

triglyceride chips. Similarly, the Acute Consumption Study showed no difference in the frequency, nature, or severity of GI complaints (including loose stools) between the placebo (triglyceride) and olestra groups after a single, ad libitum eating occasion.

At the time olestra was initially approved and first marketed, consumers had limited awareness of olestra and its potential to cause GI effects. In contrast, evidence gathered in the postapproval consumer perception studies and the tracking survey show that there is currently a high degree of awareness among the public about olestra, including a high degree of awareness of olestra's potential to cause GI effects. Results from a postapproval tracking survey show that consumers became more aware of olestra as products were introduced nationally.

FDA does not have evidence to draw conclusions about the role played by the label statement in creating consumer awareness about olestra's potential to cause GI symptoms. However, as with other products that may cause GI effects but are not so labeled, awareness of the potential to cause GI effects is maintained in the population based on common knowledge and consumer experience. Consumers are accustomed to regulating their diets based on this knowledge and experience. FDA has no reason to conclude that the case for olestra-containing foods would be different.

As previously noted, FDA has evaluated consumer perception studies conducted with the olestra label statement and has concluded that while FDA's purpose in requiring the label was to provide information to consumers, a significant number of consumers perceive the label statement as a warning about possible health consequences of olestra consumption and consider olestra-containing foods to be unsafe.⁴⁹ This is contrary to FDA's determination that olestra is safe for use in savory snacks. Thus, the agency believes that the current label does not accurately communicate information to consumers about olestra's potential to cause loose stools.

Since the 1996 final rule, additional data about olestra and the nature and frequency of loose stools have become available. This information does not supersede the previous information, but rather, extends FDA's understanding of olestra under customary conditions of use and its potential to cause loose

stools. FDA has found that olestra may increase the frequency of loose stools but the frequency of the increase is minor. FDA also has found that the severity and impact of this effect on daily activity are not different from other foods that may cause an effect such as loose stools.

In addition, the administrative record before the agency shows that consumers are now familiar with olestra's potential to cause loose stools. FDA believes that because there is currently an awareness among consumers about possible GI effects of olestra, and because the potential effects from customary or usual consumption of olestra-containing snacks are relatively insignificant, a label statement concerning loose stools for olestra-containing savory snacks is no longer needed to ensure that the product is not misbranded (sections 201(n) and 403(a)(1) of the act).

C. FDA's Conclusions Regarding Nutritional Effects

1. Basis of the 1996 Final Rule—Nutritional Effects

At the time of the 1996 final rule, FDA found that because olestra is a fat-like material that is not digested or absorbed, it may interfere with the absorption of fat-soluble components of the diet, including the fat-soluble vitamins A, D, E, and K. The agency had evaluated studies performed in humans and animals (61 FR 3118 at 3132–3252), and considered the available information concerning nutritional requirements for various fat-soluble components of the diet. FDA concluded that the addition of vitamins A, D, E, and K (§ 172.867(d)), to foods containing olestra would compensate for any inhibition of absorption of fat-soluble nutrients by olestra. The amount of vitamins added was intended to have no net effect (neither increase nor decrease) on vitamin status of olestra consumers. The agency required that the level of added vitamins be adequate to compensate for olestra's effects on absorption even if the olestra and fat-soluble vitamin are present in the gut simultaneously. Additionally, the agency set the amount of vitamins so that if there is no fat-soluble vitamin present in the gut with olestra, the level of added vitamin would not pose any safety concerns.

The added vitamins A, D, E, and K are required to be declared in the ingredient listing (section 403(i) of the act). In 1996, FDA concluded that this mandatory listing of vitamins A, D, E, and K could mislead consumers by implying that the food would provide significant amounts of these vitamins (61 FR 3118 at 3161).

Thus, FDA required a label statement to explain why these vitamins were added and why the food should not be considered fortified, so that olestra-containing food would not be misbranded (sections 201(n) and 403(a)(1) of the act).

FDA required that the label include the statement "Olestra inhibits the absorption of some vitamins and other nutrients. Vitamins A, D, E, and K have been added." FDA did not require a specific statement about carotenoids or any other fat-soluble components of the diet because such a statement could have falsely implied that their decreased absorption was known to be of significance.

2. Data in the Current Petition—Nutritional Effects

Three issues are relevant to determining whether the required statement as to olestra's effects on nutrient absorption should be modified: The additional data on absorption of the added vitamins A, D, E, and K obtained since the 1996 final rule; the current understanding of the nutritional importance of carotenoids and olestra's effect on their absorption; and the research evaluating consumer understanding of this portion of the required label statement.

As to the added vitamins A, D, E, and K, early data from the Active Surveillance Study confirm that, as the agency intended, there is no dietarily significant net loss or gain of vitamins A, D, E, and K due to the consumption of olestra-containing foods.⁵⁰

The early data from the Active Surveillance Study also provide important information regarding olestra and carotenoids. First, these data show that consumption levels of olestra-containing foods are below FDA's original estimates and further, that co-consumption of any savory snack with a carotenoid-containing food is relatively rare. Second, although there are changes in serum measures of certain carotenoids, these changes are unlikely to be the result of consumption of olestra-containing foods because the clinical cohort data reflect no association between the amount of olestra consumed and the changes in serum levels of carotenoids.

As noted, FDA has considered the recent scientific literature pertaining to carotenoids and human health and concluded that the decreased risk of cancer is associated with increased

⁴⁹ In fact, these studies show that many consumers attribute certain serious GI effects to olestra, even though there is no evidence of olestra's potential to cause such effects.

⁵⁰ There was some indication from the Active Surveillance Study cross-sectional data of a small increase in vitamin K levels in the highest olestra consumers.