his comments. Neither of these arguments raises a material question of fact that requires a hearing (§ 12.24(b)(1)).

[24] CSPI also asserts that at the Harvard meeting, P&G employee Dr. Keith Triebwasser ''stated that he could not assume that depletion of carotenoids was harmless,'' citing a letter from Dr. Alberto Ascherio (CSPI exh. 15). Importantly, however, Dr. Ascherio does not directly quote or even paraphrase Dr. Triebwasser; instead, the letter contains Dr. Ascherio's characterization of what Dr. Triebwasser said. (Dr. Ascherio stated: ''The responses of the gentleman from Procter & Gamble made it clear that there is no scientific evidence to support [a conclusion that depletion of carotenoids will not harm people's health.]'' Again, the information tendered by CSPI is insufficient to justify the factual conclusion urged and thus, FDA is denying CSPI's request for a hearing on this issue (§ 12.24(b)(3)).

[25] In fact, this concern was raised at the November 1995 FAC meeting and addressed in the preamble to the final rule. One witness, Dr. John Suttie, testified that vitamin K intake can vary from day-to-day by three or four-fold and that diet is not usually a primary factor of concern with anti-coagulation therapy. Accordingly, he concluded that changes due to consumption of vitamin-K compensated olestra would likely be within the normal range of dietary variation (61 FR 3118 at 3147).

[26] In its fourth objection, CSPI also claims that consumption of olestra causes diarrhea, which CSPI claims is an adverse health effect. However, CSPI does not further address diarrhea in this objection.

[27] As part of their objections, CSPI criticizes a P&G market research study, and the OWG's alleged reliance on it. FDA told the OWG that the agency had not used data from the market research study in its analysis. Moreover, FDA did not rely on the study in determining that olestra is safe. CSPI concedes as much (CSPI obj. at p. 33).

''harm'' for purposes of that standard.[28] CSPI has not demonstrated that FDA wrongly decided any genuine and substantial issue of fact concerning the GI effects of olestra. Rather, CSPI disagrees with FDA's application of the statutory safety standard, alleging that FDA ignored certain effects of olestra consumption that CSPI claims preclude a finding of safety.[29] In the absence of a genuine and substantial issue of fact, a hearing need not be granted because a hearing is not needed to settle issues of law (§ 12.24(b)(1)).

2. Did FDA Err in Pooling Certain GI Data for Analysis?

In its objection and request for a hearing, CSPI asserts that FDA's analysis of two 8-week studies was inappropriate because the analysis pooled the data from both studies.[30] CSPI asserts that pooling these data was inappropriate because different formulations of olestra were used in the two studies. CSPI also objects to pooling the data because it would allegedly diminish the ability to detect trends in one study.[31]

FDA is denying CSPI's request for a hearing on this issue because the organization failed to identify specifically any reliable evidence to support either of its factual allegations. That is, CSPI did not identify any data or information to support its claim that different olestra formulations precluded the pooling of the data from the two 8-week studies[32] (§ 12.24(b)(2)). Moreover, even if the data from the two studies should have been analyzed separately, as asserted by CSPI, that analysis would not have changed the outcome of this proceeding because the results would be the same whether analyzed separately or pooled (61 FR 3118 at 3153 to 3154). Accordingly, FDA is denying CSPI's hearing request on this point (§ 12.24(b)(4)).

D. Adequacy of Olestra's Label Statement[33]

In its fourth objection and request for a hearing, CSPI challenges the label statement required by the 1996 final rule, claiming that it is not sufficient to protect the public from adverse effects associated with consumption of olestra. CSPI also claims that the portion of the label statement regarding the nutritional effects of olestra consumption is inadequate. CSPI offers several specific criticisms in support of these general allegations. As shown in the following sections D.1 and D.2, none of CSPI's specific allegations raises a question of material fact that requires a hearing. In analyzing CSPI's objection regarding the olestra label statement, it is critical to recognize that FDA did not require the statement to ensure olestra's safe use (61 FR 3118 at 3160). Instead, the label statement was designed to prevent olestra-containing foods from being misbranded.

