

4. Paragraph (b) of § 210.76 is revised to read as follows:

§ 210.76 Modification or rescission of exclusion orders, cease and desist orders, and consent orders.

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(b) *Commission action upon receipt of petition.* The Commission may thereafter institute a proceeding to modify or rescind the exclusion order, cease and desist order, or consent order by issuing a notice. The Commission may hold a public hearing and afford interested persons the opportunity to appear and be heard. After consideration of the petition, any responses thereto, and any information placed on the record at a public hearing or otherwise, the Commission shall take such action as it deems appropriate. The Commission may delegate any hearing under this section to the chief administrative law judge for designation of a presiding administrative law judge, who shall certify a recommended determination to the Commission.

By Order of the Commission.
Issued: August 19, 1996.

Donna R. Koehnke,
Secretary.

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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: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing its decision 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. The agency has concluded that, based on the totality of the scientific evidence, there is significant scientific agreement among qualified experts to support the relationship between sugar alcohols (i.e., xylitol, sorbitol, mannitol, maltitol, lactitol, isomalt, hydrogenated starch hydrolysates (HSH), hydrogenated glucose syrups (HGS), or a combination of sugar alcohols) and the nonpromotion of dental caries. Therefore, FDA has concluded that claims on foods relating

sugar alcohols to the nonpromotion of dental caries are justified. FDA is announcing 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: Effective January 1, 1998. The Director of the Office of the Federal Register approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of a certain publication in 21 CFR 101.80(c)(2)(ii)(C), effective January 1, 1998.

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SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of July 20, 1995 (60 FR 37507), the agency proposed 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 proposed to exempt sugar alcohol-containing foods from the requirement in § 101.14(e)(6) (21 CFR 101.14(e)(6)) of the health claims general requirements regulation concerning disqualification criteria. Section 101.14(e)(6) provides that, except for dietary supplements or where provided for in other regulations in part 101 (21 CFR part 101), subpart E, to be eligible to bear a health claim, a food must contain 10 percent or more of the Reference Daily Intake (RDI) or the Daily Reference Value (DRV) for vitamin A, vitamin C, iron, calcium, protein, or fiber per reference amount customarily consumed before there is any nutrient addition.

The proposed rule was issued in response to a petition filed under section 403(r)(3)(B)(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(r)(3)(B)(i)). Section 403(r)(3)(B)(i) of the act states that the Secretary of Health and Human Services (the Secretary) (and, by delegation, FDA) shall promulgate regulations authorizing health 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 (see also § 101.14(c)). FDA considered the relevant scientific studies and data presented in the petition as part of its review of the scientific literature on sugar alcohols and dental caries. The agency summarized this evidence in the proposed rule (60 FR 37507).

The proposed rule included qualifying and disqualifying criteria for the purpose of identifying foods eligible to bear a health claim. The proposal also specified mandatory content and label information for health claims statements and provided model health claims. In its review of sugar alcohols eligibility for a health claim under § 101.14(b), FDA discussed potential safety issues relating to sugar alcohols and the petitioners' position that the use of sugar alcohols is safe and lawful. The agency also discussed the potential issue that some sugar alcohol-containing foods may contain other ingredients, such as refined flour, that may be cariogenic. Consequently, the agency proposed to require that sugar alcohol-containing foods not lower plaque pH below 5.7, as determined by appropriate in vivo tests. FDA requested written comments on the proposed rule, including comments on the agency's tentative conclusion that the petitioners had satisfied the requirements regarding the safe and lawful use of sugar alcohols that are the subject of the health claim and comments on the proposal to establish a minimum plaque pH test for sugar alcohol-containing foods.

II. Summary of Comments and the Agency's Responses

In response to the proposal, the agency received approximately 20 letters, each containing one or more comments, from professional organizations, industry, trade associations, and health care professionals. Comments that were not relevant to the sugar alcohol and dental caries proposed rule, but that addressed broader issues pertaining to health claims in general, are not discussed in the sections of this document that follow. A number of comments were received that dealt generally with the questions of whether health claims need to state that the disease or health-related condition is multifactorial, and whether the whole claim needs to appear in one place. These issues of broad applicability to health claims are being considered in the rulemaking entitled "Food Labeling: Nutrient Content Claims, General Principles; Health Claims, General Requirements and Other Specific Requirements for Individual Health Claims" (60 FR

66206, December 21, 1995) (hereinafter referred to as "the 1995 nutrient content and health claims proposed rule"). Therefore, FDA forwarded the comments in question to that docket for consideration as part of that rulemaking.

The majority of the comments received in response to the sugar alcohol proposal agreed with one or more provisions of the proposed rule without providing grounds for support other than those provided by FDA in the preamble to the proposal. A few of these comments also requested modification of one or more provisions of the proposed rule. A few comments disagreed with the proposed rule and provided specific support for their positions. The agency has summarized and addressed the relevant issues raised in all comments in the sections of this document that follow.

A. General Comments

Some comments addressed the basic issue of whether FDA should permit health claims about sugar alcohol and dental caries on food labeling and the claim's consistency with the general principles for health claims.

1. One comment stated that section 403(r)(1)(B) of the act, which was added by the Nutrition Labeling and Education Act of 1990 (the 1990 amendments), defines "health claims" as those statements that characterize "the relationship of any nutrient which is of the type required [to be in nutrition labeling] of the food to a disease or a health-related condition." The comment stated that in promulgating the regulations governing health claims, FDA interpreted the statutory language to include any relationship of a "substance" to a disease or health-related condition (§ 101.14(a)(2)). The comment stated that the agency used the term "substance" to make clear that health claims could be established that described relationships regarding either particular nutrients or foods bearing nutrients, such as fruits and vegetables, and a disease or health related condition. The comment stated that a health claim must describe the function of the substance in question in providing nourishment or nutriment and how the function of that nutrient relates to a disease or health condition. The comment stated that the posited relationship between sugar alcohols and noncariogenicity is not a nutrient relationship and does not satisfy the nutrient-disease relationship requirement under the act because it does not address the function of a substance in providing nourishment or nutriment.

The agency does not agree that the proposed health claim is inconsistent with health claim principles. Sugar alcohols are nutrients of the type specified in section 403(q) of the act. FDA lists them in § 101.9(c) (21 CFR 101.9(c)) as one of the nutrients that can be listed in the nutrition label. Thus, they can be the subject of a health claim.

The issue of whether claims about sugar alcohols and dental caries are health claims was discussed in the Federal Register of July 20, 1995 (60 FR 37502), final rule entitled "Food Labeling: Label Statements on Foods for Special Dietary Use; 'Useful Only in Not Promoting Tooth Decay' Disclaimer" (hereinafter referred to as "the 1995 disclaimer final rule"). The agency pointed out that a health claim provides information about how a particular type of substance (sugar alcohols) can affect a person's risk of developing a diet-related diseases (dental caries). The "Useful Only in Not Promoting Tooth Decay" statement does what a health claim does in that it tells a consumer that including foods sweetened with sugar alcohols in his or her diet will affect his or her risk of developing dental caries.

Thus, in the 1995 disclaimer final rule, the agency found that the statement on tooth decay is a health claim because it contains both elements necessary to meet the "health claim" definition under 403(r)(1)(B) of the act. FDA concluded that "useful only in not promoting tooth decay" is not a nutrient content claim because it does not characterize the level of any nutrient. Thus, regardless of how this claim has been used, as the law is now written, its use in food labeling would misbrand the food unless claims about sugar alcohols and dental caries are authorized by FDA under section 403(r)(3) (or section 403(r)(5)(D)) of the act.

Relative to the comment that a health claim must describe the function of the substance in question in providing nourishment or nutriment, the general principles for health claims do not require that the health claim, itself, contain such a statement. The agency must be fully satisfied, however, that the substance meets the general requirements for health claims under § 101.14, and under § 101.14(b)(3)(i), if the substance is consumed at other than decreased dietary levels, it must contribute taste, aroma, or nutritive value, or some technical effect listed in 21 CFR 170.3(o), to the food and retain that attribute when consumed at levels that are necessary to justify a claim. Sugar alcohols meet this requirement (see 60 FR 37507 and 37509) because they are used as sweeteners and bulking

agents (i.e., stabilizers and thickeners) and are consumed for their taste. Inasmuch as sugar alcohols are also a source of calories, they contribute nutritive value to the foods, such as chewing gums and confectioneries, in which they are used.

