

snacks. The comment stated that an ounce of baked chips provides an ounce of carbohydrate and protein, whereas an ounce of olestra-containing chips provides only two-thirds to three-fourths an ounce of carbohydrate and protein.

A comment from a potato chip manufacturer to the 1996 final rule stated that olestra-containing foods should not be allowed to declare "fat-free" and "low fat" because the fat content of olestra-fried chips is equal in quantity to that of any standard chip; therefore, the comment concluded that the label statement is misleading.

These comments on the declaration of "fat-free" on 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 the label statement is found only in § 172.867(e)(1) through (e)(3). These comments relate to a requirement found in § 172.867(e)(5).

FDA notes that the agency previously concluded that olestra shall not be considered to be a source of fat or calories for purposes of nutrition labeling or nutrient content claims because olestra is neither a triglyceride nor is it absorbed or metabolized like a fat (§ 172.867(e)(5)).

I. Appearance of the Label Statement

(Comment 41) Comments to both the current petition and the 1996 final rule addressed the appearance of the label statement. Comments from individual consumers and CSPI requested that the label statement be larger, printed in bold type, and placed on the principal display panel of the package to increase its prominence. CSPI stated that many of those who used CSPI's telephone line to report reactions did not see the label statement prior to consumption, and several comments from consumers stated this as well. In its comments to the 1996 final rule, CSPI requested that the label statement be placed far enough from the edges of the container to provide a flat unobscured surface for the wording, that there be sufficient white space around the box to set off the wording within the box, that the label statement be black on a white background, that the size of the text increase as the package size increases, that a prefatory word such as "Notice" precede the label statement, and that the box around the label statement be retained because boxed statements increase the likelihood that consumers will read the statement.

Comments from a trade association to the 1996 final rule stated that the olestra label statement should use general food labeling typography (as described in §§ 101.2, 101.3, and 101.105), like that used for labels on products containing mannitol, sorbitol, and polydextrose. Frito-Lay argued that the appearance requirements of the olestra label should be aligned with those of other substances with similar effects and levels of concern. The comment pointed out that label statements for food additives that are proven to cause serious health problems, such as sulfites (21 CFR 130.9), do not have the stringent requirements for labeling prominence that are required of olestra, which has been determined to be safe. Comments from P&G and a trade association stated that the box around the label statement should be eliminated because it increases concern about the safety of the product. P&G stated that boxed statements are appropriate only when death or very serious illness is a possible outcome of customary or usual use.

As explained previously, FDA has concluded that olestra-containing foods should no longer be required to bear the label statement required by the 1996 final rule. Therefore, the appearance of the label statement is no longer an issue. The label for olestra-containing foods will be required to provide information about the added vitamins A, D, E, and K through an asterisk, in the list of ingredients, referencing the statement "Dietarily insignificant." The prominence and placement of the phrase "Dietarily insignificant" will follow customary practice for other food products (such as §§ 101.60, 101.61, and 101.62) and will appear prominently and conspicuously as specified in § 101.2(c).

J. Labeling for Single-Serving Packages

(Comment 42) Comments from Frito-Lay and a trade association to the 1996 final rule stated that single serving packages of olestra-containing foods should be exempt from the requirement to bear a label statement because the small package of such containers is not compatible with the label statement, and because the portion contained in such packages is so small that the label statement may not disclose a material fact. Frito-Lay recommended that instead of the label statement required on larger packaging, single-serving packages include the statement, "For information on olestra call 1-800-XXX-XXXX."

In contrast, CSPI stated that single-serving packages should be required to bear the label statement because studies

by P&G show that the amount of olestra contained in such packages is sufficient to increase the incidence of GI disturbances.

As explained previously, FDA has concluded that olestra-containing foods should no longer be required to bear a label statement that informs consumers about the potential GI effects of these products. Therefore, whether single-serving containers should be required to bear the label statement is no longer an issue. FDA does not believe that single serving packages should be exempt from the required labeling of added vitamins A, D, E, and K with an asterisk and the phrase "Dietarily insignificant", nor do the comments provide a basis for such an exemption.

K. 1995 and 1998 FAC Meetings

(Comment 43) A comment from CSPI to the current petition criticized the 1995 and 1998 FAC meetings held by FDA. CSPI asserted that the 1995 FAC did not provide objective advice to FDA regarding the approval of olestra.⁷¹ CSPI also stated that the committee did not contain a single expert on carotenoids and that 9 of the 17 committee members who concluded that olestra meets the safety standard of "reasonable certainty of no harm" were affiliated with industry.

CSPI also stated that the conclusions of the 1998 FAC must be considered in light of the fact that the committee did not consider studies conducted prior to January 30, 1996, including those studies that CSPI stated prove that olestra can cause gastrointestinal symptoms and reduce serum carotenoid levels. CSPI also pointed out that the 1998 FAC did not consider the Fecal Parameters Study even though it was provided to FDA after the 1995 FAC meeting. CSPI also stated that reports of GI symptoms such as diarrhea, cramps, and nausea were downplayed at the 1998 FAC because they were not "unexpected" problems and the committee was asked only to consider whether there were any "unexpected" problems associated with olestra.

FDA does not agree that the 1995 FAC provided biased advice. CSPI raised this issue previously and FDA responded in the 1996 final rule (61 FR 3118 at 3164). As stated in the 1996 final rule, FAC members are screened prior to each meeting to determine if they have a conflict of interest with the material to be discussed at the meeting. Committee members are also expected to provide an objective opinion on the information presented. FDA believes that the committee was fairly balanced as

⁷¹ In its comment CSPI cites Ref. 36.