DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR PART 101

[Docket No. 95P–0003]

Food Labeling: Health Claims; Sugar Alcohols and Dental Caries

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to authorize the use, on food labels and in food labeling, of health claims on the association between sugar alcohols and the nonpromotion of dental caries. In addition, FDA is proposing to exempt sugar alcohol-containing foods from certain provisions of the health claims general requirements regulation. FDA is proposing these actions in response to a petition filed by the National Association of Chewing Gum Manufacturers, Inc., and an ad hoc working group of sugar alcohol manufacturers (hereinafter referred to as the petitioners).

DATES: Written comments by October 3, 1995. The agency is proposing that any final rule that may issue based upon this proposal become effective 30 days following its publication.

ADDRESSES: Written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Joyce J. Saltsman, Center for Food Safety and Applied Nutrition (HFS–165), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5916.

SUPPLEMENTARY INFORMATION:

I. Background

A. The Nutrition Labeling and Education Act of 1990

On November 8, 1990, the President signed into law the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) (Pub. L. 101–535). This new law amended the Federal Food, Drug, and Cosmetic Act (the act) in a number of important ways. One of the most notable aspects of the 1990 amendments was that they confirmed FDA's authority to regulate health claims on food labels and in food labeling. As amended by the 1990 amendments, section 403(r)(1)(B) of the act (21 U.S.C. 343(r)(1)(B)) provides that a product is misbranded if it bears a claim that characterizes the relationship of a nutrient to a disease or health-related condition, unless the claim is made in accordance with the procedures and standards contained in regulations adopted by FDA.

Under section 403(r)(3)(B)(i) of the act, the Secretary of Health and Human Services (and, by delegation, FDA) shall promulgate regulations authorizing such claims only if he or she determines, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.

Section 403(r)(3)(B)(ii) and (r)(3)(B)(iii) of the act describes the information that must be included in any claim authorized under the act. The act provides that the claim shall be an accurate representation of the significance of the substance in affecting the disease or health-related condition, and that it shall enable the public to comprehend the information and understand its significance in the context of the total daily diet. Finally, section 403(r)(4)(A)(i) of the act provides that any person may petition FDA to issue a regulation authorizing a health claim.

The 1990 amendments, in addition to amending the act, directed FDA to consider 10 substance-disease relationships as possible subjects of health claims.

B. FDA's Response

In the **Federal Register** of January 6, 1993 (58 FR 2478), FDA adopted a final rule that implemented the health claim provisions of the act. In that final rule, FDA adopted § 101.14 (21 CFR 101.14). The regulation sets out the circumstances in which a substance is eligible to be the subject of a health claim (§ 101.14(b)), adopts the standard in section 403(r)(3)(B)(i) of the act as the standard that the agency will apply in deciding whether to authorize a claim about a substance-disease relationship (§ 101.14(c)), sets forth general rules on how authorized claims are to be made in food labeling (§ 101.14(d)), and establishes limitations on the circumstances in which claims can be made (§ 101.14(e)). The agency also adopted § 101.70 (21 CFR 101.70), which establishes a process for petitioning the agency to authorize health claims about a substance-disease relationship (§ 101.70(a)) and sets out the types of information that any such petition must include (§ 101.70(d)). These regulations became effective on May 8, 1993.

In addition, FDA conducted an extensive review of the evidence on the 10 substance-disease relationships listed in the 1990 amendments. FDA has authorized claims that relate to 8 of these 10 relationships.

The present rulemaking on sugar alcohols and dental caries represents the first rulemaking that FDA has conducted in response to a health claim petition.

C. History of Sugar Alcohol Labeling

In a set of findings of fact and a tentative order on label statements for special dietary foods that the agency issued on July 19, 1977 (42 FR 37166), FDA addressed the issue of the use of the terms ''sugar free,'' ''sugarless,'' and ''no sugar.'' The agency stated that consumers may associate the absence of sugar in a product with weight control and with foods that are low calorie or that have been altered to reduce calories significantly. At that time, FDA viewed foods intended to be useful in maintaining or reducing calorie intake or body weight as foods for special dietary use, that is, as foods intended for supplying particular dietary needs that exist by reason of a physical, physiological, pathological, or other condition.

Evidence had been introduced at a public hearing in the 1977 rulemaking to show that the ''sugarless'' claim is useful to identify foods like chewing gum, which is in sustained contact with the teeth, in which the use of a sweetener other than a fermentable or cariogenic carbohydrate may not promote tooth decay. The secretary of the American Dental Association's Council on Dental Therapeutics supported the importance of advertising and labeling sugarless chewing gum and mints as noncariogenic, in the sense that they did not contribute to the development of dental caries (Ref. 80).

In the final rule on label statements for special dietary foods published in the **Federal Register** of September 22, 1978 (43 FR 43248), FDA required a statement that a food is not low calorie or calorie reduced (unless it is in fact, a low or reduced calorie food) when a ''sugar free,'' ''sugarless,'' or ''no sugar'' claim is made for the food. The agency decided to allow ''useful only in not promoting tooth decay'' as an alternative statement to accompany such claims. The agency stated that the statements that the food is not low calorie or not useful for weight control, as well as ''useful only in not promoting tooth decay,'' were needed because the