2. One comment stated that the proposed claim is not a health claim in the same sense that the other authorized claims are because the substance's effect is largely independent of other dietary practices, i.e., sugar alcohol-sweetened candy will always not promote tooth decay regardless of other elements in the diet. Another comment stated that the idea of instituting a health claim for a substance that merely replaces a nutrient that may contribute to a disease or health-related condition could open the door to questionable claims. One comment stated that the nonpromotion claim is a product descriptor that provides information on the absence of an undesirable side effect.

The agency disagrees that the claim is not valid because sugar alcohols function independently of other dietary practices, or because the substance replaces or can substitute for another substance. The comment did not demonstrate that sugar alcohols affect the risk of dental caries in a way that is independent of other dietary practices, or why, even if the did, this fact would render the claim invalid. In fact, as explained in the proposed rule (60 FR 37507 at 37524), the association between sugar alcohols and dental caries is related to dietary practices. The consumption of dietary sugars and fermentable carbohydrates in the form of gums, confectioneries, and other snack foods is widespread and frequent in the diet. There is a clear association between the onset of dental caries and the presence in the diet of sugars and other fermentable carbohydrates. By consuming foods, such as gums, mints, candies, jams and jellies, and desserts, in which sugar alcohols are used to replace the fermentable carbohydrates instead of the versions of those foods that contain the fermentable carbohydrates, the consumer, the available evidence shows, reduces his or her risk of developing dental caries. Therefore, the claim is based on dietary practices and is relevant within the context of the total daily diet.

A claim based on the substitution or replacement of one food substance for another is not inconsistent with, or prohibited under, the general principles for health claims. In fact, current dietary recommendations encourage substitution and replacement of foods in the diet, for example, the use of low-fat foods in place of high-fat foods.

However, the evidence must show that the effect of substituting one substance for another is relevant to the risk of the disease or health-related condition that is the subject of the claim. Here, the results of long-term studies in which sugar alcohol-containing foods are substituted for sugar-containing foods in the daily diet support the contention that sugar alcohols help reduce the risk of developing dental caries (see, for example, Refs. 21, 22, 23, and 25; 60 FR 37507 at 37514).

The concern in one comment that questionable claims may occur when the substitution or replacement of substances is the subject of a health claim is fully addressed by the provisions of existing principles for health claims. One of the requirements for a substance to be eligible for a health claim is that the substance must be associated with a disease, or health-related condition, or, alternatively, the petition must explain the prevalence of the disease in the U.S. population and the relevance of the claim in context of the total daily diet (see § 101.14(b)(1)). The agency finds that this as well as the other eligibility requirements for health claims provide protection against questionable claims.

3. A comment stated that in the preamble to the "General Requirements for Health Claims for Food" final rule (58 FR 2478, January 6, 1993), FDA limited the application of the health claims rule, based upon review of the 1990 amendments legislative history. The comment stated that the agency supported limiting the type of disease relationships that would be subjected to the health claim regime with the following rationale: "In the legislative history, Congress focused only on those health claims that related to chronic disease, such as cancer, heart disease, and osteoporosis" (58 FR 2478 at 2481). The comment stated, therefore, that dental caries are not the type of "chronic disease" Congress intended to be regulated as a health claim since dietary choices will have less of an impact on tooth decay than will numerous other factors (e.g., fluoridation of water supply). Additionally, several comments alleged that dental caries is in decline in this country and suggested that this trend justifies not finalizing the proposed health claim.

The statement within the preamble to "General Requirements for Health Claims for Food" final rule (58 FR 2478 at 2481) referred to in the comment was part of a discussion about applicability of health claims to classical deficiency nutrient diseases and was not a discussion on limiting claims to chronic

diseases. Nowhere in that document did the agency state that the diet/disease relationships that could be the subject of a health claim were those that involved chronic diseases. Moreover, section 403(r)(1)(B) of the act itself does not limit the Secretary's authority to regulate health claims to those pertaining to chronic diseases. In fact, the agency has recently authorized a health claim pertaining to a disease that would generally not be considered to be a chronic disease, neural tube defects.

As made clear in § 101.14(a)(6), the agency focuses on whether the disease in question, in this case dental caries, constitutes damage to an organ, part, structure, or system of the body such that it does not function properly. As outlined in the proposal, the agency tentatively concluded that dental caries meets this criterion (60 FR 37507 at 37509 through 37510), and the comments have presented no evidence to support a different conclusion. Further, dental caries is a disease for which the general U.S. population, or an identified subgroup, is at risk, and the condition is prevalent in the general population (see § 101.14(b)(1)).

Although the overall incidence of dental caries has declined in the United States, as mentioned in some comments, dental caries is still a public health issue. The disease remains one of the most prevalent infectious diseases that causes substantial expense, pain, and work loss (Ref. 89). There is evidence showing no decline in dental caries in some tooth surfaces, i.e., occlusal and proximal tooth surfaces, and a substantial subset of children continue to exhibit a high incidence of tooth decay (Ref. 95). In addition, little is known about present trends in oral health in the older population. There are some studies that suggest that the caries incidence in adults is considerable (Ref. 95). Consequently, dental caries continues to be a disease of public health concern in this country.

4. Three comments stated that the proposed sugar alcohol health claim promotes a good food/bad food dichotomy, based on whether the food contains sugar alcohols. One comment stated that the proposed health claim suggests that foods not eligible to bear the claim will automatically contribute to tooth decay. One comment stated that the health claim fails to promote health objectives. The comment also stated that children should focus on a balanced diet over time for proper growth and development rather than on the consumption of a particular ingredient. It stated that most sugar alcohol products contain little or no calories, micronutrients, or macronutrients, and

yet they may be eaten in lieu of foods that can contribute real nutrients to the diet. The comment stated that FDA should not be promoting products that are devoid of nutrition in lieu of products that provide the energy and the nutrients children need.

FDA disagrees that foods ineligible to bear a health claim will be perceived by consumers as bad for the health. The comment did not present any evidence to show that consumers interpret the absence of a health claim on food labels as evidence that the food is not healthful. For example, the agency has authorized a fat and heart disease claim, but the comment provided nothing to suggest that consumers believe that a food product that does not bear this health claim will promote heart disease.

FDA disagrees also that the health claim fails to promote health objectives and promotes consumption of a particular nutrient rather than focusing on a balanced diet. As stated above, dental caries remains a public health concern. Foods that meet the criteria for this health claim contribute to public health objectives because they do not promote tooth decay.

The comment did not provide any evidence to show that this health claim will focus the consumer's attention on one nutrient rather than on a balanced diet. The claim identifies a special characteristic of the food that is recognized to bear on the occurrence, and affect the risk, of a disease, dental caries. For those interested in reducing their risk of this disease, the claim serves to inform them, as claims of this type have done for almost 20 years, of this special characteristic.

The agency also disagrees with the comment that this health claim will promote for children foods that are devoid of nutrition. Claims for sugar alcohols, unlike claims for fruits, vegetables, and grain products and heart disease authorized under 21 CFR 101.77, for example, do not encourage increased consumption of foods to help reduce disease risk. Rather, sugar alcohol claims simply state that to the extent these foods are consumed as substitutes for foods that contain fermentable carbohydrates, they may help reduce the risk of dental caries. These claims in no way suggest adjustment in the consumption of sugar alcohol-containing foods, and to the extent they have such an effect, it would be limited to the class of foods that contain sweeteners. Given the small effect, if any, that the claim will have on the broad range of dietary choices that people make, FDA finds no merit to this comment.

5. Some comments stated that the focus on sugar alcohols in the proposed claim will detract from proper dental care, although they provided no evidence to support this contention. One comment stated that a health claim associated with these products may result in a decrease in oral health practices of much greater importance to dental health than diet, i.e., brushing, flossing, fluoride treatments, and professional dental care, including application of dental sealants and prophylaxis. The comments stated that the claim should discuss the importance of proper oral hygiene and dental care, including the use of fluoride toothpaste daily.

FDA does not agree that the proposed health claim will detract from proper dental care. As discussed in the proposed rule and as mentioned in some of the comments, the incidence of dental caries has declined over the past 20 years. Coincidentally, the claim "useful only in not promoting tooth decay" has been used for almost 20 years on sugar alcohol-containing chewing gums and confectioneries. Based on the historical use of these products and the decline in dental caries, there is no reason to conclude that the use of this claim has taken away from proper dental care. Further, the claim is consistent with public health recommendations.

However, the agency agrees that information about proper oral hygiene and dental care as part of good dental health practices may be useful to consumers of sugar alcohol products. This information is consistent with information provided in "The Surgeon General's Report on Nutrition and Health" (hereinafter referred to as the Surgeon General's report) (Ref. 7). Therefore, the agency has been persuaded to include this type of information among the types of optional information that a manufacturer may provide as part of the health claim. Section 101.80(d)(3) (21 CFR 101.80(d)(3)) provides that the claim may state that oral hygiene and proper dental care may help to reduce the risk of dental caries.

