by removing the statement ''Useful Only in Not Promoting Tooth Decay'' from those statements that can be used in conjunction with a ''sugar free'' claim. They requested a formal evidentiary hearing on their objections. Two other manufacturers submitted general comments, and a professional association resubmitted, as comments to the special dietary use final rule, comments that it had filed regarding the November 27, 1991, proposed rules on food labeling.

The provision of § 105.66(f) that was the subject of the objections was adopted under section 701(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 371(e)). Section 701(e)(1) of the act provides that any person adversely affected by a regulation issued under that section may file objections, specifying with particularity the provisions of the order ''deemed objectionable, stating reasonable grounds therefor'' and may request a public hearing based upon such objections. Under section 701(e) of the act, objections and a request for a hearing on a particular regulation act to automatically stay or delay the effective date of the action to which objections are raised (section 701(e)(2) of the act). Thus, the revision to § 105.66(f) that would remove the statement ''Useful Only in Not Promoting Tooth Decay'' from those statements that can be used in conjunction with a ''sugar free'' claim was automatically stayed as of February 5, 1993.

B. *Standards for Granting a Hearing*

FDA may deny a hearing request if the objections to the regulation do not raise genuine and substantial issues of fact that can be resolved at a hearing. Specific criteria for determining whether a hearing has been justified are set forth in 21 CFR 12.24(b). A hearing will be granted if the material submitted shows that: (1) There is a genuine and substantial issue of fact for resolution at a hearing. A hearing will not be granted on issues of policy or law; (2) the factual issue can be resolved by available and specifically identified reliable evidence. A hearing will not be granted on the basis of mere allegations or denials or general descriptions of positions and contentions; (3) the data and information submitted, if established at a hearing, would be adequate to justify resolution of the factual issue in the way sought by the person. A hearing will be denied if the Commissioner concludes that the data and information submitted are insufficient to justify the factual determination urged, even if accurate; (4) resolution of the factual issue in the way sought by the person 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 Commissioner concludes that the action would be the same even if the factual issues were resolved in the way sought, or if a request is made that a final regulation include a provision not reasonably encompassed by the proposal; and (5) the action requested is not inconsistent with any provision in the act or any regulation in this chapter particularizing statutory standards. The proper procedure in those circumstances is for the person requesting the hearing to petition for an amendment or waiver of the regulation involved.

A party seeking a hearing is required to meet a ''threshold burden of tendering evidence suggesting the need for a hearing.'' *Costle* v. *Pacific Legal Foundation,* 445 U.S. 198, 214–215 (1980) reh. den., 445 U.S. 947 (1980), citing *Weinberger* v. *Hynson, Wescott & 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. *Georgia Pacific Corp.* v. *U.S. E.P.A.,* 671 F.2d 1235, 1241 (9th Cir. 1982). If a hearing request fails to identify any factual 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 are no genuine issues of material fact in dispute 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.

A hearing request must not only contain evidence, but that evidence should raise a material issue of fact concerning which a meaningful hearing might be held. *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. *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.'' *Pactra Industries* v. *CPSC,* 555 F.2d 677 (9th Cir. 1977) (see also *Community Nutrition Institute* v. *Young,* 773 F.2d 1356 (D.C. Cir. 1985)). 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).)

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

C. *Analysis of Objections and Request for a Hearing and Related Comments*

1. The three objectors and one of the comments stated that the agency had not provided adequate notice or opportunity for comment on its decision to remove the provision providing for the use of the statement ''Useful Only in Not Promoting Tooth Decay.'' The objectors presented a number of arguments as support. First, two of the objectors stated that all of the previous proposals related to the final rule implied that the agency was going to retain the phrase ''Useful Only in Not Promoting Tooth Decay.'' Secondly, one objector stated that the meaning of the agency's statement in the nutrient content claims proposal that it planned at some point to reevaluate its earlier determination regarding sugar-free products was at least ambiguous. The other two objectors stated that this statement only served to alert interested persons that FDA may decide in the future to propose revisions to the rule allowing use of the statement ''Useful Only in Not Promoting Tooth Decay'' but that such revisions could have gone in either direction. These objectors concluded that the decisions to delete § 105.66(f) and to subject the phrase ''Useful Only in Not Promoting Tooth Decay'' to the requirements of health claims were in no sense logical outgrowths of FDA's November 1991 proposal.

In considering the objection that the agency did not provide adequate notice and opportunity for comment in its actions revoking the provision for the phrase ''Useful Only in Not Promoting Tooth Decay,'' it is important to understand exactly what FDA did in the nutrient content claims proposal. FDA was not merely proposing to carry forward the provisions of the ''sugar free'' claim unchanged from the existing regulations. Rather, FDA was proposing to find that a fundamental change in the character of this claim had been worked