

submitted are insufficient to justify the factual determination urged, even if accurate; and (4) resolution of the factual issue in the way sought by the requestor is adequate to justify the action requested; a hearing will not be granted on factual issues that are not determinative with respect to the action requested, (e.g., if the action would be the same even if the factual issue were resolved in the way sought).

A party seeking a hearing is required to meet a "threshold burden of tendering evidence suggesting the need for a hearing." (See *Costle v. Pacific Legal Foundation*, 445 U.S. 198, 214–215 (1980), *reh. den.*, 446 U.S. 947 (1980), citing *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 620–621 (1973).) An allegation that a hearing is necessary to "sharpen the issues" or to "fully develop the facts" does not meet this test. (See *Georgia-Pacific Corp. v. U.S. EPA*, 671 F.2d 1235, 1241 (9th Cir. 1982).) If a hearing request fails to identify any evidence that would be the subject of a hearing, there is no point in holding one. In judicial proceedings, a court is authorized to issue summary judgment without an evidentiary hearing whenever it finds that there is no genuine issue of material fact, and a party is entitled to judgment as a matter of law (see Rule 56, Federal Rules of Civil Procedure). The same principle applies in administrative proceedings (§ 12.28).

A hearing request must not only contain evidence, but that evidence must raise a material issue of fact concerning which a meaningful hearing might be held. (See *Pineapple Growers Association v. FDA*, 673 F.2d 1083, 1085 (9th Cir. 1982).) Where the issues raised in the objection are, even if true, legally insufficient to alter the decision, the agency need not grant a hearing. (See *Dyestuffs and Chemicals, Inc. v. Flemming*, 271 F.2d 281 (8th Cir. 1959), *cert. denied*, 362 U.S. 911 (1960).) FDA need not grant a hearing in each case where an objector submits additional information or posits a novel interpretation of existing information. (See *United States v. Consolidated Mines & Smelting Co.*, 455 F.2d 432 (9th Cir. 1971).) In other words, a hearing is justified only if the objections are made in good faith, and if they "draw in question in a material way the underpinnings of the regulation at issue." (See *Pactra Industries v. CPSC*, 555 F.2d 677 (9th Cir. 1977).) Finally, courts have uniformly recognized that a hearing need not be held to resolve questions of law or policy. (See *Citizens for Allegan County, Inc. v. FPC*, 414 F.2d 1125 (D.C. Cir. 1969); *Sun Oil Co.*

v. FPC, 256 F.2d 233, 240 (5th Cir.), *cert. denied*, 358 U.S. 872 (1958).)

Even if the objections raise material issues of fact, FDA need not grant a hearing if those same issues were adequately raised and considered in an earlier proceeding. Once an issue has been so raised and considered, a party is estopped from raising that same issue in a later proceeding without new evidence. The various judicial doctrines dealing with finality can be validly applied to the administrative process. In explaining why these principles "self-evidently" ought to apply to an agency proceeding, the D.C. Circuit wrote:

The underlying concept is as simple as this: justice requires that a party have a fair chance to present his position. But overall interests of administration do not require or generally contemplate that he will be given more than a fair opportunity. (*Retail Clerks Union, Local 1401, RCIA v. NLRB*, 463 F.2d 316, 322 (D.C. Cir. 1972).) (See also *Costle v. Pacific Legal Foundation*, *supra* at 1106, and *Pacific Seafarers, Inc. v. Pacific Far East Line, Inc.* 404 F.2d 804 (D.C. Cir. 1968).)

In summary, a hearing request must present sufficient credible evidence to raise a material issue of fact and the evidence presented must be adequate to resolve the issue as requested and to justify the action requested.

III. Objections and Supporting Documents Submitted by CSPI

In a document dated February 29, 1996, entitled "Objections and Request for Hearing" (CSPI obj.), CSPI submitted to the Division of Dockets Management, its objections to the approval of the use of olestra as a food additive in savory snacks. CSPI submitted six objections to the 1996 final rule, and requested a hearing on issues raised by each objection. CSPI raised one general objection to the 1996 final rule, asserting that FDA improperly concluded that the use of olestra in savory snacks meets the safety standard of reasonable certainty of no harm. CSPI also raised five specific objections, asserting that: (1) Olestra's potential to deplete carotenoids may present a risk of harm to health, which precludes a finding of reasonable certainty of no harm; (2) FDA's decision to require compensation with vitamin K may not solve health problems that depletion of vitamin K may cause; (3) the potential GI disturbances that olestra may cause are adverse health effects that preclude a finding of reasonable certainty of no harm; (4) the label statement required on an interim basis by the 1996 final rule is insufficient to protect the public against adverse effects associated with consumption of olestra; and (5)

problems with procedure and process tainted FDA's review of, and decision-making process for, the food additive petition for olestra to the detriment of FDA's consideration of the public health concerns raised by CSPI and others. In support of its objections and hearing requests, CSPI filed 18 exhibits (CSPI exh. 1 through 18).⁴

IV. Analysis of Objections and Response to Hearing Requests

As noted in section III of this document, CSPI raised one general objection and five specific objections to the 1996 final rule. In this document, FDA addresses each of CSPI's objections, as well as the data and information filed in support of each, comparing each to the standards for granting a hearing in § 12.24(b). Because several of the issues in the general objection overlap with the five more specific objections, FDA addresses CSPI's five specific objections first (CSPI obj. 2 through 6), followed by the general objection (CSPI obj. 1).

A. Carotenoids

In its second objection and request for a hearing, CSPI states that there are two questions central to a discussion of the depletion of carotenoids by consumption of olestra. First, are carotenoids beneficial to health? Second, if carotenoids are beneficial to health, does consumption of olestra cause depletion of carotenoids such that there would be an absence of a reasonable certainty of no harm? CSPI claims that FDA did not answer either of these questions accurately and requests a hearing on both factual issues.

1. Are Carotenoids Beneficial to Health?

In its objection and request for a hearing, CSPI asserts that FDA erroneously concluded that there is no demonstrated health benefit of carotenoids except the provitamin A function of beta-carotene.

In analyzing this objection, it is important to recognize that FDA's position on carotenoids (as articulated in the 1996 final rule) has two parts. First, although FDA concluded that there is no demonstrated association between carotenoids per se and health

⁴ In a letter dated August 26, 1996 (Docket No. 1987F-0179), CSPI requested that certain documents submitted to the agency after February 29, 1996, be considered part of their objections. As noted previously, February 29, 1996, was the final day allowed under section 409(f)(1) of the act for submission of objections and hearing requests, including supporting material. Accordingly, the material submitted in August 1996 was not timely filed and thus, has not been considered in evaluating the CSPI objections and hearing requests.