B. Safety Issues

In its proposal, the agency noted that several of the sugar alcohols that are the subject of this proceeding are listed in FDA's food additive and generally recognized as safe (GRAS) regulations, i.e., xylitol (§ 172.395 (21 CFR 172.395)), mannitol (§ 180.25 (21 CFR 180.25)), and sorbitol (§ 184.1835 (21 CFR 184.1835)) (see 60 FR 37507 at 37509). In addition, it stated that GRAS affirmation petitions have been

submitted for each of the remaining substances, i.e., maltitol (GRASP 6G0319), maltitol syrups (HGS syrups) (GRASP 3G0286), isomalt (GRASP 6G0321), lactitol (GRASP 2G0391), HSH (GRASP 5G0304), and HSH syrups (GRASP 1G0375). The agency stated that these GRAS affirmation petitions are under consideration, and that any positive action resulting from the proposed rule should not be interpreted as an indication that the agency has affirmed that the general food uses of the sugar alcohols according to their respective petitions are GRAS. FDA stated that such determinations can only be made after the agency has completed its review of each respective GRAS petition. Nonetheless, the agency stated that a preliminary review of the GRAS affirmation petitions had revealed that they contain significant evidence supporting the safety of these substances, but that some concerns about the safety of sugar alcohols do exist. The agency also stated that two of the sugar alcohols that are listed in FDA's food additive and GRAS regulations, i.e., mannitol (§ 180.25) and sorbitol (§ 184.1835), require a warning label regarding laxation if daily consumption is expected to exceed 20 grams (g) per day for mannitol and 50 g per day for sorbitol. FDA stated that nothing in the proposed rule would alter these requirements.

The agency stated that based on the totality of the evidence, it was not, at this time, challenging the petitioners' position that the use of the enumerated sugar alcohols is safe and lawful. Although FDA tentatively concluded that the petitioners satisfied the requirements of § 101.14(b)(3)(ii), the agency requested comments on its tentative conclusion.

6. Two comments noted that the Joint Food and Agriculture Organization/World Health Organization (FAO/WHO) Expert Committee on Food Additives (JECFA) has reviewed the safety data on these sugar alcohols and concluded that their use is safe, with no need for restriction other than good manufacturing practices. One of these comments stated that there is sufficient documentation to support a general recognition of safety.

Three comments stated that sugar alcohols can pose health problems, citing specifically the well-known gastrointestinal disturbances, such as stomach pain and diarrhea, that can result from excessive consumption. One of these comments also noted safety issues raised regarding animal data that associate consumption of large amounts of sugar alcohols with adrenal medullary hyperplasia and

pheochromocytomas. The comment noted that JECFA will be reviewing these issues in 1996. (The agency notes that the report from the February 1996 meeting is not yet available.) While these comments opposed indiscriminate promotion or consumption of sugar alcohol-sweetened foods, they did not argue that such ingredients were not safe or lawful as ordinarily used.

The agency concludes that these comments, taken together, accurately reflect the current understanding of the safety of sugar alcohols. They do not, however, provide a basis for the agency to reject the petitioners' position that the use of sugar alcohols is safe and lawful or for invoking warnings in addition to those already required. Therefore, the agency concludes that the requirements of § 101.14(b)(3)(ii) are satisfied.

C. Exemption from § 101.14(e)(6)

Under proposed § 101.80(c)(1), sugar alcohol containing foods must meet the requirements in § 101.14, except that sugar alcohol-containing foods are exempt from § 101.14(e)(6), the requirement that foods making health claims contain 10 percent or more of the RDI or the DRV for vitamin A, vitamin C, iron, calcium, protein, or fiber per reference amount customarily consumed before any nutrient addition.

7. One comment asked for clarification that this exemption applied to all sugar alcohol-containing confectioneries, and not just to chewing gum, hard candies, and mints.

FDA notes that the exemption applies to all sugar alcohol-containing foods. The agency did not specifically limit the exemption to chewing gum and confectioneries. Because sugar alcohols function as sweeteners, their use has been as replacements for simple and complex sugars. Sugar alcohols provide a sweet taste and serve as bulking agents and, consequently, are used only in certain product categories. However, these food categories are sufficiently diverse as to make specific definitional criteria difficult. For this reason, FDA has not limited the exemption to specific foods. However, the agency wishes to point out that a food must still meet all of the other requirements in § 101.80(c)(2)(ii) to be eligible to bear the claim.

8. Two comments that agreed with FDA's tentative decision to exempt sugar alcohol-containing foods from § 101.14(e)(6) requested that sugar alcohol-containing products also be exempt from the requirement of § 101.14(e)(3) relating to foods with disqualifying levels of fat, saturated fat, cholesterol, or sodium. One comment

stated that the agency has authority to grant exemptions from this requirement when a health claim will assist consumers in maintaining healthy dietary practices. The comment stated that an exception is warranted because the health claim will assist consumers in making decisions relating to dental health in all contexts in which the claim is used. The comments stated that the presence of high levels of fat, saturated fat, cholesterol, or sodium does not conflict with the health message because these nutrients are not adversely associated with dental health.

FDA has established different disqualifying levels for different categories of foods, depending on the role that they play in the daily diet. Section 101.14(a)(5) defines the disqualifying level for individual foods as 20 percent of the Daily Values (DV's) for total fat, saturated fat, cholesterol, and sodium. These levels translate to 13.0 g of total fat, 4 g of saturated fat, 60 milligrams (mg) of cholesterol, and 480 mg of sodium per reference amount customarily consumed, per labeled serving size, and, for foods with reference amounts customarily consumed of 30 g or less or 2 tablespoons or less, per 50 g. The regulations also make additional allowances for main dish products and meal-type products (see § 101.14(a)(5)(i) and (ii)).

A food that exceeds the disqualifying level for any of the four disqualifying nutrients may not bear a health claim unless the agency has granted an exemption "based on a finding that such a claim would assist consumers in maintaining healthy dietary practices" (section 403(r)(3)(A)(ii) of the act).

The comment requesting the exemption of sugar alcohol-containing foods from the disqualifying levels provided no evidence to demonstrate that the presence of the claim on foods containing high levels of fat, saturated fat, cholesterol, or sodium will benefit consumers other than to suggest that the claim would appear on more foods. This rationale is not consistent with the basic notion that it makes no sense to include a health claim in the labeling of a food that contains other nutrients at a level that increases the risk of other diseases unless a clear benefit for consumers can be demonstrated (see 58 FR 2478 at 2489 to 2490).

In "the 1995 nutrient content and health claims proposed rule," FDA has considered the instances where disclosure rather than disqualification may be appropriate and discussed these in this proposal to amend its regulations on nutrient content and health claims to provide additional flexibility in the use

of these claims on food products. FDA highlighted factors that it would consider in deciding whether to exempt a food from disqualification, including the level of public health importance, the availability of foods that qualify for a health claim, and evidence that the population the claim targets is not at risk for the disease associated with the disqualifying nutrients. It stated that exceptions to § 101.14(e)(3) should be granted on a case-by-case basis, using a petition process. It also proposed new § 101.70(f) (21 CFR 101.70(f)) to provide guidance for petitioners requesting an exception to the prohibition in § 101.14(e)(3) of health claims for foods exceeding the disqualifying levels identified in § 101.14(a)(5) (see 60 FR 66206 at 66224).

The comment did not submit any information of the type that FDA needs as the basis for an exemption. In the absence of such information, FDA finds that it cannot conclude that the population at risk for dental caries is not at risk, for example, for heart disease. The agency is therefore denying the request to exempt sugar alcohol-containing foods from the disqualifying levels established in § 101.14(a)(5).

D. Relationship Between Sugar Alcohols and Dental Caries

9. Some comments stated that in the proposal the agency had correctly identified the interaction between sugars and other fermentable carbohydrates and oral bacteria in the development of dental caries. However, these comments stated that the proposed health claim puts undue emphasis on sugars and sucrose in the causation of dental caries. The comments stated that the dental community is unanimous in the view that all fermentable carbohydrates, not just sugars, have the potential to contribute to tooth decay. One comment stated that to the extent that dietary factors play a role in caries, the most important factor is frequency of consumption of fermentable carbohydrates and not consumption per se. One comment quoted the report of the Dietary Guidelines Advisory Committee on the *Dietary Guidelines for Americans*, 1995 (Ref. 101) which states:

[B]oth sugars and starches can promote tooth decay. The more often you eat foods that contain sugars and starches, and the longer these foods are in your mouth before you brush your teeth, the greater the risk for tooth decay. Thus, frequent eating of foods high in sugars and starches as between-meal snacks may be more harmful to your teeth than eating them at meals and then brushing.

