

any specific information to dispute P&G's consumption pattern data; instead, CSPI simply asserted that other consumption patterns were likely.²¹ Mere allegations of this type do not require that a hearing request be granted (§ 12.24(b)(2)). Moreover, although the petitioner did present information on snack consumption patterns and their effects on carotenoid depletion, FDA did not rely on this information in its safety determination (61 FR 3118 at 3149 at footnote 51). Accordingly, even if CSPI were to prevail on this factual issue, the outcome of this rulemaking would not be altered and thus, FDA is denying this portion of CSPI's objection and hearing request (§ 12.24(b)(4)).²²

Finally, CSPI relies on the proceedings of a January 1996 workshop at the Harvard School of Public Health to support its view that olestra's depletion of carotenoids will be harmful.²³ In particular, CSPI cites estimates of the possible impact on the public health that would allegedly result from the wide-spread use of olestra in snack foods, which estimates were presented at the Harvard meeting (CSPI exh. 13). CSPI contends that if FDA had correctly understood the Harvard meeting estimates regarding carotenoid depletion, it is doubtful that olestra would have been approved²⁴ (CSPI obj. at 28).

²¹ For example, CSPI claims that the "great popularity of tomato-based salsa in recent years suggests that many consumers would consume tortilla, corn, or potato chips with this carotenoid-rich dip, with or between meals." (CSPI obj. at p. 24.) Similarly, CSPI asserts that "consumption of savory snacks is likely to increase if olestra snacks become generally available." (CSPI obj. at p. 25.) CSPI does not identify any particular information or evidence in the record to support either assertion (§ 12.24(b)(2)).

²² In questioning the petitioner's evidence on consumption patterns, CSPI also challenges the hypothesis of Dr. Penny Kris-Etherton, a P&G consultant, that consumption of olestra-containing foods between meals has no effect on carotenoid depletion. Importantly, however, CSPI fails to identify any credible data or information to support its assertion that this hypothesis is "unproven and doubtful." (CSPI obj. at p. 25.) Thus, FDA is denying CSPI's request for a hearing on this point (§ 12.24(b)(2)).

²³ CSPI raises two spurious arguments regarding carotenoids, neither of which is adequate to justify a hearing on this issue. Specifically, CSPI criticizes the agency because no one from FDA's "senior level" attended the meeting, and faults the summary prepared by the FDA staffer who did attend the meeting. In addition, CSPI claims that Dr. Stampfer was given only a limited period to speak during the November 1995 FAC meeting and that his schedule precluded him from staying for the afternoon session when he could have expanded his comments. Neither of these arguments raises a material question of fact that requires a hearing (§ 12.24(b)(1)).

²⁴ CSPI also asserts that at the Harvard meeting, P&G employee Dr. Keith Triebwasser "stated that he could not assume that depletion of carotenoids was harmless," citing a letter from Dr. Alberto Ascherio

FDA is denying CSPI's request for a hearing on this point because the data and information submitted are insufficient to establish that olestra's depletion of carotenoids will be harmful (§ 12.24(b)(3)). First, the comments of those preparing the estimates undermine their validity. In particular, in their letter transmitting the estimates, Drs. Willett and Stampfer readily acknowledge that the estimates are not based on an established cause and effect relationship and are speculative in that they are based on a number of assumptions (CSPI exh. 13, pp. 1, 3, and 4). Moreover, in the preamble to the final rule, FDA outlined several considerations to be addressed in determining whether olestra's effect on carotenoids will be harmful, including the other factors that influence carotenoid utilization (carotenoid stability, bioavailability, and absorption) and whether serum carotenoid levels are an adequate indicator of carotenoid availability (61 FR 3118 at 3148 to 3149). Neither CSPI nor the scientists who prepared the Harvard estimates addressed these considerations. Accordingly, the Harvard estimates in and of themselves are not adequate to demonstrate that olestra's effect on carotenoid levels will be harmful.

B. Vitamin K

In its third objection and request for a hearing, CSPI challenges FDA's conclusion that supplementation of olestra with vitamin K will offset the additive's effect on vitamin K and thereby prevent adverse health effects associated with vitamin K depletion in olestra consumers. CSPI claims that FDA's decision on this point is erroneous for two reasons. First, CSPI asserts that a decision on olestra's safety should not have been made in the absence of a study of the interaction between Coumadin (a widely used anticoagulant) and olestra. Importantly, however, CSPI did not specifically identify any available data or information in the record to demonstrate why data from a study of olestra's effects on Coumadin therapy are necessary.²⁵ Accordingly, FDA is

(CSPI exh. 15). Importantly, however, Dr. Ascherio does not directly quote or even paraphrase Dr. Triebwasser; instead, the letter contains Dr. Ascherio's characterization of what Dr. Triebwasser said. (Dr. Ascherio stated: "The responses of the gentleman from Procter & Gamble made it clear that there is no scientific evidence to support [a conclusion that depletion of carotenoids will not harm people's health.]" Again, the information tendered by CSPI is insufficient to justify the factual conclusion urged and thus, FDA is denying CSPI's request for a hearing on this issue (§ 12.24(b)(3)).

²⁵ In fact, this concern was raised at the November 1995 FAC meeting and addressed in the

denying CSPI's request for a hearing on this question because it is merely an unsupported allegation (§ 12.24(b)(2)). Second, CSPI asserts that olestra supplemented with vitamin K may have adverse effects on bone formation. Once again, CSPI fails to specifically identify any data or information that could be used to resolve this question. Accordingly, FDA is denying CSPI's objection and hearing request on this point (§ 12.24(b)(2)).

C. GI Effects

In its fourth objection and request for a hearing, CSPI asserts that in a significant proportion of individuals olestra causes GI disturbances, including diarrhea, that these disturbances are adverse health effects, and that these GI disturbances are of sufficient concern to warrant a finding that there is no "reasonable certainty of no harm." CSPI also asserts that FDA's analysis of the data from two 8-week studies obscured the detection of trends between olestra consumption and GI symptoms reported.

1. Are the Observed GI Symptoms Adverse Health Effects?

In its objection and request for a hearing, CSPI asserts that FDA erred by concluding that certain GI effects of olestra (such as anal leakage, underwear staining, and oil-in-the-toilet) are not relevant to the question of the safety of olestra.²⁶ In particular, CSPI asserts that these olestra-related effects can have an "adverse effect on people's lives and interfere with their daily activities" and thus implies that FDA should have considered them in determining olestra's safety. In support of this objection, CSPI relies heavily on the proceedings before the OWG and the FAC (such as the testimony of Dr. Ian Greaves and Ms. Rosie Schwartz.)²⁷

At its core, CSPI's fourth objection concerns the meaning of the statutory standard of "safe," section 409(c)(3)(A) of the act, and, specifically, what is

preamble to the final rule. One witness, Dr. John Suttie, testified that vitamin K intake can vary from day-to-day by three or four-fold and that diet is not usually a primary factor of concern with anticoagulation therapy. Accordingly, he concluded that changes due to consumption of vitamin-K compensated olestra would likely be within the normal range of dietary variation (61 FR 3118 at 3147).

²⁶ In its fourth objection, CSPI also claims that consumption of olestra causes diarrhea, which CSPI claims is an adverse health effect. However, CSPI does not further address diarrhea in this objection.

²⁷ As part of their objections, CSPI criticizes a P&G market research study, and the OWG's alleged reliance on it. FDA told the OWG that the agency had not used data from the market research study in its analysis. Moreover, FDA did not rely on the study in determining that olestra is safe. CSPI concedes as much (CSPI obj. at p. 33).