

required (§ 12.24(b)(1)). Accordingly, FDA is denying CSPI's fifth objection.³⁴

F. Alleged Absence of Reasonable Certainty of No Harm

As noted, CSPI filed six objections to FDA's decision to approve olestra, including a general objection (CSPI obj. 1) that asserts that the additive does not meet the statutory standard of "reasonable certainty of no harm."³⁵ Many of the assertions of CSPI's general objection mirror the allegations of the more specific objections (CSPI obj. 2 through 5), which FDA has considered previously and denied.³⁶ Even standing alone, however, CSPI's first objection must be denied for several reasons.

Second, although CSPI's first objection is the longest of the six, it is almost exclusively a series of allegations³⁸ without any specifically identified and available evidence to support them.³⁹ That is, CSPI did not cite specific data or other factual information in the record to demonstrate the validity of its challenges to FDA's conclusions (CSPI

obj. at pp. 8 through 18). Thus, CSPI's first objection is denied for a second, separate reason because a hearing will not be granted on the basis of mere allegations (§ 12.24(b)(2)).⁴⁰

Third, CSPI asserts that the quality of certain studies relied upon by FDA is "spotty at best," and claims that these tests were "critical" to the safety evaluation of olestra (CSPI obj. at p. 13). In support of this claim, CSPI cites parts of the 1996 final rule and supporting memoranda discussing the limitations of certain studies.⁴¹ (CSPI obj. at p. 12, footnote 8). Importantly, however, CSPI does not demonstrate how the outcome of this proceeding would have been different if, due to these alleged quality problems, FDA had not been able to rely on these "certain studies" in determining the safety of olestra. Thus, FDA is denying CSPI's first objection because a hearing will not be granted on factual issues that are not determinative of the action requested⁴² (§ 12.24(b)(4)).

Fourth, CSPI challenges FDA's conclusion that the GI effects seen in P&G's 8-week studies are not harmful health effects. As part of this challenge, CSPI criticizes the size of the two 8-week studies and asserts that a larger study would likely have shown statistical significance at the 8 grams/day (g/d) dose, citing the comments of David Allison, Ph.D., a statistician and consultant to FAC (CSPI obj. at pp. 13 through 14 and footnote 11). CSPI fails to note that Dr. Allison concluded his statement by saying that whether "to make a great deal of argument on is there or isn't there an effect at the 8 g dose is really a misleading kind of argument because it seems almost certain that there is but, rather, is it an important effect, an effect that is clinically meaningful * * * (transcript of FAC meeting, November 16, 1995, at p. 52). In the same footnote, CSPI claims that Dr. Marvin

Schneiderman performed a trend test which demonstrated an increase in incidence of "gastrointestinal disturbances above the placebo level at 8 g/day." In fact, Dr. Schneiderman's analysis concerned only anal leakage, not all GI effects (CSPI exh. 14 at p. 2). FDA found that anal leakage is not a health hazard (61 FR 3118 at 3154), a fact not disputed by CSPI in its objections and hearing requests. Accordingly, FDA is denying CSPI's objection on this point because a hearing will be denied where the data and information submitted are insufficient to justify the factual determination urged (§ 12.24(b)(3)).

Finally, CSPI disputes FDA's conclusion that the "diarrhea" experienced by olestra consumers is not clinical diarrhea and thus, not an adverse health effect.⁴³ In particular, CSPI asserts that "weight and water content of diarrheal stools was increased over those of loose and normal stools in subjects eating 20 g/day of olestra." (CSPI obj. at p. 16). Importantly, however, CSPI does not cite a reference to support this conclusion. In the absence of specifically identified and available evidence to support a disputed fact, a hearing must be denied (§ 12.24(b)(2)). Moreover, CSPI does not explain how a finding of increased stool weight among olestra consumers would alter FDA's conclusion that olestra's GI effects are not harmful to health.⁴⁴ Thus, FDA is denying a hearing on this issue because it is not determinative of the question at issue (§ 12.24(b)(4)). Likewise, although FDA concluded that increased water content of stools could be an indicator of true diarrhea (61 FR 3118 at 3158), FDA concluded that in the study in question, the data "regarding stool water concentration—expressed as a percent of stools by weight—suggests that the stool water concentration of subjects having diarrhea during the olestra 20 g/d period did not differ from that of their nondiarrheal stools during the placebo period" (61 FR 3118 at 3171; Ref. 88). Thus, even if CSPI intended to rely on Ref. 88 to support this allegation, the memorandum does not establish that