FDA agrees that all fermentable carbohydrates, including sugars and

starches, can promote tooth decay. As stated in the recently revised *Dietary Guideline for Americans* (Ref. 101), both the frequency of consumption and the duration of exposure of teeth to sugars and starches contribute to the risk of dental caries. However, the agency points out that, as outlined in the proposal, the basis for the proposed claim centers around the use of sugar alcohols in place of sugars. Sugar alcohols cannot be used in place of all fermentable carbohydrates. Rather, sugar alcohols function as sweeteners and bulking agents, and their use is primarily in the manufacture of gums and confectioneries. Moreover, the significance of the claim in the context of the total daily diet is based upon: (1) The presence in the diet of foods sweetened with simple and complex sugars, and (2) the fact that sugar alcohols, because of their very low fermentability, when substituted for other sugars, do not promote dental caries.

Nonetheless, the agency agrees that it would be helpful to consumers to be informed about the overall role of fermentable carbohydrates in the diet and thus is persuaded to revise § 101.80(a)(2) and (a)(4) to reflect that all fermentable carbohydrates, i.e., sugars and starches, are cariogenic and to include in these paragraphs information about dental caries provided in *Dietary Guidelines for Americans* (Ref. 101). In proposed § 101.80(a)(2), the agency described the relationship between dietary sugars and tooth decay, that is how bacteria metabolizes sugar, causing acid and forming plaque. This was followed by a statement that the dental plaque results in more acid that demineralizes enamel after prolonged exposure. The final statement was a precaution then, that between-meal consumption of sugary foods would cause more tooth decay. In this document, the agency is changing § 101.80(a)(2) to include the relationship between consumption of fermentable carbohydrates and starches, as well as dietary sugars, to tooth decay. The last sentence states that ongoing exposure to starches, as well as dietary sugars, increases the risk for tooth decay.

The agency notes that sucrose is still considered the most cariogenic sugar, and that this substance has been shown to promote the growth of plaque more than other sugars (Ref. 71). Therefore, the agency is highlighting, and permitting the use of the statement regarding, the cariogenicity of sucrose. In addition, consistent with § 101.4(b)(20), the term "sugar" may be used as a synonym for "sucrose."

The agency is also revising § 101.80(a)(4) to state that sugar alcohols can be used as sweeteners to replace dietary sugars, such as sucrose and corn sweeteners, in foods such as chewing gums and confectioneries, and that they are significantly less cariogenic than dietary sugars and other fermentable carbohydrates. The agency is adding the statement regarding "corn sweeteners" to reflect the fact that sugar alcohols are used to replace more than sucrose in chewing gums and confectioneries, and that they are used primarily as sweeteners. The agency is deleting the statement, "Thus, replacing dietary sugars with sugar alcohols helps to maintain dental health," from § 101.80(a)(4) because it is a statement of the significance of the relationship between sugar alcohols and dental caries which is addressed in § 101.80(b). Consequently, this statement is superfluous in § 101.80(a). The agency concludes that, with the above revisions, § 101.80(a)(2) and (a)(4) accurately reflect the relationship between fermentable carbohydrates and dental caries and are not misleading as to the role of sugar alcohols in not promoting tooth decay.

The agency is also deleting proposed § 101.80(d)(2), which permitted use of the term "sugar" or "sucrose" when referring to sucrose. Since § 101.80(d)(1) allows the claim to include information from § 101.80(a), and § 101.80(a)(2) has been revised to include "sugar" as a synonym for "sucrose," § 101.80(d)(2) is repetitive and unnecessary. As a result of this action, proposed § 101.80(d)(3) is being redesignated as § 101.80(d)(2). FDA is also adding in new § 101.80(d)(3) information regarding the importance of proper dental care in response to the comments discussed in comment 5 of this document.

10. Some comments stated that the agency's emphasis in the proposal on sticky foods as a factor in dental caries was inaccurate. One comment stated that more recent scientific evidence does not support the relationship between foods that easily stick to teeth and dental caries. The comment included a study to support this assertion. The comment stated that the high starch and low sugar foods are retained on teeth longer than high sugar and low starch foods. One comment stated that a health claim statement about foods that easily stick to teeth is misleading and could drive consumers towards erroneous food choices in the interest of avoiding what they think are sticky foods.

The agency concurs that the evidence submitted suggests that the degree of stickiness of a food, as perceived

subjectively by the consumer, does not correlate with the actual retention of the food on human dentition in vivo (Refs. 92 and 93). Therefore, the agency is deleting reference to sticky foods in § 101.80(a)(2).

11. Several comments disagreed with the statements that U.S. diets tend to be high in sugars, and that government organizations recommend decreased consumption of sugars. The comments stated that FDA's 1986 Sugars Task Force report (Ref. 94) concluded that the average daily intake for added sugars accounted for 11 percent of the daily calorie intake for the total population. One comment stated that this amount approximates the amount (10 percent) recommended by the Select Committee on Nutrition and Human Needs in its second edition of *Dietary Goals for the United States* (1977) (Ref. 100). The comments stated that current dietary guidelines advise that sugars be used only in moderation but not restriction of sugars consumption. One comment stated that the proposed health claim implicates sugars as a diet and disease concern, which will mislead consumers as to the health significance of sugar consumption.

FDA agrees that the focus of dietary guidance for the general population is to choose a diet moderate in sugars and to avoid excessive snacking (Ref. 101). Therefore, FDA has modified § 101.80(a)(3) to delete statements regarding the sugars consumption in the American diet and dietary recommendations to reduce sugars intake. In their place, FDA has included information from the recent *Dietary Guidelines for Americans* (Ref. 101) in § 101.80(a)(3), which states that dental caries is still widespread in the United States creating a burden on Americans. The government's dietary guidelines suggest selecting diets with moderation in sugars and avoidance of excessive snacking. Because snacks rich in sugars and starches may result in a greater incidence of tooth decay since they are less likely to be followed by brushing.

The agency disagrees with the comment that the health claim will mislead consumers as to the health significance of sugars consumption. Sugars consumption has long been associated with risk of dental caries, and information reflecting this fact is a common component of public health education efforts. Moreover, as a result of the changes that FDA has made, § 101.80(a)(2), (a)(3), and (a)(4) accurately reflect the relationship that exists among sugar alcohols, dietary sugars and other fermentable carbohydrates, and dental caries. Thus, there is less chance that consumers

could be misled. In light of these changes, the agency has revised the title of § 101.80(a) to more accurately reflect the contents of this paragraph. The revised title is "Relationship between dietary carbohydrates and dental caries."

12. Some comments stated that there is no indication that a sugar alcohol and dental caries health claim will have any impact on sugars consumption or on the incidence of dental caries in the U.S. population. The comments stated that sugars consumption remained stable from 1977 to 1988, and that dental caries decreased during that time. One comment stated that dietary counseling, to the general public, on sugar consumption is an ineffective caries prevention technique. The comment stated that dietary guidelines do not advocate the reduction in sugars in the diet as a means to lower the incidence of dental caries.

The intent of the health claim is to provide consumers with public health information that will enable them to make dietary choices that can affect their risk of dental disease. Dental caries are recognized as an important and widespread public health problem in the United States. Although dental caries among children are declining, the overall prevalence of the condition imposes a substantial economic burden because of the health care costs associated with care for this condition. In addition, as discussed in section II.A. of this document, there is evidence to show that the decline in dental caries may not apply to all tooth surfaces, and that a substantial subset of children continue to exhibit a high incidence of tooth decay (Ref. 94). In addition, little is known about trends in oral health in the older population. There are some studies that suggest that the caries incidence in adults is considerable (Ref. 95). Until means of preventing dental caries are available to the entire U.S. population, dietary counseling is an important element of dental care (Ref. 95).

The sugar alcohol-containing foods that have used this dental caries claim over the past 20 years have primarily been snack foods, i.e., chewing gums and confectioneries. Snack foods are a part of the diets of many Americans. As stated in the recent *Dietary Guidelines for Americans* (Ref. 101), frequent between-meal snacks that are high in sugars and starches may be more harmful to teeth than eating the same foods at meals and then brushing. Therefore, chewing gums and confectioneries that contain sugar alcohols but no fermentable carbohydrates provide an alternative

food choice for those consumers who enjoy sweetened snack foods yet are interested in dental health.

