

consumption of fruit and vegetables generally and that at the present time no specific role of carotenoids (other than the provitamin A function) has been identified.⁵¹ The agency's conclusions are consistent with the recent NAS report (Ref. 27) that determined that there is no basis at present for setting dietary requirements for any carotenoid. Similarly, this conclusion is consistent with the results of recent intervention studies, which show no benefit from treatment with carotenoids over control.^{52, 53}

FDA acknowledges that research is continuing and that the scientific community's understanding of the role of carotenoids in human health may evolve as new data emerge. The agency will review new information about the role of carotenoids in human health relevant to olestra use in savory snacks, and if necessary, take appropriate action. At this time, however, FDA concludes that no direct evidence demonstrates that the association between the consumption of diets high in fruits and vegetables and a decreased risk of cancer is due to any single carotenoid or group of carotenoids. Accordingly, FDA has determined that there continues to be no basis to require any label statement about olestra's effects on carotenoids or any other fat-soluble nutrient.

As discussed previously, FDA has also evaluated information about the effectiveness of the current olestra label statement to communicate about olestra's potential nutritional effects to consumers. In general, the evidence from consumer perception studies shows that after reading the required label statement, a majority of consumer participants did not correctly understand olestra's effect on the absorption of fat-soluble nutrients or why vitamins A, D, E, and K would be added to olestra-containing foods. Accordingly, FDA concludes that the required label statement is not an effective means of communicating to olestra consumers.

Although the currently required label statement may be misinterpreted by consumers, FDA still believes that because the presence of the added vitamins must be disclosed as ingredients of olestra-containing foods (§ 101.4(a)(1)), consumers may be misled and believe that such snacks are

fortified with the added vitamins. Therefore, in order for olestra-containing foods not to be misbranded, the agency has determined that a statement about the presence of vitamins A, D, E, and K should be required. Accordingly, this final rule requires that the label of foods containing olestra use an asterisk following each of the added vitamins in the ingredient statement which would refer to a statement, "Dietarily insignificant." Such a statement directly addresses the presence of the vitamins in the ingredient statement and closely links the message to the particular vitamin affected.⁵⁴ This format and configuration are familiar to consumers because such a configuration has been used previously in the nutrition facts panel. Likewise, as noted, the required wording, "dietarily insignificant," is similar to wording used in other label statements, and thus, is familiar to consumers (§§ 101.60(c)(1)(ii), 101.61(b)(1)(ii), and 101.62(b)(1)(ii)).

FDA further concludes that there is no need for a contextual statement about olestra's effect on the absorption of the vitamins in order to avoid misbranding of olestra-containing foods. Indeed, information from consumer perception studies shows that the 1996 required label's contextual statement about "some vitamins and other nutrients" actually tends to mislead consumers and that contextual information is not necessary to understand that olestra-containing foods do not contribute significant amounts of vitamins A, D, E, and K to the diet. In addition, although olestra may affect the absorption of other fat-soluble components of the diet, such as carotenoids, there is no known basis for adding back carotenoids or nutrients other than vitamins A, D, E, and K to olestra-containing food. Finally, there is no representation made on the label about "other nutrients" that would require a specific statement about such nutrients. For these reasons, this final rule eliminates the requirement that the label for foods containing olestra include the sentence "Olestra inhibits the absorption of some vitamins and other nutrients."

In sum, having considered all of the evidence of record, FDA has determined that the olestra regulation, § 172.867, should be revised to require that vitamins A, D, E, and K listed in the ingredient statement be labeled with an asterisk (appearing as a superscript) following the listing of each of these vitamins, and that the asterisk reference

the phrase, "Dietarily insignificant," which shall appear immediately following the ingredient statement.

V. Response to Comments on the Label

In this section, FDA responds to comments not previously addressed in this document. FDA considered these comments and responds in this section of the document.

A. Label Statement for GI Effects

(Comment 10) In comments to both the 1996 final rule and the current petition, Frito-Lay recommended that the statement about the GI effects of olestra be eliminated. Frito-Lay based its recommendation on the results of studies, such as the petitioner's postapproval studies, showing that consumption of snack foods made with olestra produces no meaningful GI effects. Frito-Lay also cited a consumer perception study suggesting that consumers may attribute GI effects to olestra when their symptoms are caused by a more serious condition requiring medical attention. In that study, 58 percent of consumers said they would delay medical attention if GI changes occurred after eating products bearing the olestra label statement. A comment from P&G to the 1996 final rule argued that the label statement is inconsistent with data from the postapproval studies and has the potential to mislead consumers. P&G objected to the suggestion at the 1998 meeting of the FAC that the GI effects statement be amended and subject to a sunset clause, rather than dropped entirely, by arguing that discontinuing the GI effects portion of the label statement would be more consistent with the existing data and prevailing legal precedent.

In contrast, several comments to the 1996 final rule specifically stated that a GI effects statement was warranted but provided no factual evidence or rationale for their recommendation.

FDA agrees that the requirement for a label statement about olestra's potential to cause GI effects should be eliminated. As noted previously, P&G's postapproval studies show that customary or usual consumption of olestra in savory snacks causes only minor GI effects, and that the public is now aware of olestra's potential to cause GI effects. Therefore, the agency has no basis to require a label statement regarding olestra's potential to cause GI effects.

(Comment 11) A comment from CSPI to the current petition stated that instead of eliminating the label statement about GI effects, the statement should be amended to indicate that GI effects may occur in a "small percentage

⁵¹ The FAC reached the same conclusion in June 1998.

⁵² This is true with respect to the NIH/NEI AREDS study, which showed no specific vitamin or carotenoid was protective of macular degeneration.

⁵³ Indeed, in at least one subpopulation (smokers), treatment with carotenoids was associated with an increased risk.

⁵⁴ This asterisk format is supported by P&G, CSPI, and a majority of the FAC members present at the 1998 FAC meeting.