³⁴ In fact, CSPI raised most of these complaints in comments to FDA prior to olestra's approval, and the agency addressed each such complaint in the preamble to the final rule (61 FR 3118 at 3163 to 3165). CSPI's fifth objection and hearing request does not dispute FDA's resolution of these challenges in the final rule.

³⁵ The act prohibits FDA from approving a food additive if it has not been shown to be "safe" for its intended use, section 409(c)(3) of the act; FDA's regulation, relying on the legislative history of the Food Additives Amendment of 1958, defines "safe" as "a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use. It is impossible in the present state of scientific knowledge to establish with complete certainty the absolute harmlessness of the use of any substance." (§ 170.3(i) (21 CFR 170.3(i)).

First, CSPI's first objection challenges FDA's finding that olestra is safe for use in savory snacks.³⁷ As noted, resolving the question of olestra's safety requires the application of the legal standard ("safe") as defined by FDA's regulations ("reasonable certainty of no harm") to a set of facts. As such, the question of whether olestra is safe for its intended use is a question of law, not fact. Accordingly, FDA is denying CSPI's first objection because a hearing will not be granted on issues of policy or law (§ 12.24(b)(1)).

³⁶ In these circumstances and for reasons of economy, FDA does not restate its analysis and basis for denial of the specific objections.

³⁷ CSPI asserts that FDA's approval of olestra is "arbitrary and capricious" and thus erroneous (CSPI obj. at p. 12). In fact, the standard of review for a food additive approval is "a fair evaluation of the entire record * * * (section 409(g)(2) of the act). CSPI provides no evidence that FDA did not conduct a fair evaluation of the entire record.

³⁸ For example, in its discussion of the "Inadequate Safety Base" for olestra, CSPI notes Dr. Klish, a witness at OWG, testified that at 1 year, children's GI tracts are the same as adults and therefore, data from adults can be extrapolated to children. On this subject CSPI simply asserts, "Life experience, however, does not support that view. After all, why do one- and two-year-olds experience 'toddlers' diarrhea' * * * ?" (CSPI obj. at p. 8.)

³⁹ In the carotenoids portion of its first objection, for example, CSPI refers to a "selection of letters from noted scientists opposing the approval of olestra" (CSPI exh. 8.) Notably, however, CSPI does no more to identify the specific facts these experts dispute or to specify the data and other information on which these experts rely (§ 12.24(b)(2)).

⁴⁰ It is not surprising that CSPI's allegations are unsupported because, in some cases, the allegations are clearly false. For example, CSPI claims that "the FDA staff declined to consider" certain data regarding carotenoids (CSPI obj. at p. 6). In fact, FDA devoted a significant amount of attention to the carotenoids issue (61 FR 3118 at 3147 to 3149 and 3161), but ultimately reached a different conclusion than that urged by CSPI.

⁴¹ In particular, CSPI quotes excerpts from the 1996 final rule in which FDA identified certain limitations of these studies of olestra. Identifying such limitations is consistent with FDA's obligation to make a "fair evaluation of the data" in the record when determining olestra's safety (section 409(c)(4) of the act).

⁴² For example, CSPI offers several criticisms of a P&G marketing study which the company presented to illustrate consumption patterns for savory snacks (CSPI obj. at p. 13, footnote 10). In fact, as CSPI noted (CSPI obj. at p. 33), FDA told OWG that FDA had not relied on data from this study in its safety evaluation (Transcript of the FAC meeting, November 16, 1995, at p. 55).

⁴³ CSPI refers to a December 26, 1995, memorandum of Karl Klontz, M.D., erroneously describing it as Ref. 87 to the final rule (CSPI obj. at p. 16, footnote 14). In fact, Dr. Klontz's December 26, 1995, memorandum is Ref. 88 of the final rule (61 FR 3118 at 3171).