The comments incorrectly suggest this health claim is intended to imply that sugar alcohol-containing foods will prevent dental caries. The agency wishes to highlight the difference between a prophylactic effect and a nonpathologic effect. The proposed claim does not state that sugar alcohols provide a prophylactic benefit, i.e., the claim is not that they will prevent tooth decay. Rather, the claim states that sugar alcohols do not promote dental caries. The evidence supports a beneficial role of sugar alcohols in the absence of other carbohydrates in maintaining plaque pH above a level that promotes enamel demineralization.

E. Significance of the Relationship Between Sugar Alcohols and Dental Caries

Under proposed § 101.80(b), the agency stated that sugar alcohols do not promote dental caries because they are slowly metabolized by bacteria to form some acid. The rate and amount of acid production from sugar alcohols is significantly less than that from sucrose, and therefore consumption of sugar alcohols does not cause the loss of minerals from tooth enamel.

13. Some comments argued that there is scientific evidence to show that oral bacteria can adapt to sorbitol, thus making it cariogenic. One comment stated that there is considerable debate over the potential for an adaptive shift in the oral ecology in response to the consumption of sugar alcohols, specifically that plaque bacteria may adapt to xylitol, thus making it potentially cariogenic.

FDA notes that the fermentability of sorbitol and other sugar alcohols, in human and animal models and in vitro, was discussed in the proposed rule (60 FR 37507) and has been reviewed in a number of published articles (Refs. 95 to 99 and 102). This information shows that fermentation of sorbitol proceeds at a slow rate, with a final pH remaining above the low pH levels achieved with glucose or sucrose.

In vitro studies have shown that dental plaque, when incubated with sorbitol, did not produce enough acid to cause enamel decalcification. Some investigators note, however, that it may be very misleading to extrapolate from an in vitro pure culture situation to that of a mixed microbial community in vivo (Ref. 102).

In addition to the fact that the use of a purified culture does not reflect a normal mix of the types of oral bacteria, the results of in vitro studies that

showed acid production from sorbitol after a prolonged period of incubation (22 hours) have little relevance to the in vivo situation. In vivo studies have shown that plaque pH drops only marginally after consumption of sorbitol-containing foods (Ref. 95). Moreover, plaque pH telemetry tests have been used to assess the acidogenic potential of sorbitol on plaque in situ (Ref. 95). These tests have demonstrated consistently that the consumption of sorbitol is not associated with an acidification of dental plaque that would suggest cariogenic risk.

As discussed in the proposed rule (60 FR 37507 at 37523), there is evidence that suggests that long-term, uninterrupted consumption of sorbitol results in adaptation by oral bacteria and, therefore, in more acid production. However, microbiological studies have shown that the final pH obtained after long-term exposure to sorbitol remained above a plaque pH level associated with cariogenic risk (Ref. 96, 98, 99, and 102), and that pre- and post-adaptation rates of acid production from sorbitol in vitro are very similar and very low compared to glucose (Ref. 102). Additionally, adaptation is inhibited in the presence of glucose, as bacterial metabolism preferentially switches to the metabolic substrate that is more readily used as an energy source (Refs. 46, 95, and 60 FR 37507 at 37512). At the same time that bacteria switch to glucose as the preferred energy source, the mechanism that enables them to metabolize sorbitol is repressed (Ref. 95).

Bacteria in plaque may also show some level of adaptation to long-term exposure to mannitol (Ref. 97). As with sorbitol, however, the amount of acid produced from bacterial metabolism of mannitol is small and very slow compared to bacterial metabolism of glucose. The study results showed that final plaque pH levels in situ did not drop to levels that demineralized dental enamel (Ref. 97).

In response to the comment that plaque bacteria may adapt to xylitol, thus making it potentially cariogenic, the agency notes that some in vitro studies have isolated plaque microorganisms capable of metabolizing xylitol. Incubating certain strains of bacteria over prolonged time showed increased acid production from xylitol (Ref. 97). The amount of acid produced, however, was very small and has not been shown to promote dental enamel demineralization. There is no evidence to show that adaptation to xylitol is maintained when plaque bacteria are exposed to other fermentable carbohydrates in the daily diet.

The agency concludes, based on the evidence, that frequent or long-term use of sugar alcohols, especially in the context of a daily diet that contains other carbohydrates that are preferentially metabolized by oral bacteria, may result in some adaptation by the bacteria in plaque to these substances. The effect, however, would not be such that consumption of sugar alcohols would contribute in any way to the risk of dental caries in the general population.

F. Nature of Claim and Optional Information

In § 101.80(c)(2)(i), the agency proposed specific requirements on the nature of the claim, including the use of statements such as "does not promote," "useful in not promoting," or "expressly for not promoting" dental caries. In § 101.80(c)(2)(i)(C), FDA proposed, that for packages with a total surface area available for labeling of 15 or more square inches, the claim state that dental caries depends on many factors.

14. Several comments stated that the proposed regulation should require that the labeled claim identify other dietary factors that are associated with dental caries. One comment stated that the claim should allude to the role of all fermentable carbohydrates in the development of dental caries, although the comment did not provide data to show that the term "fermentable carbohydrates" is meaningful to consumers. Other comments emphasized the importance of addressing issues related to frequent consumption of fermentable carbohydrates.

Issues related to providing information about dietary factors are relevant to the requirement that the claim enable the public to understand the significance of the information in the context of a total daily diet (section 403(r)(3)(B)(iii) of the act). Therefore, in considering these comments, the agency reviewed the dietary context in which the claim would be presented. While the claim for sugar alcohols is about the effect of using them to replace dietary sugars, the agency is persuaded that the claim should include information to set the message within the broader context of fermentable carbohydrates so as to provide overall dietary information potentially beneficial to consumers. It is well accepted that the relationship between diet and the development of dental caries is based on the interaction between oral bacteria and the presence of substances that support the growth and development of these bacteria, especially the bacteria in plaque, and on the production of acid in dental plaque.

As noted in several of the comments, it is also well accepted that dietary carbohydrates, such as dietary sugars and starches, are readily fermented by oral bacteria and can promote the growth and development of these bacteria.

Further, in its review of the scientific evidence in the proposal (60 FR 37507), the agency tentatively concluded that, in the absence of other fermentable carbohydrate-containing foods, sugar alcohol-containing foods did not promote dental caries because they do not lower plaque pH to the level associated with enamel demineralization. The agency received no comments or additional data to cause it to change this tentative finding. Therefore, the agency now concludes that, for the public to understand fully, in the context of other dietary components, the relationship between consumption of sugar alcohols and the promotion of dental caries, information about other carbohydrates needs to be included as part of the claim.

In addition, the agency acknowledges the comments' emphasis on issues related to frequency of consumption. The importance of this factor is supported by the *Dietary Guidelines for Americans* (Ref. 101). FDA addressed this aspect of the diet-disease relationship when it included a statement concerning frequent between meal consumption in an example of a model health claim.

Therefore, in response to the comments, FDA is adding § 101.80(c)(2)(i)(A), which provides that the claim must include the information that frequent between-meal consumption of foods high in sugars and starches can promote tooth decay. This information is consistent with the information provided to consumers in the *Dietary Guidelines for Americans* (Ref. 101), which states that frequent eating of foods high in sugars and starches as between-meal snacks can promote tooth decay. The agency is using the phrase "sugars and starches," which is used by the *Dietary Guidelines for Americans* (a document intended for the general public), because it is apparently more familiar to consumers, and thus likely to be better understood by them, than is the phrase "fermentable carbohydrates."

Consistent with the proposal, the information that FDA is requiring on packages with a total surface area available for labeling of 15 or more square inches must include a statement that the sugar alcohols present in the food do not promote tooth decay or (as discussed in comment 17 of this

document) may reduce the risk of tooth decay (§ 101.80(c)(2)(i)(B)).

Further, to assist consumers in comprehending the information specific to this claim within the context of the total daily diet, and to avoid confusion about sugar alcohols' role in the diet given the inclusion of information about starches, FDA is providing in § 101.80(d)(4) that the claim may state that the sugar alcohol serves as a sweetener. This information will clarify that the sweetener used in the product does not promote tooth decay.

Additionally, the agency recognized in preparing the final rule that it had inadvertently failed to provide for the declaration of the nutrient in proposed § 101.80(c)(2)(i). Therefore, FDA is adding § 101.80(c)(2)(i)(C) which states that in specifying the nutrient, the claim shall state "sugar alcohol," "sugar alcohols," or use the name of the specific sugar alcohol. This approach is consistent with the approach that the agency has taken in § 101.9(c)(6)(iii) on the declaration of sugar alcohols within the Nutrition Facts panel.

