

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. 2000F-0792]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to remove the requirement for the label statement prescribed specifically for savory snack products that contain olestra. This action is in response to a petition filed by the Procter and Gamble Co.

DATES: The regulation is effective August 5, 2003. Submit written objections and requests for a hearing by September 4, 2003.

ADDRESSES: Submit written objections to the Division of Dockets Management (HFA-305), Food and Drug Administration, rm. 1061, 5630 Fishers Lane, Rockville, MD 20852. Submit electronic objections to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Mary D. Ditto, Center for Food Safety and Applied Nutrition (HFS-255), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 202-418-3102.

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I. Subject of Petition

In a notice in the **Federal Register** of March 3, 2000 (65 FR 11585-11586), FDA announced that a food additive petition had been filed by the Procter & Gamble Co., 6071 Center Hill Ave., Cincinnati, OH 45224 (P&G, the petitioner) proposing that the food additive regulations be amended in § 172.867 *Olestra* (21 CFR 172.867) to remove the requirement for the label statement prescribed in § 172.867(e).

II. Background

In the **Federal Register** of January 30, 1996 (61 FR 3118, "the 1996 final rule") FDA announced the approval of olestra for use as a fat substitute in prepackaged ready-to-eat savory snacks. Olestra is the common name for a mixture of substances formed by chemical combination of sucrose with six, seven, or eight fatty acids. The fatty acids, bound to sucrose by ester bonds, are derived from edible fats and oils.

Olestra is essentially not absorbed or metabolized and passes unchanged through the gastrointestinal (GI) system (61 FR 3118 at 3125-3127). Therefore, olestra has the potential to affect GI physiology and function. Additionally, because of olestra's physical properties, fat-soluble nutrients present in olestra-containing foods¹ or other foods in the GI tract at the same time as olestra can partition into olestra and pass through the GI tract without being absorbed by the body. Therefore, FDA required the addition of fat-soluble vitamins A, D, E, and K, to savory snacks containing olestra to compensate for any inhibition of absorption by olestra (§ 172.867(d)).

At the time of the 1996 final rule, FDA concluded that, to avoid being misbranded within the meaning of sections 201(n) and 403(a)(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(n) and 343(a)(1)), olestra-containing foods would need to bear a label statement to inform consumers about possible effects of olestra on the GI system. The label statement also would clarify that the added vitamins were present to compensate for any nutritional effects of olestra, rather than to provide enhanced nutritional value. Therefore, the 1996 final rule required that foods containing olestra be labeled with the following statement in a boxed format: "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)). FDA included the term "other nutrients" because any nutrient that is as lipophilic as these vitamins would also be affected, although there was no known basis for adding such nutrients back. The agency also required that the statement be made in a standardized format that specifies, among other things, type style and type size, and that

¹ Olestra has only been approved for use as a fat substitute in savory snacks. Throughout this document, we refer to olestra-containing foods to include those savory snacks made with olestra as well as other olestra-containing foods used in the preapproval studies for olestra.