

such approval would result in the misbranding of a food containing the food additive. Misbranding includes labeling that is misleading because it fails to reveal facts material with respect to consequences resulting from use of the additive under "customary or usual" conditions (sections 201(n) and 403(a)(1) of the act). Thus, the data and information of principal relevance to evaluating whether olestra must bear a label that discloses, for example, the possible GI effects of olestra, are those that evaluate the additive's effects when eaten at levels, and in patterns of consumption, that are customary or usual.<sup>45</sup> As the preceding discussion reflects, FDA has considered all of the evidence in the record and has considered the preapproval studies in light of the postapproval investigations reflecting customary or usual patterns of consumption.

FDA does not ordinarily require special labeling on a food that may have consequences of consumption (such as GI effects) when the available information shows that consumers are aware that such food cause the effects. Psyllium husk is an example of an ingredient that may cause GI effects. Consumers are aware of these potential effects because psyllium husk has been used as a laxative. However, FDA's health claim regulation for psyllium husk does not require a label disclosing these effects (§ 101.81). In those situations in which consumers understand the possible consequences of consuming a particular food, information describing those consequences is not new information for consumers and thus, such disclosure would not be material within the meaning of section 201(n) of the act. Thus, information about consumer knowledge of olestra and its potential to cause effects (such as GI effects) is relevant to determining whether labeling is required to prevent misbranding of olestra-containing food.

<sup>45</sup> This would be in contrast to the preapproval studies which were designed to assess safety.

In addition, it is critical to recognize that the issue presented by this petition is not whether olestra is safe for use in savory snacks; that issue was addressed in the 1996 final rule. Instead, the question before the agency is what labeling, if any, must be required for foods containing olestra to ensure that they are not misbranded (section 403(a)(1) of the act). Accordingly, the act's "reasonable certainty of no harm" safety standard in § 170.3(i) (21 CFR 170.3(i)), does not apply here.

### *B. FDA's Conclusions Regarding Gastrointestinal Effects*

#### 1. Basis of the 1996 Final Rule—GI Effects

a. *Abdominal cramping.* In 1996, the agency concluded that olestra had the potential to cause abdominal cramping. FDA's conclusion was based primarily on two 8-week studies designed to assess olestra's safety in terms of its potential nutritional effects. These 8-week studies maximized participants' exposure to olestra in order to maximize the additive's possible nutritional effects. Although FDA estimated an intake of 20 g/d for the "high" acute consumer of olestra (every day for 12 weeks) (61 FR 3118 at 3124), the highest dose used in these studies (32 g/d) well exceeded this estimate. In addition, in these preapproval studies, olestra was incorporated into savory snacks as well as a variety of foods for which it is not approved for use, and these foods were eaten at every meal for 56 consecutive days. Finally, diets in these studies contained all the ambient levels of fat with no adjustment for the olestra added to the diet. As such, the 8-week studies were not designed to address the effects of customary consumption of olestra-containing snack foods. Based on the information available in 1996, the agency found that there were no safety concerns with the use of olestra in savory snacks.

Although FDA determined in 1996 that the 8-week studies did not reflect conditions of use that are usual or customary for the consumption of savory snacks, there were no other data or information available reflecting the usual or customary use of olestra-containing snack foods. Thus, FDA concluded that it would be prudent to rely on the available data that indicated that under some circumstances olestra had the potential to cause abdominal cramps. Because snack foods containing olestra were new, the agency further concluded that consumers would not know to associate abdominal cramps with these foods. Accordingly, FDA required that products containing olestra bear a label statement indicating that olestra may cause abdominal cramps. The agency imposed the requirement for this label statement because it concluded that consumers were not familiar with the newly approved food additive, olestra, and a label statement would allow consumers to associate GI symptoms they might experience with olestra and preclude unnecessary concern about such effects (61 FR 3118 at 3161).

b. *Loose stools.* In 1996, the agency also concluded that olestra had the

potential to cause the GI effect "loose stools."<sup>46</sup> The studies on which this conclusion was based are the same studies discussed above on abdominal cramps, *i.e.*, the two 8-week studies. These studies were designed to measure the potential nutritional effects from consumption of olestra-containing foods, and were not designed to address potential GI effects from usual or customary consumption of olestra-containing savory snacks. Nevertheless, in the absence of more specific data, FDA relied on the data from the 8-week studies, which the agency concluded showed that at high doses, olestra increased the potential for loose stools. Accordingly, FDA required a label statement about the potential of olestra consumption to cause loose stools (61 FR 3118 at 3153). FDA believed that information on the label would enable consumers to associate olestra with any GI effects and preclude any unnecessary concerns about the origin of such effects. FDA evaluated the data available in 1996 and concluded that a label statement telling consumers that olestra may cause loose stools was necessary so that olestra-containing food products would not be misbranded within the meaning of section 201(n) of the act. In addition, FDA required the label statement about loose stools because at the time of the final rule, consumers were familiar neither with olestra itself, nor its potential to cause GI symptoms such as loose stools.

#### 2. Data in the Current Petition—GI Effects

Three issues are relevant to determining whether the required statement concerning olestra's potential to cause loose stools and abdominal cramping should be modified: The additional data on olestra's association with these effects under customary or usual conditions of use; research concerning consumer understanding of this portion of the required label statement; and the evidence regarding the status of consumer knowledge of olestra and its potential to cause such effects.<sup>47</sup>

<sup>46</sup> As noted previously, FDA concluded in 1996 that these effects are not adverse health effects.

<sup>47</sup> The agency also reviewed data from the petitioner's Stool Composition Study, which address the safety of olestra (*i.e.*, do the loose stools that olestra may cause constitute diarrhea that would be harmful from a health risk standpoint?). As noted, in 1996, FDA concluded that olestra was safe for use in savory snacks, specifically determining that loose stools caused by consumption of the additive were not "harm" within the meaning of the applicable safety standard (section 409(c) of the act; § 170.3(i)). The results of the Stool Composition Study confirm that