In light of these revisions, FDA has redesignated proposed § 101.80(c)(2)(i)(A) (see 60 FR 37507 at 37530) as § 101.80(c)(2)(i)(B) and redesignated proposed § 101.80(c)(2)(i)(B), in which the agency stated that the terms "dental caries" or "tooth decay" be used to specify the disease, as § 101.80(c)(2)(i)(D). There were no comments on the latter provision.

15. One comment agreed with the abbreviated claim and stated that it carries the necessary consumer message. The comment further stated that, as a result, package size should not determine the length of the health claim.

The agency disagrees. As discussed in the agency's response to comment 14., issues related to providing information about dietary factors are relevant to the requirement that the claim enable the public to understand the significance of the information in the context of a total daily diet (section 403(r)(3)(B)(iii) of the act). While the claim for sugar alcohols is about the effect of using them to replace dietary sugars, the agency is persuaded by other comments that the claim should include information to set the message within the broader context of fermentable carbohydrates and their frequency of consumption so as to provide overall dietary information that is useful to consumers. The importance of fermentable carbohydrates and of the frequency of consuming such foods between meals is supported by the *Dietary Guidelines for Americans* (Ref. 101).

16. One comment stated that the elements of the claim for small packages do not adequately explain the significance to a person's diet of including the particular food product bearing the claim.

As discussed in the proposed rule (see 60 FR 37507 at 37525), the claim "useful in not promoting tooth decay" has been used on a limited number of foods, primarily chewing gums and confectioneries, for 20 years. This claim has a history of being used by consumers without particular confusion. Thus, the agency concludes that it is not necessary to include additional information as part of this claim when it appears on small packages to prevent it from being misleading.

17. Some comments stated that it was important that label statements of the claim include reference to nondietary factors, particularly oral hygiene, that are associated with dental caries. One comment stated that dental care and oral hygiene are more important factors in the nonpromotion of dental caries than the substitution of sugar alcohol-containing foods for sugar-containing foods.

One comment, however, stated that the requirement that a claim state that tooth decay depends on many factors (for larger packages) does not add to an understanding of the claim and would only confuse the message that sugar alcohol-containing products do not promote tooth decay. Other comments supported an abbreviated claim and asserted that reference to the multifactorial etiology of dental caries does not add information needed by consumers.

As discussed in the proposal, the agency acknowledges that the development of dental caries involves a complex interplay of many factors, both dietary and nondietary. Nonetheless, while there is an important role for dental care and oral hygiene in reducing the incidence of dental caries, the agency notes that current and well recognized recommendations also stress the role of diet.

In response to comments described above, the agency has considered the need for the inclusion of statements within the label claim concerning the multifactorial nature of dental caries and information on nondietary factors to help reduce the risk of this disease.

The agency notes that comments that requested that the agency require that nondietary factors be included in the health claim provided no evidence that claims about the relationship among sugar alcohols, fermentable carbohydrates, and dental caries are

misleading if a reference to nondietary factors is not included in the claim. Given the unique history of this claim, i.e., that it has been used for approximately 20 years, and the fact that the incidence of dental caries has decreased over that period, the agency is not persuaded that the absence of reference to specific nondietary factors in this claim has had adverse effects that would suggest that the claim is misleading.

Moreover, FDA has decided not to require that the statement "depends on many factors" be included as part of the claim on products with 15 or more square inches of space available for labeling. The fact that the incidence of dental caries has declined over the past 20 years strongly suggests that public health education, including information in preventive dental measures, that has been available to consumers during this period has been effective (Ref. 95). Moreover, as stated above, FDA is aware of the unique history of this claim. Given the history of this claim and the public education that has been available, FDA has reconsidered its tentative view that the statement "depends on many factors" is necessary to the consumer understanding of the claim. FDA concludes that the available evidence demonstrates that the claim is complete without this information, and, therefore, that this information need not be made a required element of this health claim. However, the agency is providing that the information may be included in the health claims.

Thus, in this document, the agency is deleting proposed paragraphs § 101.80(c)(2)(i)(C) and (c)(2)(i)(D). It is modifying § 101.80(d)(2) to provide that the claim may state that the development of dental caries depends on many factors and list those risk factors. In place of proposed § 101.80(c)(2)(i)(C), the agency is requiring in § 101.80(c)(2)(i)(F) that the claim not imply that consumption of foods containing sugar alcohols is the only recognized means of achieving reduced risk of dental caries. Consistent with these changes, FDA has deleted the model claim in proposed § 101.80(e)(2) that illustrated a claim with the statement "depends on many factors."

18. One comment suggested since the agency had proposed to authorize a claim using the terminology "does not promote," then a claim relative to reducing the risk for dental caries was a separate claim that would not be authorized by a final rule in this proceeding. The comment suggested that it would be necessary to obtain separate authorization for such a claim as a means of conveying the relative

superiority of certain sugar alcohols in affecting the occurrence of dental caries.

The proposal on sugar alcohols focused on the nonpromotion of dental caries, but it was not the agency's intent to specifically exclude the concept of risk reduction from the claim. In response to this comment, the agency considered the coverage of the claim and noted that, in proposed § 101.80(d)(3), it had listed risk factors for dental caries. One factor listed was the frequent consumption of sucrose or other fermentable carbohydrates. The substitution of sugar alcohols in diets for foods containing sucrose or other fermentable carbohydrates reduces exposure to one risk factor for dental caries. Thus, FDA has concluded that it is appropriate to characterize the relationship as "may reduce the risk." To make this finding explicit, the agency has inserted the phrase "may reduce the risk" in § 101.80(c)(2)(i)(B).

As for claims of superiority, the agency notes that the provision of the act that authorizes health claims focuses on diet/disease relationships. Once a relationship is established, there is no further provision within the health claim regime for claims of superiority in affecting the disease in question. A manufacturer who makes a statement on the label or in labeling of a food concerning the superiority of the effect of one substance compared to another does so at the risk that FDA will find the claim to be false and misleading and thus subject to regulatory action under section 403(a) of the act.

G. Plaque pH Test

In § 101.80(c)(2)(ii)(C), FDA proposed to provide that to qualify to bear a claim, the sugar alcohol-containing food not lower plaque pH below 5.7 by bacterial fermentation either during consumption or up to 30 minutes after consumption, as measured by *in vivo* tests. The agency asked for comments on this approach.

19. Two comments asked that FDA clarify that sugar alcohol-containing chewing gums and confectioneries will be exempt from any plaque pH test requirement. One comment stated that the plaque pH requirement should be specific to sugar alcohol-containing foods that also contain fermentable carbohydrates. One comment stated that manufacturers can tell from the composition of the food if the plaque pH test is needed. One comment stated that the agency should give manufacturers flexibility in selecting the best protocol for testing plaque pH. One comment requested that the agency be more specific as to the type of test used to determine plaque pH. The comment

stated that the pH of 5.7 is an appropriate threshold value for the pH when measured at the inner plaque surface (i.e., at the interface between plaque and dental enamel) at interproximal sites. The comment stated that a different threshold pH value is appropriate for plaque pH measurements obtained with other techniques and at other sites.

In the proposed rule, the agency also stated that the acidogenicity of HSH and other sugar alcohol mixtures is related to the manufacturing process, and that the process may vary among manufacturers. The agency asked for comments on how to determine whether sugar alcohol mixtures, such as HSH, when used in a food whose label bears a dental caries health claim, are in compliance with any final rule resulting from the proposal (60 FR 37507 at 37524). One comment stated that the agency's concern regarding the potential acidogenicity of HSH is covered with the plaque pH test.

When FDA asked for comments in the proposal about establishing a minimum plaque pH requirement, it was addressing concerns that a sugar alcohol-containing food might also contain a fermentable carbohydrate that would render the food cariogenic (60 FR 37507 at 37526). The application of the plaque pH test is thus predicated on the inclusion of fermentable carbohydrates in a food that contains sugar alcohols. Consequently, there is no need to exempt certain sugar alcohol-containing foods from the plaque pH test. Rather, if sugar alcohols are used as sweeteners in a food, and there are no fermentable carbohydrates in the food, testing is not necessary.

In response to the comment concerning the need for manufacturers to have flexibility in selecting the method for measuring plaque pH, the agency points out that it does not require manufacturers who wish to make the health claim to perform the plaque pH test, nor does it require that a specific procedure be used when the test is performed. However, the agency is specifying in § 101.80(c)(2)(ii)(C) the method that it will use to determine whether a food complies with the plaque pH requirement in this regulation. In doing so, FDA is responding to the comment that requested that the agency specify the procedure. Manufacturers are free to decide for themselves whether and how to test their products to satisfy themselves that the foods comply with § 101.80(c)(2)(ii)(C). If they fail to do so, they risk that FDA will find in its compliance testing of their food that the food does not comply with the plaque

pH standard and thus is subject to regulatory action.

