

“harm” for purposes of that standard.²⁸ CSPI has not demonstrated that FDA wrongly decided any genuine and substantial issue of fact concerning the GI effects of olestra. Rather, CSPI disagrees with FDA’s application of the statutory safety standard, alleging that FDA ignored certain effects of olestra consumption that CSPI claims preclude a finding of safety.²⁹ In the absence of a genuine and substantial issue of fact, a hearing need not be granted because a hearing is not needed to settle issues of law (§ 12.24(b)(1)).

2. Did FDA Err in Pooling Certain GI Data for Analysis?

In its objection and request for a hearing, CSPI asserts that FDA’s analysis of two 8-week studies was inappropriate because the analysis pooled the data from both studies.³⁰ CSPI asserts that pooling these data was inappropriate because different formulations of olestra were used in the two studies. CSPI also objects to pooling the data because it would allegedly diminish the ability to detect trends in one study.³¹

FDA is denying CSPI’s request for a hearing on this issue because the organization failed to identify specifically any reliable evidence to support either of its factual allegations. That is, CSPI did not identify any data or information to support its claim that different olestra formulations precluded the pooling of the data from the two 8-week studies³² (§ 12.24(b)(2)). Moreover, even if the data from the two studies should have been analyzed separately, as asserted by CSPI, that analysis would

not have changed the outcome of this proceeding because the results would be the same whether analyzed separately or pooled (61 FR 3118 at 3153 to 3154). Accordingly, FDA is denying CSPI’s hearing request on this point (§ 12.24(b)(4)).

D. Adequacy of Olestra’s Label Statement³³

In its fourth objection and request for a hearing, CSPI challenges the label statement required by the 1996 final rule, claiming that it is not sufficient to protect the public from adverse effects associated with consumption of olestra. CSPI also claims that the portion of the label statement regarding the nutritional effects of olestra consumption is inadequate. CSPI offers several specific criticisms in support of these general allegations. As shown in the following sections D.1 and D.2, none of CSPI’s specific allegations raises a question of material fact that requires a hearing. In analyzing CSPI’s objection regarding the olestra label statement, it is critical to recognize that FDA did not require the statement to ensure olestra’s safe use (61 FR 3118 at 3160). Instead, the label statement was designed to prevent olestra-containing foods from being misbranded.

1. Label Statement Regarding GI Effects

CSPI alleges that the GI effects portion of the olestra label statement is not adequate for three reasons. First, CSPI claims that the word “laxative” should be used to describe olestra’s GI effects. Second, CSPI asserts that all GI effects of olestra should be disclosed, including diarrhea, underwear staining, oil-in-toilet, and anal leakage because they “might distress” consumers of olestra-containing snacks. Third, CSPI claims that the GI portion of the olestra label statement ought to advise consumers to seek medical treatment if the effects of olestra consumption do not subside within 48 hours of consumption. Importantly, CSPI does not dispute any facts that underlie FDA’s decision regarding the label statement. Fundamentally, CSPI’s allegation in this instance is that olestra-containing foods are misbranded in the absence of these three pieces of information. Whether foods that bear the olestra label statement set out in § 172.867 are misbranded is a question of law. Thus, FDA is denying CSPI’s hearing request on this point because a hearing will not be granted on issues of law

(§ 12.24(b)(1)). Moreover, even if such questions are questions of fact, CSPI did not specifically identify any data or other information to support its position. Thus, on this basis, FDA is denying this hearing request (§ 12.24(b)(2)).

2. Label Statement Regarding Absorption of Nutrients

CSPI also challenges that portion of the olestra label statement that relates to absorption of nutrients. CSPI asserts that this portion of the olestra label statement has several deficiencies. Specifically, CSPI claims that the word “compensation” should be substituted for “added,” that carotenoid depletion resulting from olestra consumption should be disclosed, that consumers should be advised that there are “no data” about the vitamin K repletion, and that the statement should begin with the word “warning” and appear on the front of the package. Again, in presenting this portion of the fifth objection, CSPI fails to identify specifically any underlying factual dispute that could be resolved by a hearing. The question of whether olestra-containing foods that bear the required label statement are misbranded is a question of law. Accordingly, FDA is denying CSPI’s request for a hearing on this point because a hearing will not be granted on issues of law (§ 12.24(b)(1)).

E. Alleged Procedural Problems in the Olestra Proceeding

In its fifth objection and hearing request, CSPI claims that there were a number of problems with the procedures utilized by FDA to reach a decision about the safety of olestra. CSPI raises the following six complaints: (1) Its White Paper was not provided promptly enough to the members of OWG and FAC, (2) the presentation by FDA’s staff to OWG did not adequately address carotenoids, (3) the 1996 final rule unfairly described support for olestra and discounted letters from CSPI members opposing olestra’s approval, (4) the petitioner engaged in a letter writing campaign to gain olestra’s approval, (5) FDA discounted the opinions of CSPI’s experts and ignored the “scientific information” in the letters from these experts, and (6) members of OWG and FAC were biased. As is the case with its fourth objection and hearing request, CSPI specifically identifies no factual issue underlying any of its six procedural complaints. In such circumstances, a hearing is not

²⁸ As noted in the preamble to the final rule, “safe” means “proof of a reasonable certainty of no harm,” a standard drawn from the legislative history of section 409 of the act; harm in this context means “hazardous to the health of man or animal.” (61 FR 3118 at 3119 to 3120.) FDA concluded that “an effect is harmful if it affects health, not if it is simply an undesirable or unexpected effect that has no adverse health consequences.” (61 FR 3118 at 3120.)

²⁹ Contrary to CSPI’s assertions, FDA’s evaluation of the evidence in the record did address a broad range of GI symptoms, including loose stools, cramping and bloating, fecal urgency, oil-in-the toilet, and anal leakage (61 FR 3118 at 3152 to 3159). In applying the statutory standard of “safe,” FDA concluded that none of these effects is harmful to health (61 FR 3118 at 3159). CSPI’s objection identifies no factual evidence to contradict this conclusion.

³⁰ FDA explained that pooling the data from the two studies increased the number of study subjects, thereby increasing the power of the data to detect trends (61 FR 3118 at 3153).

³¹ In its first objection, CSPI alludes to the pooling issue but does not elaborate on or support its challenge to pooling data (CSPI obj. 1 at p. 16).

³² In fact, although the two formulations of olestra differed in the degree of stiffness, each was within the range of stiffness permitted by the 1996 final rule (§ 172.867(b)(14)).

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