1. Label Statement Regarding GI Effects

CSPI alleges that the GI effects portion of the olestra label statement is not adequate for three reasons. First, CSPI claims that the word ''laxative'' should be used to describe olestra's GI effects. Second, CSPI asserts that all GI effects of olestra should be disclosed, including diarrhea, underwear staining, oil-in-toilet, and anal leakage because they ''might distress'' consumers of olestra-containing snacks. Third, CSPI claims that the GI portion of the olestra label statement ought to advise consumers to seek medical treatment if the effects of olestra consumption do not subside within 48 hours of consumption. Importantly, CSPI does not dispute any facts that underlie FDA's decision regarding the label statement. Fundamentally, CSPI's allegation in this instance is that olestra-containing foods are misbranded in the absence of these three pieces of information. Whether foods that bear the olestra label statement set out in § 172.867 are misbranded is a question of law. Thus, FDA is denying CSPI's hearing request on this point because a hearing will not be granted on issues of law (§ 12.24(b)(1)). Moreover, even if such questions are questions of fact, CSPI did not specifically identify any data or other information to support its position. Thus, on this basis, FDA is denying this hearing request (§ 12.24(b)(2)).

2. Label Statement Regarding Absorption of Nutrients

CSPI also challenges that portion of the olestra label statement that relates to absorption of nutrients. CSPI asserts that this portion of the olestra label statement has several deficiencies. Specifically, CSPI claims that the word ''compensation'' should be substituted for ''added,'' that carotenoid depletion resulting from olestra consumption should be disclosed, that consumers should be advised that there are ''no data'' about the vitamin K repletion, and that the statement should begin with the word ''warning'' and appear on the front of the package. Again, in presenting this portion of the fifth objection, CSPI fails to identify specifically any underlying factual dispute that could be resolved by a hearing. The question of whether olestra-containing foods that bear the required label statement are misbranded is a question of law. Accordingly, FDA is denying CSPI's request for a hearing on this point because a hearing will not be granted on issues of law (§ 12.24(b)(1)).

E. Alleged Procedural Problems in the Olestra Proceeding

In its fifth objection and hearing request, CSPI claims that there were a number of problems with the procedures utilized by FDA to reach a decision about the safety of olestra. CSPI raises the following six complaints: (1) Its White Paper was not provided promptly enough to the members of OWG and FAC, (2) the presentation by FDA's staff to OWG did not adequately address carotenoids, (3) the 1996 final rule unfairly described support for olestra and discounted letters from CSPI members opposing olestra's approval, (4) the petitioner engaged in a letter writing campaign to gain olestra's approval, (5) FDA discounted the opinions of CSPI's experts and ignored the ''scientific information'' in the letters from these experts, and (6) members of OWG and FAC were biased. As is the case with its fourth objection and hearing request, CSPI specifically identifies no factual issue underlying any of its six procedural complaints. In such circumstances, a hearing is not

[28] As noted in the preamble to the final rule, ''safe'' means ''proof of a reasonable certainty of no harm,'' a standard drawn from the legislative history of section 409 of the act; harm in this context means ''hazardous to the health of man or animal.'' (61 FR 3118 at 3119 to 3120.) FDA concluded that ''an effect is harmful if it affects health, not if it is simply an undesirable or unexpected effect that has no adverse health consequences.'' (61 FR 3118 at 3120.)

[29] Contrary to CSPI's assertions, FDA's evaluation of the evidence in the record did address a broad range of GI symptoms, including loose stools, cramping and bloating, fecal urgency, oil-in-the toilet, and anal leakage (61 FR 3118 at 3152 to 3159). In applying the statutory standard of ''safe,'' FDA concluded that none of these effects is harmful to health (61 FR 3118 at 3159). CSPI's objection identifies no factual evidence to contradict this conclusion.

[30] FDA explained that pooling the data from the two studies increased the number of study subjects, thereby increasing the power of the data to detect trends (61 FR 3118 at 3153).

[31] In its first objection, CSPI alludes to the pooling issue but does not elaborate on or support its challenge to pooling data (CSPI obj. 1 at p. 16).

[32] In fact, although the two formulations of olestra differed in the degree of stiffness, each was within the range of stiffness permitted by the 1996 final rule (§ 172.867(b)(14)).

[32] In fact, although the two formulations of olestra differed in the degree of stiffness, each was within the range of stiffness permitted by the 1996 final rule (§ 172.867(b)(14)).

required (§ 12.24(b)(1)). Accordingly, FDA is denying CSPI's fifth objection.[34]

F. Alleged Absence of Reasonable Certainty of No Harm

As noted, CSPI filed six objections to FDA's decision to approve olestra, including a general objection (CSPI obj. 1) that asserts that the additive does not meet the statutory standard of ''reasonable certainty of no harm.''[35] Many of the assertions of CSPI's general objection mirror the allegations of the more specific objections (CSPI obj. 2 through 5), which FDA has considered previously and denied.[36] Even standing alone, however, CSPI's first objection must be denied for several reasons.