The plaque pH test that the agency will use to determine whether a food is in compliance with this final rule is the indwelling plaque pH method, an intraoral telemetry method. The Swiss have used this method since 1969 for regulatory purposes, and it has been shown to be very reliable (Ref. 75). The indwelling plaque pH method is considered by many as the benchmark for plaque pH testing (Ref. 46). It is not the agency's intent to use this method of plaque pH testing as a means to rank the relative cariogenicity of foods; rather, the agency will use this method to determine whether foods that contain both sugar alcohols and fermentable carbohydrates qualify to bear this health claim.

With regard to the agency's request for comments about the potential acidogenicity of HSH and other sugar alcohol mixtures, the agency agrees with the comment that stated that the agency's concern regarding the potential acidogenicity of HSH is covered with the plaque pH test. Manufacturers who produce HSH will be responsible to ensure that their product, when used in a food that bears a dental caries health claim, is in compliance with the § 101.80. If sugar alcohol mixtures, such as HSH, are used as sweeteners in a food, and there are no fermentable carbohydrates contributed by the sugar alcohol mixture or in the food, plaque pH testing is not necessary. If fermentable carbohydrates are present, manufacturers will need to ensure that the mixture does not lower plaque pH below 5.7.

H. Applicability of Claim to Other Substances

In proposed § 101.80(c)(2)(ii)(B), the agency specified the substances (i.e., sugar alcohols) that are the subject of the sugar alcohol and dental caries proposed regulation.

20. Two comments requested that proposed § 101.80(c)(2)(ii)(B) be modified to allow any sugar alcohol that may be developed in the future to fall under this health claim without amending the regulation.

FDA is denying this request. Under the general requirements for health claims, the petitioner must show how the substance that is the subject of the health claim conforms to the requirements of § 101.14(b). For those substances that are to be consumed at other than decreased dietary levels, the petitioner must demonstrate to FDA's satisfaction that the substance is safe and lawful under the applicable food safety provisions of the act

(§ 101.14(b)(3)(ii)). Moreover, the agency would expect, in the case of a new sugar alcohol, to see evidence that the substance will not lower plaque pH below 5.7. If such showing is made, FDA will take action to add the substance to the list in this regulation, which has been renumbered as § 101.80(c)(2)(ii)(B).

21. Two comments requested that FDA make provision in this regulation for additional FDA approved ingredients, e.g., polydextrose, that satisfy the requirement that they do not lower plaque pH below 5.7. The comments stated that this would obviate the need to amend the regulation as additional ingredients become available in the future. One comment stated that the plaque pH test serves as the true marker of noncariogenicity, not the presence of sugar alcohols or the absence of sugars. The comment suggested that the plaque pH test is the only critical endpoint necessary to justify use of this health claim.

One comment noted that the agency suggested that this claim will apply primarily to snack foods that do not play a fundamental role in structuring a healthy diet. The comment stated that other food products could be designed to not lower plaque pH below the required level of 5.7. The comment stated that products widely known to be noncariogenic and to have a role in a healthy diet, e.g., cheese, would be unable to bear this claim. The comment suggested that the claim be limited to chewing gums and confectioneries, although the comment provided no background on how to differentiate confectioneries from snack foods, nor did it provide evidence as to how this limitation would advance the purposes of the health claim provisions of the act.

FDA is denying the requests to make provision in this final rule for other ingredients, such as polydextrose, that do not lower plaque pH below 5.7. The requirement that the food not lower plaque pH below 5.7 is not the only criterion that must be satisfied for a food to bear the health claim. The agency recognizes that there may be scientific evidence to show that foods that do not contain sugar alcohols would qualify to bear a nonpromotion of dental caries health claim. However, the health claim petition that is the subject of this rulemaking (Ref. 1), which was filed in accordance with the requirements of § 101.70, addressed only certain sugar alcohols and presented the scientific evidence pertaining to those substances. The agency did not review the totality of publicly available evidence on the cariogenicity of other ingredients or other foods. Without assurances that the

substance in question, e.g., polydextrose, meets the entire set of criteria for a health claim, the authorization for the claim cannot be broadened to include other substances.

In response to the comment as to why the claim is being allowed on foods that contain sugar alcohols (and meet other criteria) and is not limited to only gums and confectioneries, the agency points out that the claim is based upon the substitution of sugar alcohols for fermentable carbohydrates, not on the use of certain foods. To the extent that consumers can select foods that contain fewer fermentable carbohydrates, their chances of reducing their risk of developing dental caries are increased. Limiting the claim to certain categories of foods would limit the significance of the claim and not serve the interests of the consumer.

I. Other Issues

The agency proposed that any final rule that may issue based upon the proposal become effective 30 days following its publication.

22. Two comments requested that FDA change the effective date of the final rule to 6 months following its publication. The comments stated that this change would allow time for industry to change labels on products that may need changing if wording changes on the claim are needed.

FDA has considered the issue of the compliance date and has concluded that the compliance date for this regulation will be January 1, 1998. This date is consistent with that proposed by FDA in the "Uniform Compliance Date for Food Labeling Regulations" proposal rule (hereinafter referred to as the "uniform compliance date" proposed rule) (61 FR 16422, April 15, 1996). In that document, the agency stated that it periodically has announced uniform compliance dates for new food labeling requirements. It stated that use of a uniform compliance date provides for an orderly and economical industry adjustment to new labeling requirements by allowing sufficient lead time to plan for the use of existing label inventories and the development of new labeling materials. FDA stated that this policy also serves consumers' interests because the increased cost of multiple short-term label revisions that would otherwise occur would likely be passed on to consumers in the form of higher food prices. Although FDA is adopting January 1, 1998, as the compliance date, the agency is encouraging firms to begin voluntary compliance as early as possible after publication of this rule and to begin making changes when they reprint their labels.

III. Decision to Authorize a Health Claim Relating Sugar Alcohols to Dental Caries

FDA has considered all of the comments that it received in response to the sugar alcohol and dental caries health claim proposal. The agency concludes that the relationship between sugar alcohols and dental caries is truthful, not misleading, and scientifically valid in that there is significant scientific agreement based on the totality of publicly available scientific evidence that sugar alcohols do not promote dental caries. Therefore, FDA is authorizing this claim, although based on some of the comments, the agency has been persuaded to make a number of editorial changes in the proposed codified material of the health claim.

IV. Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the proposed rule (60 FR 37507). At that time, the agency determined under 21 CFR 25.24(a)(11) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

V. Analysis of Impacts

FDA has examined the economic implications of the final rule establishing a health claim for sugar alcohols and dental caries as required by Executive Order 12866 and the Regulatory Flexibility Act (Pub. Law 96-354) as amended by the Small Business Regulatory Enforcement Fairness Act of 1996. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). FDA finds that this final rule is not a significant rule as defined by Executive Order 12866.

In response to the proposal, FDA received two comments suggesting that the costs of the proposed health claim exceed the benefits. One comment suggested that parents who substitute sugar alcohol containing snacks for other snack foods will be trading dental caries for gastric problems in their

young children. The second comment stated that, because gums and candies that contain sugar alcohols are more expensive than other sweets, some consumers may purchase them with funds that otherwise would be used for preventive dental health measures.

The agency is unconvinced by these comments. Because the claim is already being used on many products in ways that would satisfy the conditions for use as approved by this regulation, the agency does not agree that the claim will cause consumers to switch from sugar-containing products to existing products containing sugar alcohols. Therefore, it is unlikely that this regulation will result in any significant changes in consumer behavior. In fact, any change in consumer behavior because of sugar alcohols most likely has already taken place. This regulation is thus not expected to cause an increase in gastric problems.

The agency also does not agree that this regulation is likely to result in a decrease in preventive dental health measures. Consumers of sugar alcohol containing foods purchase the products either because of their dietetic attributes or because of their role in preventive dental health. The majority of sugar alcohol containing foods that would qualify for the health claim currently have sugar-free claims which are required to be accompanied by a statement that the product is not a low-calorie food. Therefore, it is unlikely that these products are being consumed by calorie-conscious individuals.

The health claim should have no impact on the purchases of consumers who consume these products for the dietetic properties because neither sugary foods nor preventive dental health measures are substitutes for dietetic foods. The agency is aware of no evidence that sugar alcohol containing foods and preventive dental health measures are substitutes for dentally concerned consumers. In fact, it is more likely that these consumers view the two categories as complementary products working together as a part of a dental health regime. It is likely that the cross elasticity of demand, a numerical measure of the connection between two goods, for sugar alcohol containing foods and preventive dental health measures is either not significantly different from zero, or negative. In other words, the two product categories are either not close substitutes or are complementary products. Therefore, the agency rejects the assertion that the use of preventive dental health measures will decline as a result of this rule.

