

people who consume olestra, because such symptoms can have significant clinical effects on patients with many different medical conditions.

In addition, some comments to the 1996 final rule specifically stated that olestra-containing foods should bear a special label statement. One comment stated that the label statement required by the 1996 final rule is clear and should be retained. One comment supported the need for labeling by citing reports from a number of constituents who had consumed olestra-containing foods and had experienced severe GI reactions that they believe were caused by olestra. Other comments requested that olestra-containing foods bear a label statement so that these products can be avoided.

As explained previously, FDA has concluded that olestra-containing foods should no longer be required to bear a label statement. FDA does not agree that it should require special labeling for olestra-containing foods on the basis that consumers are not familiar with olestra and the potential GI symptoms it may cause. In reaching its decision on this food additive petition, FDA considered the public's awareness of olestra's potential to cause GI effects. As stated previously, the postapproval consumer perception studies and the tracking surveys show that there is currently a high degree of awareness about olestra and its potential to cause GI effects. FDA does not typically require special labeling of products that may cause GI symptoms when consumers are aware that such foods may cause such effects. FDA notes that, even in the absence of the label statement, consumers who wish to avoid olestra will still be able to identify olestra-containing foods because olestra is required to be declared in the ingredient list of such products.

The agency concluded in 1996 that olestra was safe for use in savory snacks and that olestra's GI effects were not adverse health effects (61 FR 3118 at 3159). The comments reporting GI reactions provide no basis to conclude that the GI symptoms reported are actually caused by olestra. The new data and information submitted by the petitioner show that customary or usual olestra consumption causes no increase in the frequency of abdominal cramps and only a minor increase in the frequency of loose stools and bowel movements and that these effects do not have a meaningful impact on daily activity. Moreover, the petitioner's most recent studies show that the label statement could be misleading and cause consumers of olestra to attribute

serious problems to olestra when this is unlikely to be the case.

(Comment 31) Some comments from individual consumers to the current petition stated that olestra-containing foods should bear a label statement because the public has a right to know about the potential side effects of olestra-containing foods.

FDA notes that the act does not provide the agency with the authority to require labeling simply because consumers appear to want such information. (*See Stauber v. FDA*, 895 F. Supp 1178, 1193 (N.D.Wisc. 1995); *Alliance for Biointegrity v. Shalala*, 116 F. Supp 166, 179 (DDC Sept. 29, 2000).) FDA could require the suggested labeling if, without such labeling, the product labeling failed to reveal facts that are material in light of the consequences which may result from the conditions of use prescribed in the labeling or under conditions of use that are customary or usual.

(Comment 32) A comment from Frito-Lay to the 1996 final rule stated that the label statement should contain only a message directing consumers to a telephone number for more information instead of the current label statement. The Frito-Lay comment cited a consumer study showing that none of the label statements evaluated in the study eliminated consumer misperception and that consumers interpreted the current label statement as a safety warning. The comment concluded that this type of labeling, however worded, has a strong negative effect on the consumer's perception of the safety of olestra-containing foods. In a comment to the 1996 final rule, P&G stated that as an alternative to the nutritional effects statement or the labeling of the added vitamins in the ingredient list with an asterisk, the agency could consider requiring manufacturers to provide a telephone number for consumers to obtain nutritional information. In its comments to both the current petition and the 1996 final rule, CSPI stated that the label statement should include a telephone number for consumers to obtain more information or to report adverse effects.

FDA does not agree that it should require the labeling of olestra-containing foods to include a telephone number. As explained previously, FDA has concluded that olestra-containing foods should no longer be required to bear a label statement and that vitamins A, D, E, and K required to be added to olestra-containing foods should be labeled in the ingredient list with an asterisk that refers to the statement "Dietarily insignificant." FDA is requiring this labeling to ensure consumers

understand that such foods do not contribute significant amounts of the vitamins A, D, E, and K to the diet. FDA does not agree that it should require manufacturers to provide a telephone number in place of this information. FDA believes that there is no basis to require that the label for olestra-containing foods include a telephone number for consumers to obtain more information or report adverse effects, nor do the comments explain why such a number is necessary to prevent the misbranding of these foods. FDA recognizes that some firms voluntarily include telephone numbers on their food labels. For those products that do not contain a telephone number, consumers may obtain more information or report adverse effects by contacting the company using the company's name and address, both of which are required to appear on the food label in accordance with § 101.5.

E. Data and Information Considered in This Rulemaking

(Comment 33) A comment from CSPI to the current petition stated that the postapproval studies should be considered, but they should not supersede or override the preapproval studies. The comment asserted that the postapproval studies are not a reason to reject all the previous evidence that olestra can cause GI symptoms. The comment also asserted that the lack of adverse effects reported during P&G's postapproval studies may be due to the small doses of olestra consumed, relative to the preapproval studies, and that rules should be based on the possibility that a greater number of olestra-containing foods would be consumed more frequently in the future. CSPI also stated that the postapproval studies cannot disprove that olestra-containing foods cause adverse effects in a small percentage of consumers.

In deliberations on this petition, FDA has considered all evidence of record (including both preapproval and postapproval studies). The agency notes that the petitioner's postapproval studies are meant to complement, not supersede, the preapproval studies. The preapproval studies were designed to address safety while the postapproval studies were, with the exception of the Stool Composition Study, designed to address labeling.

FDA's 1996 decision to require special labeling of olestra-containing foods was based on preapproval studies which were designed to address the safety standard for food ingredients—reasonable certainty of no harm under the intended conditions of use (§ 170.3(i)). These studies examined the