term ''sugar free'' meant only that the food was sucrose free. A ''sugar free'' food could contain other fermentable carbohydrates. Thus, the information about the effect of sugar alcohol-containing foods on the risk of developing dental caries was originally placed on the food label primarily to clarify that the product was not necessarily useful in weight control, not to highlight the effect of sugar alcohol on dental caries production.

In the **Federal Register** of November 27, 1991 (56 FR 60421), in response to the 1990 amendments, FDA published a proposed rule entitled ''Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms'' (the nutrition labeling general principles proposal). In that document, FDA recognized that developments in nutrition science had established that the focus of nutrient content claims for providing dietary guidance had shifted from special populations with particular conditions to the general population (see 56 FR 60421). Therefore, in the nutrition labeling general principles proposal, FDA proposed to treat several claims that had been subject to regulation in § 105.66 (21 CFR 105.66) as special dietary use claims as nutrient content claims for the general population. To eliminate redundancy in the regulations and to conform § 105.66 to the 1990 amendments, FDA proposed to define these claims in part 101 (21 CFR part 101) and to remove them from part 105 (21 CFR part 105). Specifically, FDA proposed to adopt definitions for terms such as ''low calorie'' and ''reduced calorie,'' for other comparative calorie claims, and for sugar claims under section 403(r)(2) of the act and to codify them in § 101.60. It also proposed to delete these claims from § 105.66.

In the **Federal Register** of January 6, 1993 (58 FR 2302), FDA published its final rules on nutrient content claims. FDA adopted definitions for claims for the calorie content of foods in § 101.60 (58 FR 2302 at 2415). FDA defined claims regarding the sugars content of a food, e.g., ''sugar free,'' ''free of sugar,'' ''no sugar,'' in § 101.60(c). In addition, FDA published a final rule that deleted these claims from § 105.66 (58 FR 2427).

However, based on its consideration of comments on the use of the statement ''useful only in not promoting tooth decay'' to qualify the ''sugarless'' claim, FDA concluded that the statement was actually an unauthorized health claim (58 FR 2302 at 2326). The claim is a health claim because it characterizes the relationship of a substance (sugar alcohols) to a disease (dental caries).

In the nutrient content claim general principles proposal (56 FR 60421 at 60437), the agency stated that it intended to reevaluate the usefulness of chewing gums sweetened with sugar alcohols in not promoting tooth decay. The agency stated that the data supporting the claim were over 20 years old and requested that new data be submitted in accordance with the final rule on health messages. In the nutrient content claim final rule, FDA stated that it had received data on the validity of a claim about this nutrient-disease relationship, and that it would make a determination on whether to authorize a claim in accordance with the final rule on health claims (58 FR 2302 at 2326).

On February 5, 1993, under the procedure established in section 701(e) of the act (21 U.S.C. 371(e)), a group of sugar alcohol manufacturers submitted an objection to the revocation of § 105.66(f) (Ref. 2) and asked for a hearing on their objection. At the same time, the group petitioned for reconsideration of the agency's decision and for a stay of any administrative action by FDA pursuant to the determination announced in the preamble of the nutrient content claims rules that ''useful only in not promoting tooth decay'' is an unauthorized health claim.

Filing objections to the revocation of § 105.66(f) stayed the effect of the final rule as a matter of law. FDA's response to these objections and to the petitions is set forth elsewhere in this issue of the **Federal Register**.

In the **Federal Register** of August 18, 1993 (58 FR 44036), FDA published technical amendments to the health claim regulations in response to comments that the agency received on the implementation final rule that was published with the other final rules that responded to the 1990 amendments in January of 1993 (see 58 FR 2066, August 18, 1993). One of the comments stated that if a petition were submitted for the claim ''Useful Only in Not Promoting Tooth Decay,'' virtually none of the sugar-free products on the market would be eligible to bear the claim based on the requirements of a subsection of health claims general principles regulation, § 101.14(e)(6). FDA acknowledged that certain food products of limited nutritional value that have been specially formulated relative to a specific disease condition, such as dental caries, may be determined to be appropriate foods to bear a health claim (58 FR at 44036). The agency commented that it was its intention to deal with such situations within the regulations authorizing specific health claims. Therefore, FDA amended § 101.14(e)(6) to state that:

> Except for dietary supplements or where provided for in other regulations in part 101, subpart E, the food contains 10 percent or more of the Reference Daily Intake or the Daily Reference Value for vitamin A, vitamin C, iron, calcium, protein, or fiber per reference amount customarily consumed prior to any nutrient addition.

II. Petition for the Noncariogenicity of Sugarless Food Products Sweetened With Sugar Alcohol

A. Background

On August 31, 1994, the petitioners submitted a health claim petition to FDA requesting that the agency authorize a health claim on the relationship of sugar alcohols (i.e., xylitol, sorbitol, mannitol, maltitol, lactitol, isomalt, hydrogenated starch hydrolysates, and hydrogenated glucose syrups) in sugarless foods to dental caries (Ref. 1). On September 15, 1994, FDA sent the petitioners a letter stating that study reports that are needed to support the petition, and that are required for a health claim petition under § 101.70, were not included in the petitioners' submission. The agency stated that no further action would be taken until that information was received (Ref. 3).

On September 27, 1994, the petitioners filed an amendment to their petition submitting the required information. On October 7, 1994, the agency sent the petitioners a letter acknowledging receipt of the additional information and stating that the agency had begun its scientific review of the petition (Ref. 4).

In this document, the agency will consider whether a health claim on the relationship between sugar alcohols and dental caries is justified under the standard in section 403(r)(3)(B)(i) of the act and § 101.14(c) of FDA's regulations. In addition, the agency will consider the petitioners' request that the agency provide in any regulation authorizing a claim that foods sweetened with sugar alcohols be exempt from the requirement in § 101.14(e)(6). The following is a review of the health claim petition.

B. Preliminary Requirements

1. The Substances That Are the Subjects of the Petition

Sugar alcohols are a class of organic compounds that contain chains of carbon atoms that bear two or more hydroxyl groups and have only hydroxyl functional groups (Ref. 1). The hydroxyl groups replace ketone or aldehyde groups that are found in sugars (§ 101.9(c)(6)(iii)). The specific sugar alcohols that are the subject of this petition are xylitol, sorbitol, mannitol,