

GI reactions of a child who had consumed an olestra-containing food.

CSPI submitted comments to the 1996 final rule requesting that the olestra label contain statements directed toward certain populations of consumers. In particular, CSPI stated that the label statement should contain special notification for children and for the elderly because olestra is poorly studied in children and there are inadequate data regarding the possible hazards of olestra consumption over both the long and short terms. The comment also quoted a 1995 FDA review memorandum of the petitioner's preapproval Fecal Parameters Study which expresses concern for two populations not represented in the study, the elderly and young children, because of the potential for increased water loss through the stool of subjects reporting olestra-associated diarrhea (Ref. 22). CSPI also stated that the label of olestra-containing foods should include statements directed toward pregnant women because there are inadequate data regarding the safety of olestra for use by pregnant women. CSPI suggested that the label statement indicate that those with inflammatory bowel diseases, irritable bowel diseases, and malabsorption disorders should contact a physician before eating olestra-containing foods because, in CSPI's opinion, the study of inflammatory bowel disease patients was too small and too brief to determine conclusively that olestra is safe for people with these illnesses.

FDA does not agree that the agency should require olestra-containing foods to bear a label statement directed toward special populations. In the 1996 final rule (61 FR 3118 at 3156–3157), the agency stated its conclusion that olestra was safe for use by children. Three studies submitted in support of the original petition reported GI symptoms in the young. FDA noted that GI symptoms seen in children were similar to those seen in the 8-week studies of adults. FDA concluded that the safety of olestra for use by children could be addressed by extrapolating the GI effects in adults to the young. This approach was fully consistent with the expert views provided by the OWG and the members of the FAC. Further, the petitioner's Home Consumption Study submitted in support of the current petition shows no olestra-related effects in the group of subjects younger than 18 years (Ref. 15). The comments provide the agency with no new data to show that olestra-containing foods should not be consumed by children, or should be specially labeled or packaged for children.

Similarly, FDA does not agree that olestra-containing foods should be required to bear a label statement directed toward the elderly. The agency is not aware of any safety issues specific to olestra-consumption by the elderly, nor does the comment provide evidence of such issues. Since submission of this comment, the agency has received several postapproval studies from the petitioner that have included subjects over the age of 65. These studies have not identified any concerns specific to the elderly that would require specialized labeling.

FDA does not agree with CSPI's conclusion that the agency's memorandum (Ref. 22), should drive the overall conclusion about the effects of consumption of olestra-containing food on children and the elderly. The agency considered this memorandum in its analysis of the original food additive petition on olestra (61 FR 3118 at 3155). In the 1996 final rule, FDA concluded that the Fecal Parameters Study showed there is no difference in stool composition (*e.g.*, water and electrolyte content) between those olestra-consuming subjects who reported diarrhea and those who did not (61 FR 3118 at 3155). In its overall conclusions on the effects of olestra on the GI tract, the agency stated that even those olestra-consuming subjects in the preapproval studies who experienced loose stools continuously for several weeks did not show any evidence of fluid loss, such as hemoconcentration or electrolyte imbalance (61 FR 3118 at 3159). Since publication of the 1996 final rule, P&G submitted the Stool Composition Study, which examined the effect of olestra on the water content of stools. The Stool Composition Study used a dose of olestra that was greater than the highest dose used in the Fecal Parameters Study and collected stools from study subjects for a longer period of time. As discussed previously, based upon the agency's evaluation of the Stool Composition Study, FDA has concluded that the GI effects observed are not clinically significant (Ref. 18), and that the stools study subjects characterized as "diarrhea" were not associated with an increase in stool water (Ref. 10).

In addition, FDA does not agree that olestra-containing foods should be required to bear a label statement directed toward pregnant women. FDA concluded in 1996 that olestra is safe for its intended use in savory snacks (§ 172.867). FDA has no basis to conclude that there are consequences associated with the consumption of olestra that are specific to pregnant women. Importantly, the comment

provides no information to demonstrate that olestra-containing foods present a unique risk to pregnant women.

Finally, FDA does not agree that olestra-containing foods should be required to bear a label statement directed toward those with inflammatory bowel disease, irritable bowel disease, or malabsorption disorder. Once again, the comment provides no evidence to establish that there are consequences of olestra consumption specific to patients with inflammatory bowel disease, irritable bowel syndrome, or malabsorption disorder, that warrant special labeling. Moreover, FDA considered data regarding inflammatory bowel disease at the time of the 1996 final rule. In particular, P&G conducted a study to address concerns as to whether the presence of olestra in the GI tract exacerbates the disease state of patients with inflammatory bowel disease. FDA acknowledged that the study of inflammatory bowel disease patients was limited in size and duration (61 FR 3118 at 3155–56). The study does, however, provide reassurance that consumption of 20 g olestra/d for up to 31 days did not cause an observable effect in populations with inflammatory bowel disease. In addition to this human study, the petitioner conducted studies to assess the potential for increased absorption of olestra in guinea pigs with compromised GI tracts containing lesions similar to those seen in ulcerative colitis and Crohn's disease. The studies showed that the absorption of intact olestra is no greater in guinea pigs with compromised GI tracts than in guinea pigs with normal GI tracts (61 FR 3118 at 3126–3127).

(Comment 28) One comment from an individual consumer to the 1996 final rule expressed concern that it is important for diabetics to know that sucrose is part of the olestra molecule.

FDA disagrees with this comment. As discussed in the 1996 final rule, olestra is a chemical combination of sucrose with six, seven, or eight fatty acids (61 FR 3118 at 3118). While olestra is made from nutritive ingredients, only a minuscule amount of olestra is absorbed by the body (61 FR 3118 at 3120 at 3126–3127), and therefore, most of the sucrose present in olestra is not biologically available. Similarly, FDA noted that rats administered the formulation of olestra proposed for human consumption absorbed only 0.14 percent of the administered dose (61 FR 3118 at 3126). Thus, at most, only trivial amounts of sucrose could be obtained from the ingestion of olestra. FDA concluded in 1996 that all safety issues regarding olestra had been addressed