

adequately and that the use of olestra in savory snacks is safe (61 FR 3118 at 3168). The comment provides no evidence that the small amount of sucrose potentially obtained from olestra is hazardous to diabetics or warrants disclosure on the food label. Therefore, FDA concludes that there is no basis for the agency to require that the label of olestra-containing foods disclose that olestra is made from sucrose.

D. Label Statement in Its Entirety

(Comment 29) Frito-Lay and P&G submitted comments stating that the olestra label should be eliminated in its entirety and that the added vitamins should be labeled in the ingredient list with an asterisk and a statement such as “*Not a nutritionally significant source.” The comment from P&G to the 1996 final rule reported the findings of an expert panel it convened to examine whether the label statement should be maintained. The comments from both Frito-Lay and P&G provided arguments for the elimination of the GI and nutritional effects statements. FDA responded to these arguments in the previous sections discussing comments on the GI and nutritional effects statements. Both comments argued that the current scientific evidence does not support retention of the label statement and that the label is misleading. Frito-Lay also pointed out that the sentence “This product contains olestra.” is not needed in the label statement because olestra is listed in the ingredient statement, and manufacturers that use olestra generally place the logo of the olestra brand name, Olean, on the front panel of olestra-containing foods.

In contrast, a comment from CSPI to the current petition supported the retention of a label statement. In its comment CSPI proposed the following label statement enclosed in a box:

THIS PRODUCT CONTAINS OLESTRA. Olestra may cause abdominal cramping and loose stools in a small percentage of consumers. If you experience adverse effects that may be caused by olestra, call 1-800-OLESTRA. If your symptoms persist or are severe, contact a health professional. Frequent consumption of olestra may reduce your body's absorption of fat-soluble nutrients (carotenoids). Carotenoids, found in fruits and vegetables, may protect you against certain chronic illnesses.⁶⁹

⁶⁹ FDA notes that since the 1996 final rule, CSPI has submitted several versions of a suggested label statement. The version presented is CSPI's most recent version. Previous versions are generally characterized as including a greater number of possible GI symptoms, statements about olestra's effect on the absorption of vitamins A, D, E, and K, statements that loss of carotenoids may increase the risk of certain health conditions, and statements

CSPI argued that a nondescript declaration of the word “olestra” in the ingredient listing does not inform consumers of the side effects of consuming olestra, and unless consumers are aware of the potential side effects, they would have no reason to consult the ingredient list to determine if a food contains olestra. CSPI asserted that a similar concern was raised about the use of the terms “pasteurized” or “unpasteurized” in the preamble to the final rule requiring warning label statements for unpasteurized juices (63 FR 37030, July 8, 1998). CSPI pointed out that the final rule stated that some consumers do not know the significance of pasteurization and therefore would not be able to make an informed decision on whether to purchase and consume the products and that use of the term “pasteurized” or “unpasteurized” alone would not give consumers information about the risks presented by untreated juices (63 FR 37030 at 37034). CSPI noted that the final rule for labeling of unpasteurized juices argues that the presence of some pathogens that have been responsible for recent outbreaks of food borne illnesses associated with untreated juice products is a relatively new phenomenon. Therefore, consumers do not associate such pathogens and the risks they present with the consumption of untreated juice (63 FR 37030 at 37032–33). CSPI asserted that label statements for olestra are unnecessary to inform consumers of the unexpected, potential consequences of consuming foods that have long been consumed without adverse effects and that simply disclosing the presence of olestra in the ingredient statement does not inform consumers of olestra's potential side effects.

FDA agrees with the comments from Frito-Lay and P&G that olestra-containing foods should no longer be required to bear a label statement. FDA concluded in the 1996 final rule that olestra was safe for its intended use in savory snacks. As part of the 1996 final rule, FDA required a label statement to appear on olestra-containing foods. The label statement was required to inform consumers of the potential for olestra to cause GI effects and because consumers had no experience with this food ingredient. The label was also required in order to prevent consumers from erroneously concluding that the vitamins added to olestra-containing foods would contribute significant amounts to their diet when, in fact,

directed toward special populations (such as children, patients taking Coumadin, and those with bowel disorders).

these vitamins were added to offset any vitamin losses caused by the consumption of olestra-containing foods. The rationale used in the labeling of untreated juice products cannot be directly applied to the labeling of olestra-containing foods because untreated juice products were labeled to warn consumers of potential health hazards such as serious illness, while olestra-containing foods were labeled to inform consumers of potential effects that do not represent health hazards.

In determining the wording of the warning statement for unpasteurized juices, FDA determined from focus group research that most participants had a good understanding of what pasteurization was, but a significant number of participants did not (63 FR 37030 at 37034). The agency also concluded that use of the terms “pasteurized” or “unpasteurized” alone would not give consumers information about the risks presented by untreated juices (63 FR 37030 at 37034). In contrast, as discussed previously, postapproval consumer perception studies and tracking surveys show that there is currently a high degree of awareness about olestra and its ability to cause GI effects. Indeed, it appears that consumers are more likely to overestimate rather than underestimate the potential for olestra to cause GI effects. FDA does not typically require label statements for products that may cause GI symptoms when consumers are aware that such foods may cause such effects. As noted in the response to previous comments, FDA does not believe that the label of olestra-containing foods should be required to contain information about the effect of olestra on serum carotenoid levels. FDA will require that vitamins A, D, E, and K added to olestra be labeled in the ingredient list with an asterisk and the phrase “Dietarily insignificant” to prevent consumers from being misled to believe that the added vitamins contribute significant amounts to the diet.

(Comment 30) Many comments to the current petition specifically stated that olestra-containing foods should bear a label statement. Most of these comments were from consumers who reported experiencing GI reactions that they associated with consuming olestra-containing foods. One comment stated that the label statement was important in identifying the cause of their GI symptoms. Another comment expressed concern that there is insufficient knowledge about olestra. Another comment stated that a side effect such as severe abdominal cramping and diarrhea should be made known to