

interpreted the label statement in the context of their experience with other foods that are not labeled. Because there are other foods that cause GI symptoms but are not labeled (e.g., psyllium,<sup>41</sup> wheat fiber, and beans), consumers infer from the olestra label statement that olestra's effects must be worse. The petitioner characterized a typical participant reaction during the focus group testing to be, "If it's like my other experiences, then why does it have this label?"

The petitioner found that a label statement with an explanation of why olestra might cause GI effects ("Because olestra is not digested, it may cause intestinal discomfort or a laxative effect.") added significantly to participant understanding. When specific symptoms were mentioned, such as "loose stools" and "abdominal cramping," more participants responded that they would expect those GI symptoms, compared to panelists who viewed statements that did not mention specific symptoms. The petitioner also found that general GI symptom terms, such as "laxative effect" and "intestinal discomfort" communicate the same expectations in GI changes as the specific terms for other GI symptoms, especially for the range of symptoms related to stool changes.

The petitioner also investigated consumer reaction to the boxed configuration of the label statement, and concluded that statements not boxed had less connotation of harm.

Frito-Lay, an interested party and producer of olestra-containing snack foods, also submitted to the agency results from consumer studies on the label statement conducted prior to marketing of olestra-containing foods (sent as comments to Docket No. 87F-0179, dated March 28, 1996, and March 29, 1996). The purpose of these studies was to test the effect and communication value of the required label statement and alternative statements developed by Frito-Lay. The same type of methodology described above for the quantitative assay was used to obtain responses from 1,183 individuals from 5 sites around the country. Respondents were shown a label statement and then asked, based on this label statement, whether they believed that products containing

olestra were safe. Frito-Lay said that in response to all the tested label statements, including the required statement, most respondents were uncertain as to the safety of olestra (66 to 71 percent), or thought it unsafe (14 to 19 percent). Because none of the label statements Frito-Lay tested eliminated consumer misconception about safety (including a label statement declaring that olestra has been found safe for consumption by the FDA), Frito-Lay concluded that there should be no special label statement. Additionally, Frito-Lay found that 63 to 65 percent of respondents believed that some people would experience GI discomfort. About half of these respondents said that they would delay going to a doctor if they ate a product containing olestra and then experienced GI discomfort for which they would normally seek medical attention. Additionally, a majority of the respondents (68 to 71 percent) believed that olestra would decrease the level of vitamins A, D, E, and K in their bodies, and a majority believed that other nutrients are affected by olestra.

FDA reviewed the consumer perception studies submitted in 1996 by P&G and Frito-Lay (Ref. 32). FDA noted that the studies were an attempt to evaluate what the olestra label statement communicated to consumers regarding several issues. These issues include the following subjects: (1) The safety of olestra; (2) whether the portion of the label statement about GI effects communicates reasonable expectations about the severity, frequency and duration of potential symptoms, and whether alternate wording or presentations communicate more effectively; and (3) whether the portion of the label statement about the potential nutrient absorption effects of olestra effectively communicates the reason for the addition of vitamins A, D, E, and K, as well as the scope and potential severity of the consequences of eating olestra, and whether alternate wording or presentations communicate more effectively.

FDA found the mall intercept studies to be adequate in methodology and sample size to differentiate between the communication effectiveness of the statements tested, including such changes as alternate wordings, or separation of portions of the label statement. For example, in part of Frito-Lay's quantitative study, participants were asked about the safety of olestra before, as well as after, viewing the test label statement. This use of a question before viewing the label statement serves to measure the impact of the label statement on participants' opinions or whether that opinion was established

prior to viewing the label statement. However, the studies were limited to some extent by the choice and wording of questions. For example, P&G's quantitative study did not include, as a control, a "no information" statement, so the communication value of simply having a statement on the product package cannot be evaluated.

Regarding the safety of olestra, FDA found that the results of the consumer perception studies conducted by the petitioner and by Frito-Lay show that the label statement is misunderstood by respondents and thought to be a warning about possible health consequences of olestra consumption. FDA notes that Frito-Lay's data demonstrate that there was an increase in the level of concern about the safety of olestra after participants read a label statement. Specific wordings or presentations contributed little to the level of expressed concern. Only when a label statement included wording that FDA has found olestra to be safe for consumption was some of the concern alleviated. FDA also noted that when participants were given the opportunity to respond to the question of whether olestra is safe by opting for "uncertain," a majority chose this response to every label statement examined. When response options were limited to yes or no, the majority chose "no" (*i.e.*, not safe).

Regarding GI symptoms, FDA concluded that there was no indication from these studies that consumer expectations about the severity, frequency, or duration of GI symptoms was influenced by specific wording or qualifications on effects or by whether there were any directions about when to contact a physician. There also was no indication from these studies that consumers' expectations about the GI symptoms were influenced by whether the nutrient portion of the label statement was present. Participants tended to use the same words used in the label statement to describe potential symptoms (*i.e.*, loose stools, abdominal cramping), but alternate words to describe certain GI effects (loose stools, more frequent bowel movements, diarrhea) were all understood to mean the same thing. When asked what proportion of the population might experience symptoms, modifiers had little effect on respondents' answers.

Regarding the nutrient absorption portion of the label statement, FDA found that the results of the 1996 consumer perception studies show that the current label statement is not effective in explaining the rationale for and quantitative consequences of adding the four fat-soluble vitamins to

<sup>41</sup> FDA assumes that the term "psyllium" refers to the soluble fiber component of the psyllium husk that is the subject of the agency's regulation in part 101 (21 CFR part 101) authorizing a health claim for soluble fiber from certain foods and coronary heart disease (§ 101.81). FDA considers both "psyllium seed husk" and "psyllium husk" to be common or usual names for this substance, but uses the term "psyllium" where it was used by the petitioner or comments.