

(Comment 20) Some comments to the 1996 final rule suggested specific language changes to the vitamin statements because the statements in the label are too vague or misunderstood by consumers. All of the suggested language changes indicated that olestra interfered with the absorption of vitamins A, D, E, and K and that these vitamins were added to compensate for potential losses.⁶¹ A comment from P&G also suggested that, if the label statement is retained, it should explain why olestra has effects on vitamin absorption.

Based on consumer studies, FDA believes that the current label statement is not an effective means of communicating to consumers that olestra affects the absorption of fat-soluble vitamins or why vitamins A, D, E, and K are added to olestra-containing foods. As part of this rulemaking, the agency has concluded that a statement about olestra's effects on the absorption of fat-soluble vitamins is not needed in order to understand that olestra-containing foods do not contribute significant amounts of vitamins A, D, E, and K to the diet. Therefore, the agency believes that the label statement about olestra's effects on vitamin absorption should be eliminated, not simply reworded. The agency does, however, believe that the label of olestra-containing foods must communicate that the vitamins A, D, E, and K added to such foods will not change consumers' vitamin status. Accordingly, this final rule requires the use of an asterisk and short explanatory phrase, "Dietarily insignificant," a configuration that will communicate the intended message more clearly than the current statement. FDA notes that the petitioner concluded from consumer studies that the asterisk/statement configuration best communicates to consumers the fact that the vitamins A, D, E, and K added to olestra-containing foods would have no net effect on consumers' vitamin status. It is also a format and configuration familiar to consumers because it is used in the Nutrition Facts panel and is similar to language used in other label statements (§§ 101.60, 101.61, and 101.62).

(Comment 21) A comment from a trade association to the 1996 final rule stated that the vitamin statement should be eliminated because the statement is

a nutrient content claim for added vitamins and therefore violates §§ 101.13, 101.54, and 101.9(c)(8)(ii). The comment stated that to satisfy a nutrient content claim for added vitamins, the product must provide an additional 10 percent of the reference daily intake (RDI) compared to a reference food. The comment claimed that vitamin addition to olestra would not always contribute an additional 10 percent of the RDI for the added vitamins; therefore, the vitamin statement violates §§ 101.13 and 101.54. The comment also argued that the label statement violates § 101.9(c)(8)(ii) because any claimed nutrient must be included on the nutrition label. Under the current policy, the vitamins added to olestra are not included on the nutrition label.

Because the olestra label statement will no longer be required to appear on the package of olestra-containing foods, whether the label statement contains a nutrient content claim is no longer an issue.

(Comment 22) A comment from CSPI to the 1996 final rule recommended that the label statement advise consumers not to consume olestra with meals or vitamin supplements because such consumption would maximize nutrient loss. In contrast, a comment from P&G opposed such a label statement. In its comment, P&G cited preliminary data from its Active Surveillance Study showing that consumption of olestra-containing food does not result in any meaningful decrease in serum carotenoids. P&G also stated that the compensation levels of vitamins A, D, E, and K required by the agency are based on data reflecting worst-case consumption scenarios. P&G also noted that the majority of members of the FAC concluded in 1998 that there were no new data showing that olestra will adversely affect health by interference with the absorption of fat-soluble vitamins or other lipophilic substances.

FDA does not agree that olestra-containing foods should be required to bear a label statement advising consumers against consumption of olestra with meals or vitamin supplements. FDA required the addition of vitamins A, D, E, and K to compensate for the known effects of olestra and established compensation levels that would be adequate for those individuals who consume olestra-containing snacks at meals. For carotenoids, FDA concluded in the 1996 final rule that there was no basis to require compensation of olestra-containing foods with specific carotenoids (61 FR 3118 at 3147–3149). Moreover, in its comments, CSPI

provided no data to show that customary or usual consumption of olestra-containing snacks with meals or vitamin supplements causes nutrient losses that warrant a statement advising consumers not to consume olestra-containing snacks with meals or vitamin supplements.

(Comment 23) A comment from CSPI to the 1996 final rule stated that the olestra label statement should include information directed toward those using coumarin derivatives to control blood clotting because there are no clinical data in the olestra petition showing that the addition of vitamin K to olestra-containing foods would be safe and efficacious for people who use coumarin derivatives. The comment also suggested that the label statement include information directed toward those with hemophilia or "other blood diseases." A comment from academia also requested that the label statement provide information directed at those taking coumarin derivatives and cited an article in the *New England Journal of Medicine* (Ref. 36) as support for a warning label statement. The comment asserted that olestra's inhibition of vitamin K absorption could result in extreme elevation of prothrombin time and that patients taking this medication would need a careful and more frequent monitoring system to regulate and adjust drug administration. The comment also asserted that safety studies with olestra should be performed in patients taking coumarin derivatives. Another comment requested that the label statement indicate that olestra could cause blood clots, but provided no data or rationale to support this assertion.

One comment opposed the use of "hemophilia" in statements directed toward users of coumarin derivatives, stating that vitamin K status is not a factor in hemophilia. The comment also opposed use of the phrase "other blood diseases" in any statement directed toward users of coumarin derivatives because it is too vague. The comment also stated that the routine monitoring by physicians of patients taking coumarin derivatives will result in alterations in drug dosing if major and persistent alterations of vitamin K-compensated olestra-containing food intakes are found to influence drug efficacy.

FDA does not agree that olestra-containing foods should be required to bear a label statement directed toward those using coumarin derivatives to control blood clotting. FDA concluded in 1996 that consumption of olestra would not significantly influence the rate or extent of absorption of drugs (61

⁶¹ Two examples of wording suggested by the comments are: "Because olestra interferes with your body from absorbing certain nutrients and the vitamins A, D, E, and K, these essential vitamins have been added to this product." and "Olestra reduces the absorption of some nutrients, and vitamins A, D, E, and K have been added to compensate."