

effect of conditions of use that did not reflect expected intake and thus, do not provide information about the effects of olestra consumption under customary or usual conditions. In contrast, the petitioner's recent Acute Consumption Study, Home Consumption Study, and Rechallenge Study more closely address the factual predicate of the legal standard for requiring special labeling—facts that are material with respect to consequences which may result under the conditions of use prescribed in labeling or advertising or under such conditions of use that are customary or usual (section 201(n) of the act). Thus, FDA concludes that the petitioner's preapproval studies should be considered, but they must be considered in light of the postapproval studies which more directly address whether olestra-related effects warrant special labeling.

During FDA's review of P&G's petition for the use of olestra in savory snacks, FDA assumed that olestra-containing foods may be consumed more frequently than they are presently. For example, when estimating daily intake of olestra from savory snacks, the agency assumed that all savory snacks consumed would be olestra-containing savory snacks (61 FR 3118 at 3125). Such conservative assumptions are likely to over-estimate consumption.

Olestra is currently approved for use as a fat substitute only in ready-to-eat savory snacks. Any additional use will require agency approval through the food additive petition process in accordance with § 171.1 (21 CFR 171.1). When considering the approval of olestra for additional uses, FDA will consider consumers' cumulative exposure to olestra through the currently approved uses (savory snacks) as well as through any additional uses requested.

The question raised by this petition is not simply whether olestra causes GI effects, but whether customary or usual olestra consumption causes GI effects that warrant special labeling. As mentioned previously, while no study can rule out the possibility that olestra may cause GI effects in a small percentage of consumers, the petitioner's postapproval studies do show that customary or usual consumption of olestra-containing savory snacks does not cause GI symptoms with a frequency, severity, or impact on daily activity that warrant special labeling.

(Comment 34) A comment from CSPI to the current petition cited a study (Ref. 42) showing that consumption of 40 g olestra/day resulted in levels of fecal fat commonly observed in patients with

steatorrhea caused by malabsorption syndrome. CSPI quoted the researchers' concerns that physicians may suspect malabsorption syndrome in patients who consume olestra and subject them to unnecessary diagnostic tests. CSPI stated that while the results of the study alone may not warrant label statements they should be factored in with studies demonstrating olestra's effects on nutrient levels and GI symptoms.

Consideration of the study cited by CSPI does not change the agency's decision on this food additive petition. CSPI does not explain how the study should be considered in the context of labeling or why the results warrant special labeling of olestra-containing foods. CSPI provides no reason to believe that customary or usual olestra consumption has resulted in patients having to undergo unnecessary diagnostic tests for malabsorption syndrome or that malabsorption syndrome has been incorrectly diagnosed because of customary or usual olestra consumption.<sup>70</sup> FDA notes that the study cited in the comment serves to alert physicians to the potential effects of olestra consumption on the measurement of fecal fat so that such misdiagnoses may be avoided.

(Comment 35) A comment from CSPI to the current petition addressed a statement that P&G made in its petition that the First Amendment, which includes the right not to speak, may bar the requirement of anything other than material information or information deemed essential under the act to appear on the food label. In its comment, CSPI stated that consumers must be informed of the possible side effects of olestra-containing foods so that they can avoid needless medical treatment or avoid the possibility of suffering side effects altogether. CSPI also stated that the disclosure of potential side effects provides material information and is "reasonably related" to the agency's interest in preventing misleading food labels. Therefore, in CSPI's view, the label statement does not violate the First Amendment right

<sup>70</sup> Subjects in the study cited by CSPI were fed 40 g olestra per day for 6 days. Based on the agency's preapproval estimate of olestra consumption, this level of olestra consumption is unlikely to be achieved under customary or usual consumption conditions. FDA's preapproval estimate of chronic daily olestra intake was 7 g/p/d at the 90th percentile snack eater and 20 g/p/d for short-term "high" consumption consumers (61 FR 3118 at 3124–3125). The estimate of chronic daily olestra intake assumes that olestra will be consumed at this level every day. FDA estimated that a "high" short-term consumer would consume olestra at a level equivalent to eating a 2 oz bag of olestra chips each day for 12 weeks (61 FR 3118 at 3124–25).

not to speak, as asserted by the petitioner.

FDA did not rely on the petitioner's First Amendment argument in concluding that olestra-containing products should no longer be required to bear the label statement required by the 1996 final rule. The issue raised by the current petition and the comment is whether olestra-related side effects are consequences of customary or usual olestra consumption that require disclosure in labeling. As stated previously, the agency has concluded that olestra-related side effects do not warrant required labeling because these effects are not consequences of customary or usual olestra consumption, and the comment provides no such data or information to demonstrate the contrary.

(Comment 36) A comment from CSPI to the current petition pointed out that the petition states that FDA may decline to require disclosure of material information when to do so would crowd other important information or confuse consumers. CSPI argued that a label statement revised for increased clarity would not confuse consumers, and snack food packages are large enough to provide a label statement without crowding other important information.

As noted, this final rule requires that the label of olestra-containing foods list vitamins A, D, E, and K in the ingredient statement followed by an asterisk and the phrase "Dietarily insignificant." FDA has determined that, for the remainder of the label statement required by the 1996 final rule, the underlying factual basis no longer exists and thus, is removing the relevant requirement from § 172.867. These changes in the requirements for labeling of olestra-containing foods render moot the issue of "label crowding."

#### *F. Safety of Olestra*

(Comment 37) Several comments from individual consumers to the current petition stated that olestra-containing foods should no longer be sold. One comment stated that olestra-containing foods should no longer be sold because even a more prominent label statement would not prevent illness in those who ingest such products in situations where the products are served in unlabeled containers. These comments relayed GI reactions that were attributed to olestra. A comment from CSPI stated that other countries have not approved petitions for the use of olestra and that such decisions not to approve olestra should provide some guidance as to how a substance like olestra should be regulated.