

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.

FOR FURTHER INFORMATION CONTACT:

Mary Ditto, Center for Food Safety and Applied Nutrition (HFS-255), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 202-418-3102.

SUPPLEMENTARY INFORMATION:

Table of Contents

- I. Background and Procedural History
- II. Standard for Granting a Hearing
- III. Objections and Supporting Documents Submitted by Center for Science in the Public Interest (CSPI)
- IV. Analysis of Objections and Response to Hearing Requests
 - A. Carotenoids
 - 1. Are Carotenoids Beneficial to Health?
 - 2. Does Consumption of Olestra Cause a Harmful Depletion of Carotenoids?
 - B. Vitamin K
 - C. Gastrointestinal (GI) Effects
 - 1. Are the Observed GI Symptoms Adverse Health Effects?
 - 2. Did FDA Err in Pooling Certain GI Data for Analysis?
 - D. Adequacy of Olestra's Label Statement
 - 1. Label Statement Regarding GI Effects
 - 2. Label Statement Regarding Absorption of Nutrients
 - E. Alleged Procedural Problems in the Olestra Proceeding
 - F. Alleged Absence of Reasonable

Certainty of No Harm
V. Summary and Conclusion

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.