Second, although CSPI's first objection is the longest of the six, it is almost exclusively a series of allegations[38] without any specifically identified and available evidence to support them.[39] That is, CSPI did not cite specific data or other factual information in the record to demonstrate the validity of its challenges to FDA's conclusions (CSPI obj. at pp. 8 through 18). Thus, CSPI's first objection is denied for a second, separate reason because a hearing will not be granted on the basis of mere allegations (§ 12.24(b)(2)). [40]

Third, CSPI asserts that the quality of certain studies relied upon by FDA is ''spotty at best,'' and claims that these tests were ''critical'' to the safety evaluation of olestra (CSPI obj. at p. 13). In support of this claim, CSPI cites parts of the 1996 final rule and supporting memoranda discussing the limitations of certain studies.[41] (CSPI obj. at p. 12, footnote 8). Importantly, however, CSPI does not demonstrate how the outcome of this proceeding would have been different if, due to these alleged quality problems, FDA had not been able to rely on these ''certain studies'' in determining the safety of olestra. Thus, FDA is denying CSPI's first objection because a hearing will not be granted on factual issues that are not determinative of the action requested[42] (§ 12.24(b)(4)).

Fourth, CSPI challenges FDA's conclusion that the GI effects seen in P&G's 8-week studies are not harmful health effects. As part of this challenge, CSPI criticizes the size of the two 8-week studies and asserts that a larger study would likely have shown statistical significance at the 8 grams/day (g/d) dose, citing the comments of David Allison, Ph.D., a statistician and consultant to FAC (CSPI obj. at pp. 13 through 14 and footnote 11). CSPI fails to note that Dr. Allison concluded his statement by saying that whether ''to make a great deal of argument on is there or isn't there an effect at the 8 g dose is really a misleading kind of argument because it seems almost certain that there is but, rather, is it an important effect, an effect that is clinically meaningful * * *'' (transcript of FAC meeting, November 16, 1995, at p. 52). In the same footnote, CSPI claims that Dr. Marvin Schneiderman performed a trend test which demonstrated an increase in incidence of ''gastrointestinal disturbances above the placebo level at 8 g/day.'' In fact, Dr. Schneiderman's analysis concerned only anal leakage, not all GI effects (CSPI exh. 14 at p. 2). FDA found that anal leakage is not a health hazard (61 FR 3118 at 3154), a fact not disputed by CSPI in its objections and hearing requests. Accordingly, FDA is denying CSPI's objection on this point because a hearing will be denied where the data and information submitted are insufficient to justify the factual determination urged (§ 12.24(b)(3)).

Finally, CSPI disputes FDA's conclusion that the ''diarrhea'' experienced by olestra consumers is not clinical diarrhea and thus, not an adverse health effect.[43] In particular, CSPI asserts that ''weight and water content of diarrheal stools was increased over those of loose and normal stools in subjects eating 20 g/day of olestra.'' (CSPI obj. at p. 16). Importantly, however, CSPI does not cite a reference to support this conclusion. In the absence of specifically identified and available evidence to support a disputed fact, a hearing must be denied (§ 12.24(b)(2)). Moreover, CSPI does not explain how a finding of increased stool weight among olestra consumers would alter FDA's conclusion that olestra's GI effects are not harmful to health.[44] Thus, FDA is denying a hearing on this issue because it is not determinative of the question at issue (§ 12.24(b)(4)). Likewise, although FDA concluded that increased water content of stools could be an indicator of true diarrhea (61 FR 3118 at 3158), FDA concluded that in the study in question, the data ''regarding stool water concentration—expressed as a percent of stools by weight—suggests that the stool water concentration of subjects having diarrhea during the olestra 20 g/d period did not differ from that of their nondiarrheal stools during the placebo period'' (61 FR 3118 at 3171; Ref. 88). Thus, even if CSPI intended to rely on Ref. 88 to support this allegation, the memorandum does not establish that

[34] In fact, CSPI raised most of these complaints in comments to FDA prior to olestra's approval, and the agency addressed each such complaint in the preamble to the final rule (61 FR 3118 at 3163 to 3165). CSPI's fifth objection and hearing request does not dispute FDA's resolution of these challenges in the final rule.

[35] The act prohibits FDA from approving a food additive if it has not been shown to be ''safe'' for its intended use, section 409(c)(3) of the act; FDA's regulation, relying on the legislative history of the Food Additives Amendment of 1958, defines ''safe'' as ''a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use. It is impossible in the present state of scientific knowledge to establish with complete certainty the absolute harmlessness of the use of any substance.'' (§ 170.3(i) (21 CFR 170.3(i)).)

