

A comment from CSPI to the 1996 final rule suggested that the label should include a statement indicating that the long-term effects of olestra consumption are not known. The comment expressed concern that the human studies were too brief compared to the length of time people will be eating olestra-containing foods and stated that the problems observed in the human and animal studies warrant a broader advisory about the possible long-term effects of olestra consumption. CSPI also stated that labeling should be complemented with point-of-purchase health-hazard information and mass media consumer information campaigns. Comments from manufacturers of baked snacks expressed concern that without clear labeling consumers will believe that olestra-containing foods are as safe as baked snacks.

In comments to the 1996 final rule, CSPI and an individual consumer requested that the label statement be placed on restaurant menus so that diners will not unknowingly consume olestra at a restaurant.

FDA disagrees with these comments. FDA concluded in the 1996 final rule that the use of olestra in savory snacks meets the safety standard for food additives, reasonable certainty of no harm (61 FR 3118 at 3167). The label statement required by the 1996 final rule was never intended to prevent illness or warn against conditions of use that may be harmful as the agency concluded in 1996 that olestra is safe for its intended use in savory snacks even without the label statement. FDA required that olestra-containing foods bear the label statement to provide information about the presence of the vitamins listed in the ingredient statement and about potential nutrient and GI effects of olestra. FDA determined that these statements were necessary at the time to ensure that olestra-containing foods are not misbranded within the meaning of the act (61 FR 3118 at 3168).

Because olestra-containing foods are safe even in the absence of the label statement, olestra-containing foods served in unlabeled containers or in a restaurant do not represent a health risk. FDA has no evidence to confirm that there is a group of individuals who are so sensitive or intolerant to olestra when it is consumed under customary or usual conditions that such consumption presents a health concern or warrants special labeling. In fact, the petitioner's Rechallenge Study shows that when consumers who reported effects that they attributed to olestra, were rechallenged with olestra chips, they were no more likely to report GI

symptoms compared to when they were challenged with triglyceride chips.

G. Allergenicity of Olestra or Olestra-Containing Foods

(Comment 38) A comment from CSPI to the current petition stated that while there is no reason to think that olestra itself causes allergic reactions, the agency or the petitioner should conduct tests to determine whether a contaminant in olestra, or another ingredient in olestra-containing chips, causes allergic reactions because allergic responses were reported. The comment added that FDA cannot design an accurate label statement until such studies have been conducted.

FDA does not agree that allergenicity testing of olestra or olestra-containing foods must be conducted before ruling on this petition. The agency addressed the potential allergenicity of olestra in the 1996 final rule (61 FR 3118 at 3166). Food allergens are generally known to be protein or glycoprotein in nature. Olestra, composed of six, seven, or eight fatty acids esterified to sucrose, is neither a protein nor a glycoprotein and does not contain these substances even as minor constituents. The comment provides no basis to alter FDA's original conclusion that olestra is unlikely to cause allergic reactions.

FDA acknowledges that some reports allege that unspecified allergic reactions or symptoms of allergic reactions were caused by an olestra-containing food. The comment provides no evidence or reason to conclude that the effects reported were caused by olestra. FDA notes that a published article reports that when individuals who reported an allergic reaction to olestra were rechallenged, none of the individuals were found to have a positive response to olestra upon eating olestra-containing potato chips or when given a skin prick test with olestra (Ref. 43).

FDA notes that olestra-containing foods, like non-olestra-containing foods, contain other ingredients that may be allergens to some individuals. Consumers are informed of the presence of such potential food allergens through the product ingredient statement, as is the case for products containing potentially allergenic substances like milk and eggs.

H. Nutrition Labeling and Claims

(Comment 39) A comment from CSPI to the current petition asserted that the amount of olestra contained in snacks should be declared in the Nutrition Facts label. The comment stated that the amount of total fat per serving should be listed with an asterisk pointing to a note stating, "This product contains x grams

of olestra, which is not digested by the body. These figures have been adjusted to reflect that reduced availability." The comment states that the amount of available fat, saturated fat, and polyunsaturated fat would be listed. Alternatively, the comment stated that if the Nutrition Facts label states "Fat 0 g" an asterisk should reference the statement, "Contains x grams of olestra, which is not absorbed by the body."

In a related comment to the 1996 final rule, P&G stated that the amount of olestra per serving should not be included on the label because the presence of olestra is already declared in the ingredient statement and because the position of olestra within the ingredient statement will reflect its predominance based on weight in the food. P&G's comment also stated that there is no precedent for requiring the declaration of the amount of an ingredient on the food label, and that many manufacturers offer consumers access to phone numbers from which they could obtain quantitative information about ingredients.

These comments on the information that should appear on the Nutrition Facts panel of olestra-containing foods fall outside the scope of this document. As stated in the notice of filing, this petition proposed to amend the food additive regulations by removing the requirement for the label statement prescribed in § 172.867(e), the requirement for which is found only in paragraphs (e)(1) through (e)(3).

FDA notes, however, that the current regulation on ingredient labeling (§ 101.4) requires food ingredients to be declared by their common or usual names in the ingredient statement of the food. Accordingly, olestra-containing foods must declare olestra as an ingredient of the food. Olestra's placement in the declaration of ingredients is determined by its predominance based on weight in the food. In addition, § 101.4(e) provides manufacturers with a uniform method to voluntarily declare the percentage of each ingredient in their product (58 FR 2850 at 2865, January 6, 1993).

(Comment 40) A comment from CSPI to the current petition stated that olestra-containing food should not be allowed to use the phrase "fat-free." The comment stated that olestra is a fat; therefore, the term "fat-free" on the label of olestra-containing foods is inaccurate. Instead of using the phrase "fat-free," CSPI suggested that olestra-containing food could declare "no calories from fat" or "contains x grams of olestra." This type of labeling statement would help to differentiate baked snacks from olestra-containing