''sugar free'' claim as a special dietary use claim, and the fact that section 403(j) of the act on foods for special dietary use says such food is misbranded ''unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the Secretary determines to be, and by regulation prescribes as, necessary in order fully to inform purchasers of its value for such uses.''

Assuming that section 403(j) of the act is relevant to how a nutrient content claim is defined, what the objectors do not recognize or deal with is the fact that section 403(j) of the act is a grant of discretion to the Secretary (''as the Secretary determines'') with regard to what information is necessary to inform consumers of the value of a food for special dietary use. FDA must exercise its discretion in accordance with the law, however. Section 403(r)(1)(B) of the act on its face makes the statement ''Useful Only in Not Promoting Tooth Decay'' a health claim and not a nutrient content claim or an indispensable part of a nutrient content claim. Thus, the act, as revised by the 1990 amendments, precludes the agency from treating this statement in any other way than as a health claim. Thus, the agency's discretion under section 403(j) of the act (and, given the agency's decision to treat ''sugar free'' as a nutrient content claim, under section 403(r)(1)(A) of the act) is limited by section 403(r)(1)(B) of the act. ''Useful Only in Not Promoting Tooth Decay'' simply is not available for use as part of a nutrient content claim.

5. The objectors argued that, because ''Useful Only in Not Promoting Tooth Decay'' had not been viewed as a drug claim, it is not a health claim. The objectors stated that there has never been any indication during the use of the statement that it constituted a drug claim.

FDA believes that this argument misinterprets the intent of the 1990 amendments and is without merit. The fact that, under section 201(g)(1) of the act (21 U.S.C. 321(g)(1)), a claim that is authorized under section 403(r)(3) or 403(r)(5)(D) of the act would not subject a food to regulation as a drug has apparently somehow created the incorrect impression that the process for authorizing a health claim for a food is an alternative to obtaining approval for a drug claim. There is nothing in either section 201(g)(1) or section 403(r) of the act that either states or implies that health claims are claims that would be drug claims if not authorized by the agency. The fact that an authorized health claim will not make a food product a drug does not mean that an unauthorized health claim will.

In contrast to a drug claim, a health claim provides information about how diet can help reduce a person's risk of developing certain diet-related diseases. The ''Useful Only in Not Promoting Tooth Decay'' statement does exactly what a health claim is supposed to do. It tells the consumer that including foods sweetened with sugar alcohols in his or her diet will affect his or her risk of developing dental cavities. (The question of the scientific validity of this claim is addressed in a proposal published elsewhere in this issue of the **Federal Register**.) Thus, there is nothing in the act that would preclude regulating ''Useful Only in Not Promoting Tooth Decay'' as a health claim. Quite the contrary, the act compels that this claim be regulated as such a claim.

6. A comment from a manufacturer noted that the date for submission of objections to the final rule provided that objections must be submitted by December 10, 1992, rather than being 30 days after the date of publication in the **Federal Register** (i.e., February 4, 1993). The letter contained no specific objections concerning the content of the final rule.

The error identified in the comment occurred in the ''Objections'' section of the special dietary use final rule (58 FR 2427 at 2430). The caption **DATES** at the beginning of the document listed the correct date of February 5, 1993, for the submission of objections and requests for hearing. Additionally, FDA published a document in the **Federal Register** of April 1, 1993 (58 FR 17104), correcting the reference to December 10, 1993. FDA is not aware of any difficulty presented to objectors by the presence of the incorrect date in the special dietary use final rule. Therefore, it finds nothing in their comment that would warrant further action by the agency.

D. *Conclusions on Objections and Request for a Hearing*

Under part 12 (21 CFR part 12), a request for a hearing shall be granted if there is a genuine and substantial issue of fact. The arguments presented by the various objectors did not present any genuine and substantial issues of fact. Accordingly, having fully considered the issues raised by the objectors in regards to the special dietary use final rule, FDA finds that they have no merit and is hereby denying the requests for a hearing.

III. Amendment to Section 101.60

A. *Request for a Stay of Effectiveness*

A trade association and a ''working group'' of manufacturers independently submitted the same joint petition requesting that the agency stay the effectiveness of the issuance of § 101.60(c) while the specific issues raised in their joint petition are being reconsidered. They also asked for a stay of any administrative action by FDA under its determination that ''Useful Only in Not Promoting Tooth Decay'' is an unauthorized health claim. Finally, they asked that FDA issue an affirmative statement on enforcement policy with respect to the disclaimer during the period of May 8, 1993, to May 8, 1994.

FDA provides in part 10 (21 CFR part 10) of its regulations that an interested person may request that the agency stay the effective date of any administrative action (§ 10.35).

The agency is responding to the various requests for reconsideration in this document. Because FDA has determined that a hearing need not be held on the amendments to § 105.66 and that there is no basis for reconsideration of the decision and regulations in question, the question of a stay pending reconsideration is moot. However, FDA notes that the new provisions of § 105.66(f) were stayed automatically by the operation of section 701(e) of the act upon the filing of objections to the special dietary use final rule. Additionally, the agency notes that it has refrained administratively from taking any action pending its resolution of the objections and requests for a hearing. Also, under its enforcement discretion, the agency plans no regulatory action on the use of the phrase ''Useful Only in Not Promoting Tooth Decay'' pending its final action on the proposal published elsewhere in this issue of the **Federal Register** in response to the health claim petition that has been submitted for sugar alcohols.

B. *Request for Reconsideration*

A trade association of manufacturers and a ''working group'' of manufacturers independently filed a joint petition for reconsideration of the agency's decision ''concerning the use of the 'useful only in not promoting tooth decay' disclaimer for 'sugar free' foods.'' The petitioners requested reconsideration of the agency's decisions to: (1) Remove existing § 105.66(f) from the republished rules governing the labeling of foods for special dietary uses; (2) add new § 101.60(c) without including ''Useful Only in Not Promoting Tooth Decay'' as a permitted disclaimer, where appropriate for caloric sugar free products; and (3) take the position in the preamble to the nutrient content claims regulation that this disclaimer represents an unauthorized health