

of consumers.” CSPI asserted that consumers need information on GI effects so that they can learn to associate olestra with possible symptoms and can avoid olestra in the future if such symptoms occur. CSPI also asserted that olestra’s GI effects are material consequences that may result from customary consumption and that the label statement would be misleading without a statement about GI effects. CSPI asserts that P&G’s two 8-week studies, together with a clinical study published in the *British Journal of Nutrition*<sup>55</sup> (Ref. 34), show an association between consumption of olestra (in the case of P&G) or sucrose polyester (in the case of the study published in the *British Journal of Nutrition*) and GI symptoms. CSPI also stated that the postmarketing studies provide some reassurance that no more than a small percentage of consumers experience GI symptoms.

FDA does not agree that olestra-containing foods should be required to bear a label statement indicating that GI effects may occur in a small percentage of consumers. The standard for determining whether this information must be required on the label is whether the labeling fails to reveal 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 that are customary or usual (section 201(n) of the act). The fact that olestra-containing foods can cause GI effects under conditions such as those in P&G’s two 8-week studies and the study published in the *British Journal of Nutrition* must be considered in light of the data from studies addressing the GI effects associated with customary or usual olestra consumption. As with other foods, GI symptoms may occur in a small percentage of olestra consumers, but the available data show that customary or usual consumption of olestra-containing foods does not cause GI symptoms with a frequency, severity, or impact on daily activity that are different from those from triglyceride snacks. In addition, the agency has determined that consumer perception

studies and tracking surveys show that there is a high degree of public awareness concerning olestra and its potential effects. Based on the minor GI effects associated with customary or usual consumption of olestra-containing foods and the public’s awareness of the potential for olestra to cause GI symptoms, the agency has concluded that olestra-containing foods should not be required to bear a label statement informing consumers of possible GI symptoms resulting from olestra consumption.

(Comment 12) Several comments to the current petition stated that the wording of the GI effects statement should be changed to indicate that symptoms may be “severe.” Many of these comments were from consumers who reported having GI effects that they attributed to olestra. Another comment supported the suggested change by citing consumers’ GI effects reported to CSPI.

Comments from CSPI, individual consumers, and manufacturers of baked, fat-free snacks to the 1996 final rule stated that the wording of the GI effects statement should be changed to describe a greater number of potential side effects<sup>56</sup> and to indicate that the side effects could be “severe.” Several comments also suggested that the label statement should indicate that symptoms occur “commonly.” Some comments cited reports submitted to CSPI and P&G that report severe GI effects after olestra consumption as the rationale for the suggested labeling. CSPI asserted that if all pertinent symptoms are not identified, consumers might continue to eat olestra-containing foods even when GI disturbances are occurring, because many consumers will not make the connection between consumption of the fat substitute and symptoms not specified on the label statement. CSPI reported the results of a telephone survey that showed that 7.4 percent of consumers experienced GI effects or headache after an average of 4.8 exposures to olestra over a 2-month period. CSPI also stated that P&G’s two 8-week studies showed that half of the subjects experienced diarrhea or other symptoms during the study. The comment also reported data from a study conducted by Frito-Lay that showed a 9 percent increase in anal oil leakage associated with olestra

consumption.<sup>57</sup> CSPI compared the labeling for adverse effects caused by drugs to the labeling of olestra related effects, and argued that because olestra is consumed more widely, at greater amounts, and over longer periods of time than drugs, labeling for effects should be more complete and explicit.

In contrast, a comment to the 1996 final rule from P&G opposed a GI effects statement listing all GI symptoms that may possibly occur following olestra consumption. The comment stated that the clinical data show that the digestive effects of olestra are similar to the effects that consumers experience from eating certain other foods and food products (such as products that contain psyllium or wheat fiber) that are not specially labeled. The comment also stated that olestra’s effects are similar to those of other foods that have no impact on daily activities and are not specially labeled.

FDA does not agree that olestra-related GI symptoms should be labeled as “severe.” FDA has no basis for concluding that the GI symptoms caused by olestra are severe when olestra-containing snacks are consumed under customary or usual conditions. Moreover, these comments provide no evidence that any severe symptoms were actually caused by olestra. As noted earlier (section III.B of this document), the reports of the type cited in the comments cannot be used to draw conclusions about cause and effect. Furthermore, the Home Consumption Study and the Acute Consumption Study demonstrate that the GI symptoms caused by customary or usual olestra consumption are not severe. In fact, the petitioner’s postapproval studies show that customary or usual consumption of olestra in savory snacks causes only a minor increase in the frequency of loose stools.

FDA does not agree that the wording of the label statement should disclose a greater number of potential side effects. As described above, the postapproval studies show customary or usual consumption of olestra-containing foods causes only a minor increase in the frequency of loose stools and bowel movements, and no increase in the frequency of abdominal cramps. The results of the studies do not provide evidence that there are other GI symptoms resulting from customary or usual consumption of olestra-containing foods that warrant special labeling.

<sup>55</sup> FDA notes that this study was a double-blind, placebo-controlled, randomized, cross-over trial in which subjects consumed 20 to 40 g sucrose polyester or triacylglycerol per day. Each treatment was administered for three months. The study included measurements of the effect of each treatment on GI symptoms and plasma carotenoid concentrations. The article does not state whether the sucrose polyester used meets the specifications for olestra. Sucrose polyester was incorporated into chips, beefburgers, meat pies, sausages, sausage rolls, fruit pies, milk, margarine, salad cream, fruit dessert, processed cheese, biscuits, peanut butter, cake, crisps, chocolate spread, and chocolate bars.

<sup>56</sup> In its comments, CSPI suggested that symptoms such as diarrhea, loose stools, increased bowel movements, fecal urgency, nausea, gas, cramps, bloating, anal leakage, yellow-orange underwear staining, greasy bowel movements, yellow-orange discoloration of stools, and oil in toilet appear on the label statement.

<sup>57</sup> FDA believes that CSPI is referring to a marketing study conducted by Frito-Lay. Frito-Lay informed FDA that the execution of the study was flawed. FDA relied on data from the petitioner’s safety studies to address the issue of anal oil leakage (61 FR 3118 at 3154–3155).