

olestra-containing foods. Therefore, the specific characterization of these GI effects by terms such as "laxative effect" is no longer an issue.

(Comment 17) A comment from CSPI to the 1996 final rule stated that olestra causes diarrhea and the word "diarrhea" should appear in the label statement. CSPI stated that olestra-related diarrhea meets the criteria established for "clinical diarrhea" discussed at the 1995 meetings of the Olestra Working Group (OWG)⁵⁹ and FAC. In support of its comment, CSPI quotes portions of the FDA memorandum that discusses data from the preapproval Fecal Parameters Study (Ref. 22). CSPI quotes portions of the memo discussing subjects' ability to distinguish between "normal," "loose," and "diarrhea" stool as well as portions of the memorandum discussing water loss through diarrheal and nondiarrheal stools. CSPI states that one of the criteria for "clinical diarrhea" discussed at the 1995 meeting of the OWG and FAC was increased water content of diarrheal stool compared to normal or loose stool. CSPI also asserted that in the petitioner's preapproval Oil Loss Study, bowel movements exceeded 3/d for subjects in all the study groups who consumed olestra potato chips while no such increase was reported for subjects who consumed chips with triglyceride. CSPI also reports that some subjects in the preapproval study of patients with inflammatory bowel disease reported an increased frequency of bowel movements. CSPI states that bowel movement frequency exceeding three per day was a criteria for "clinical diarrhea" considered at the 1995 meetings of the OWG and FAC. CSPI also quotes an FDA memorandum that reviews a preapproval study of the effect of olestra on intestinal micro flora (Ref. 35). CSPI quotes a portion of the memorandum stating that the projected means for fecal volume for the olestra-fiber consuming groups⁶⁰ in the study indicate diarrhea at 24 g of olestra if the strict definition of diarrhea used by research gastroenterologists (200 g/d) is applied.

FDA does not agree that olestra-containing foods should be required to bear a label statement indicating that olestra causes diarrhea. FDA considered the evidence presented by CSPI during the agency's review of the original petition for the use of olestra in savory snacks. Upon evaluation of all of the data considered in the original petition, FDA concluded that the "diarrhea" reported by study subjects was not diarrhea in the medical sense because it was not associated with objective measures of diarrhea (*i.e.*, the loss of water or electrolytes) (61 FR 3118 at 3159). Moreover, as discussed previously, data from the petitioner's Stool Composition Study support FDA's 1996 decision that consumption of olestra does not cause medical diarrhea. Therefore, FDA has no basis to require a label statement indicating that olestra causes diarrhea.

(Comment 18) A comment from CSPI to the 1996 final rule stated the group's opposition to any use of the phrase "excessive consumption of olestra" in the label statement because P&G's data show that consumption of even modest amounts of olestra can cause GI disturbances. CSPI also opposed labeling indicating that olestra's GI symptoms were "usually minor," arguing that diarrhea is not a minor symptom and that some subjects experienced moderate or severe symptoms.

At the time of the 1996 final rule, FDA believed that it was prudent to rely on the data generated from the safety studies as a basis for requiring labeling to disclose potential GI effects of olestra-containing foods. The data generated from the safety studies did not provide a basis to characterize the frequency of GI symptoms or the consumption levels at which consumers would experience such effects under customary or usual consumption of savory snacks. Data and information obtained since the 1996 final rule examining the effect of customary or usual consumption of olestra-containing foods show that olestra causes only minor increases in the frequency of loose stools and bowel movements, and no increase in the frequency of abdominal cramps. Based on these findings, the agency believes that there is no longer a basis to require a label statement about the possible GI effects associated with the consumption of olestra-containing foods. Therefore, use of specific phrases such as "excessive consumption of olestra" and "usually minor" in the label statement are no longer at issue.

B. Label Statement for Nutritional Effects

(Comment 19) Comments from CSPI and Frito-Lay to the current petition suggested that the label statement regarding the addition of vitamins A, D, E, and K should be replaced with an asterisk and a phrase such as "Not nutritionally significant" because the current statement is confusing. Frito-Lay stated that the suggested labeling will ensure that consumers know the product has not been fortified to provide a nutritional benefit with respect to vitamins A, D, E, and K. Frito-Lay also stated that the vitamin statements should be eliminated from the olestra label because they are widely misunderstood and P&G's postapproval research shows that the added vitamins compensate for any absorptive effect of olestra.

Similarly, comments from P&G, Frito-Lay, trade associations, and academia to the 1996 final rule stated that the statements regarding added vitamins should be dropped from the label. Some of these comments asserted that the added vitamins should be labeled instead in the ingredient list with an asterisk directing consumers to a statement such as "Not a nutritionally significant source." Arguments presented in support of this recommendation were summarized briefly as follows: (1) Consumer studies submitted by P&G and Frito-Lay arguably show that the current label statement is difficult for consumers to understand; (2) quantitative research submitted by P&G shows that the suggested labeling (use of an asterisk and referencing language such as "Not a nutritionally significant source") best communicates the fact that olestra will have no net effect on the status of vitamins A, D, E, and K; (3) the suggested label statement is consistent with the views expressed by the FAC at the 1995 and 1998 meetings; and (4) consumers are accustomed to seeing the suggested-type of labeling on the nutrition label for skim milk and some fat-free products; therefore, they are more likely to understand it.

FDA agrees with these comments. As discussed previously, by this final rule, a label statement that explains olestra's potential effects on the absorption of fat-soluble vitamins and other nutrients is no longer required, and information that informs consumers that olestra-containing foods have not been fortified with vitamins A, D, E, and K will be provided through an asterisk and the statement "Dietarily insignificant" that will follow the ingredient list of olestra-containing foods.

⁵⁹ The OWG was a subcommittee of the 1995 FAC functioning as a special working group on olestra. The OWG was made up of several members of the FAC as well as consultants and indepth review experts who represented scientific disciplines appropriate for the evaluation of a macro-ingredient fat substitute. The OWG met for 3 days (November 14–16, 1995) and reported its findings to the FAC in a meeting on November 17, 1995. The transcripts for the 1995 FAC meetings are available at the Division of Dockets Management (*see ADDRESSES*).

⁶⁰ FDA notes that subjects in the study were fed breakfast meals daily containing 7 g or 24 g of fiber with 24 g of either olestra or triglyceride for 28 days.