

Based on the results of the postapproval studies, reviewed in light of the preapproval investigations, FDA has determined that there is no longer a basis to require special labeling for loose stools, abdominal cramps, or any other GI symptom.

(Comment 13) P&G stated in a comment to the 1996 petition that the GI effects statement is inconsistent with FDA's handling of psyllium-containing foods. The comment stated that the digestive effects that occur after eating psyllium-containing foods at levels necessary to support the agency's health claim are the same as for olestra, softer fecal contents and more frequent bowel movements, but are likely more pronounced than those that occur after eating olestra-containing foods. The comment stated that no label information related to GI effects is required on psyllium-containing foods.

As explained previously, FDA has concluded that olestra-containing foods should no longer be required to bear a statement about olestra's potential to cause GI effects. Therefore, whether the GI effects statement originally required in the olestra label is inconsistent with the labeling of psyllium husk-containing foods is no longer an issue.

(Comment 14) A comment from CSPI to the current petition objected to P&G's argument that the required labeling of olestra-containing foods is not consistent with the labeling of GI effects from psyllium-containing foods. CSPI argued that the GI effects of psyllium and olestra are different by citing FDA's published statements that psyllium would have no effect on the bowel other than to promote normal function by softening fecal contents and increasing fecal volume (63 FR 8103 at 8115, February 18, 1998) while olestra may cause bloating, loose stools, abdominal cramps, and diarrhea-like symptoms (61 FR 3118 at 3159). CSPI also states that psyllium's mild GI effects would not cause consumers significant discomfort, undue concern, or cause them to seek unnecessary medical treatment. CSPI points out that FDA does require disclosure of the material effects of psyllium consumption, the potential for esophageal blockage from not consuming adequate amounts of fluids. CSPI concludes that the requirement for disclosure of psyllium's material effects, the potential to cause choking, and the fact that disclosure of psyllium's nonmaterial mild bowel-normalizing effects, are not required to be disclosed is consistent with requiring disclosure of the material GI and carotenoid effects of olestra.

FDA determines the need for special labeling on a case-by-case basis. In this

case, FDA must consider not only whether the potential GI effects of olestra-containing foods rise to the level that warrant special labeling, but also whether consumers are aware of the potential GI effects associated with the consumption of olestra-containing foods. Customary or usual consumption of psyllium husk-containing foods may cause stool softening effects and increases in stool volume and frequency of bowel movements (63 FR 8103 at 8115). Products containing psyllium husk are not specially labeled for GI effects because FDA believes consumers are aware that psyllium husk is dietary fiber and consumers know the effects of dietary fiber. Therefore, the labels of psyllium husk-containing foods are not required to disclose the stool softening effects and increases in stool volume and frequency of bowel movements associated with customary or usual consumption of foods containing psyllium husk. Based upon data and information obtained since the 1996 final rule, FDA believes that the GI effects of customary or usual consumption of olestra-containing foods are not significantly different from the stool softening effects and increases in stool volume and frequency of bowel movements associated with the customary or usual consumption of psyllium husk-containing foods.<sup>58</sup> In addition, FDA believes that there is now a high degree of awareness concerning olestra and its potential to cause GI effects. Based on the nature of the GI effects caused by olestra-containing foods and the public's awareness of such effects, the agency does not believe that olestra's potential to cause GI effects warrants special labeling.

(Comment 15) A comment from CSPI to the current petition stated that the olestra label statement should advise consumers to contact a health professional if GI symptoms persist because such symptoms may represent a problem more serious than those associated with the consumption of olestra-containing foods.

FDA disagrees with this comment. While FDA agrees that consumers experiencing persistent GI symptoms should contact a health professional because such symptoms may represent a condition more serious than those caused by olestra, a food label is not the proper place to provide medical advice unrelated to the product (61 FR 3118 at 3162). FDA notes, however, that the

decision to delete the label statement requirement is consistent with the expressed concern that consumers may erroneously conclude that GI symptoms are related to olestra when, in fact, they are caused by something else.

(Comment 16) Assuming that the label statement would be retained, comments from P&G, Frito-Lay, academia, and several trade associations to the 1996 final rule stated that the wording of the GI effects statement should be changed to indicate that olestra causes a "laxative effect." Comments cited focus group studies showing that the current statement creates unwarranted alarm and implies that the product is harmful. A comment from P&G reported research demonstrating that the phrase "laxative effect" was able to communicate the idea of loose stools and was more effective in communicating the range of other possible symptoms than the phrase "loose stools." This comment also stated that the suggested changes are consistent with the views expressed by the FAC at its 1995 meeting. Other comments supported use of the term "laxative effect" by arguing that the current label statement is not consistent with the precedent set by the labeling of other food additives that cause similar effects, such as mannitol, sorbitol, and polydextrose.

In contrast, one comment opposed use of the term "laxative effect" because it puts olestra in the category of psyllium, and expressed the opinion that olestra does not belong in the same category as psyllium but provided no rationale for the opinion expressed. A comment from CSPI opposed a label statement indicating that olestra is similar to fiber because such a label statement would confuse the public. The comment asserted that although fiber and olestra cause similar GI symptoms, the appearance and disappearance of symptoms are so different that the label statement would be "highly deceptive."

FDA does not agree that olestra-containing foods should be required to bear a label statement indicating that olestra causes a "laxative effect." Use of the term "laxative effect" in a label statement was discussed in the 1996 final rule. The agency chose not to use the term "laxative effect" in the label statement because such use may imply the therapeutic use of olestra as a laxative (61 FR 3118 at 3162). These comments provide no basis for the agency to change its position on this matter. Moreover, given the results of the postapproval studies, FDA believes that there is no longer a basis for requiring special labeling about the potential GI effects associated with customary or usual consumption of

<sup>58</sup> The published statement about olestra's GI effects referenced in the comment by CSPI represents effects seen under the consumption conditions associated with the petitioner's preapproval studies that were designed to demonstrate the safety of olestra.