First, CSPI's first objection challenges FDA's finding that olestra is safe for use in savory snacks.[37] As noted, resolving the question of olestra's safety requires the application of the legal standard (''safe'') as defined by FDA's regulations (''reasonable certainty of no harm'') to a set of facts. As such, the question of whether olestra is safe for its intended use is a question of law, not fact. Accordingly, FDA is denying CSPI's first objection because a hearing will not be granted on issues of policy or law (§ 12.24(b)(1)).

[36] In these circumstances and for reasons of economy, FDA does not restate its analysis and basis for denial of the specific objections.

[37] CSPI asserts that FDA's approval of olestra is ''artibrary and capricious'' and thus erroneous (CSPI obj. at p. 12). In fact, the standard of review for a food additive approval is ''a fair evaluation of the entire record * * *'' (section 409(g)(2) of the act). CSPI provides no evidence that FDA did not conduct a fair evaluation of the entire record.

[38] For example, in its discussion of the ''Inadequate Safety Base'' for olestra, CSPI notes Dr. Klish, a witness at OWG, testified that at 1 year, children's GI tracts are the same as adults and therefore, data from adults can be extrapolated to children. On this subject CSPI simply asserts, ''Life experience, however, does not support that view. After all, why do one- and two-year-olds experience 'toddlers' diarrhea' * * * ?'' (CSPI obj. at p. 8.)

[39] In the carotenoids portion of its first objection, for example, CSPI refers to a ''selection of letters from noted scientists opposing the approval of olestra'' (CSPI exh. 8.) Notably, however, CSPI does no more to identify the specific facts these experts dispute or to specify the data and other information on which these experts rely (§ 12.24(b)(2)).

[40] It is not surprising that CSPI's allegations are unsupported because, in some cases, the allegations are clearly false. For example, CSPI claims that ''the FDA staff declined to consider'' certain data regarding carontenoids (CSPI obj. at p. 6). In fact, FDA devoted a significant amount of attention to the carotenoids issue (61 FR 3118 at 3147 to 3149 and 3161), but ultimately reached a different conclusion than that urged by CSPI.

[41] In particular, CSPI quotes excerpts from the 1996 final rule in which FDA identified certain limitations of these studies of olestra. Identifying such limitations is consistent with FDA's obligation to make a ''fair evaluation of the data'' in the record when determining olestra's safety (section 409(c)(4) of the act).

[42] For example, CSPI offers several criticisms of a P&G marketing study which the company presented to illustrate consumption patterns for savory snacks (CSPI obj. at p. 13, footnote 10). In fact, as CSPI noted (CSPI obj. at p. 33), FDA told OWG that FDA had not relied on data from this study in its safety evaluation (Transcript of the FAC meeting, November 16, 1995, at p. 55).

[43] CSPI refers to a December 26, 1995, memorandum of Karl Klontz, M.D., erroneously describing it as Ref. 87 to the final rule (CSPI obj. at p. 16, footnote 14). In fact, Dr. Klontz's December 26, 1995, memorandum is Ref. 88 of the final rule (61 FR 3118 at 3171).

the subjects' stool water content increased when they consumed olestra. Thus, FDA is denying CSPI's hearing on this point (§ 12.24(b)(3)).

V. Summary and Conclusion

The act requires that a food additive be shown to be safe prior to marketing under section 409 of the act. Under § 170.3(i), a food additive is ''safe'' if there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use. In the agency's January 30, 1996, final rule approving olestra, FDA concluded that the studies conducted to establish the safety of this additive demonstrate that olestra is safe for its intended use in savory snacks.

The petitioner has the burden to demonstrate the safety of the additive in order to gain FDA approval. Nevertheless, once FDA makes a finding of safety in an approval document, the burden shifts to an objector, who must come forward with evidence that calls into question FDA's conclusion (*American Cyanamid Co.* v. *FDA*, 606 F2d. 1307, 1314–1315 (D.C. Cir. 1979)).

Despite its many allegations, CSPI has not established that FDA overlooked significant information in the record in reaching its conclusion that olestra is safe. In such circumstances, FDA has determined that the objections do not raise any genuine and substantial issue of fact that would justify an evidentiary hearing on any of the objections raised (§ 12.24(b)). Accordingly, FDA is overruling CSPI's objections and is denying CSPI's requests for a hearing in their entirety.

Dated: July 23, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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