Although the benefits of this rule are minimal, the costs of this regulation are also anticipated to be small. FDA is aware that some firms are already using similar claims on product labels. It is likely that most of these claims satisfy the criteria described in this rulemaking. However, because FDA is requiring er claims for larger package sizes, some product labels may need to be revised. To the extent that labels need revision, this final rule will impose costs. On average, the administrative, redesign, and inventory disposal costs of revising a label for the affected product categories within a six month compliance period are between \$800 and \$1525 per label depending on the location of the claim. Because FDA does not know the number of sugar alcohol claims currently being made nor the proportion of existing claims that do not meet FDA's criteria, the agency cannot estimate the total costs of this regulation.

The Regulatory Flexibility Act as amended requires analyzing options for regulatory relief for small businesses. According to the information currently available to the agency, of the relatively small number of products that would require relabeling as a result of this final rule, none are produced by small firms. Therefore, the agency certifies that this rule will not have a significant impact on a substantial number of small businesses.

VI. Paperwork Reduction Act

This final rule contains no information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

VII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a. m. and 4 p. m., Monday through Friday.

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List of Subjects in 21 CFR Part 101

Food labeling, Incorporation by reference, Nutrition, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 101 is amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 is revised to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

2. New § 101.80 is added to subpart E to read as follows:

§ 101.80 Health claims: dietary sugar alcohols and dental caries.

(a) *Relationship between dietary carbohydrates and dental caries.* (1) Dental caries, or tooth decay, is a disease caused by many factors. Both environmental and genetic factors can affect the development of dental caries. Risk factors include tooth enamel crystal structure and mineral content, plaque quantity and quality, saliva quantity and quality, individual immune response, types and physical characteristics of foods consumed, eating behaviors, presence of acid producing oral bacteria, and cultural influences.

(2) The relationship between consumption of fermentable carbohydrates, i.e., dietary sugars and starches, and tooth decay is well established. Sucrose, also known as sugar, is one of the most, but not the only, cariogenic sugars in the diet. Bacteria found in the mouth are able to metabolize most dietary carbohydrates, producing acid and forming dental plaque. The more frequent and longer the exposure of teeth to dietary sugars and starches, the greater the risk for tooth decay.

(3) Dental caries continues to affect a large proportion of Americans. Although there has been a decline in the prevalence of dental caries among children in the United States, the disease remains widespread throughout the population, imposing a substantial burden on Americans. Recent Federal government dietary guidelines recommend that Americans choose diets that are moderate in sugars and avoid excessive snacking. Frequent between-meal snacks that are high in sugars and starches may be more harmful to teeth

than eating such foods at meals and then brushing.

(4) Sugar alcohols can be used as sweeteners to replace dietary sugars, such as sucrose and corn sweeteners, in foods such as chewing gums and certain confectioneries. Dietary sugar alcohols are significantly less cariogenic than dietary sugars and other fermentable carbohydrates.

(b) *Significance of the relationship between sugar alcohols and dental caries.* Sugar alcohols do not promote dental caries. Sugar alcohols are slowly metabolized by bacteria to form some acid. The rate and amount of acid production is significantly less than that from sucrose and other fermentable carbohydrates and does not cause the loss of important minerals from tooth enamel.

(c) *Requirements.* (1) All requirements set forth in § 101.14 shall be met, except that sugar alcohol-containing foods are exempt from section § 101.14(e)(6).

(2) Specific requirements. (i) *Nature of the claim.* A health claim relating sugar alcohols, compared to other carbohydrates, and the nonpromotion of dental caries may be made on the label or labeling of a food described in (c)(2)(ii) of this section, provided that:

(A) The claim shall state that frequent between-meal consumption of foods high in sugars and starches can promote tooth decay.

(B) The claim shall state that the sugar alcohol present in the food “does not promote,” “may reduce the risk of,” “useful [or is useful] in not promoting,” or “expressly [or is expressly] for not promoting” dental caries;

(C) In specifying the nutrient, the claim shall state “sugar alcohol,” “sugar alcohols,” or the name or names of the sugar alcohols, e.g., “sorbitol.”

(D) In specifying the disease, the claim uses the following terms: “dental caries” or “tooth decay.”

(E) The claim shall not attribute any degree of the reduction in risk of dental caries to the use of the sugar alcohol-containing food.

(F) The claim shall not imply that consuming sugar alcohol-containing foods is the only recognized means of achieving a reduced risk of dental caries.

(G) Packages with less than 15 square inches of surface area available for labeling are exempt from paragraphs (A) and (C) of this section.

(ii) *Nature of the food.* (A) The food shall meet the requirement in § 101.60(c)(1)(i) with respect to sugars content.

(B) The sugar alcohol in the food shall be xylitol, sorbitol, mannitol, maltitol, isomalt, lactitol, hydrogenated starch hydrolysates, hydrogenated glucose syrups, or a combination of these.

(C) When fermentable carbohydrates are present in the sugar alcohol-containing food, the food shall not lower plaque pH below 5.7 by bacterial fermentation either during consumption or up to 30 minutes after consumption, as measured by the indwelling plaque pH test found in “Identification of Low Caries Risk Dietary Components,” T. N. Imfeld, Volume 11, *Monographs in Oral Science*, 1983, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Karger AG Publishing Co., P. O. Box, Ch-4009 Basel, Switzerland, or may be examined at the Center for Food Safety and Applied Nutrition’s Library, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(d) *Optional information.* (1) The claim may include information from paragraphs (a) and (b) of this section, which describe the relationship between diets containing sugar alcohols and dental caries.

(2) The claim may indicate that development of dental caries depends on many factors and may identify one or more of the following risk factors for dental caries: Frequent consumption of fermentable carbohydrates, such as dietary sugars and starches; presence of oral bacteria capable of fermenting carbohydrates; length of time fermentable carbohydrates are in contact with the teeth; lack of exposure to fluoride; individual susceptibility; socioeconomic and cultural factors; and characteristics of tooth enamel, saliva, and plaque.

(3) The claim may indicate that oral hygiene and proper dental care may help to reduce the risk of dental disease.

(4) The claim may indicate that the sugar alcohol serves as a sweetener.

(e) *Model health claim.* The following model health claims may be used in food labeling to describe the relationship between sugar alcohol-containing foods and dental caries.

(1) Example of the full claim:

(i) Frequent eating of foods high in sugars and starches as between-meal snacks can promote tooth decay. The sugar alcohol [name, optional] used to sweeten this food may reduce the risk of dental caries.

(ii) Frequent between-meal consumption of foods high in sugars and starches promotes tooth decay. The sugar alcohols in [name of food] do not promote tooth decay.

(2) Example of the shortened claim for small packages:

(i) Does not promote tooth decay.

(ii) May reduce the risk of tooth decay.

Dated: August 16, 1996.

William K. Hubbard,
Associate Commissioner for Policy
Coordination.

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21 CFR Parts 182 and 184

[Docket No. 85N-0548]

Direct Food Substances Affirmed as Generally Recognized as Safe; High Fructose Corn Syrup

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations for substances that are generally recognized as safe (GRAS) to affirm that high fructose corn syrup (HFCS), prepared from high dextrose equivalent corn starch hydrolysate by partial enzymatic conversion of glucose

(dextrose) to fructose utilizing one of several glucose isomerase enzyme preparations, is GRAS as a direct human food ingredient. This action is in response to six petitions filed by members of the food industry.

DATES: Effective August 23, 1996. The Director of the Office of the Federal Register approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of a certain publication in 21 CFR 184.1866, effective August 23, 1996.

FOR FURTHER INFORMATION CONTACT: James C. Wallwork, Center for Food Safety and Applied Nutrition (HFS-217), Food and Drug Administration, 200 C St. SW., Washington, DC 20204-0001, 202-418-3078.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of February 8, 1983 (48 FR 5716), FDA published a document that listed HFCS as GRAS for use in food (§ 182.1866 (21 CFR 182.1866)) and also affirmed that certain insoluble glucose isomerase enzyme preparations are GRAS for use in the manufacture of HFCS (§ 184.1372 (21 CFR 184.1372)) (hereinafter referred to as the 1983 final rule). The agency published this final rule in response to six industry petitions that requested GRAS affirmation for certain insoluble glucose isomerase enzyme preparations used to make HFCS and for the manufactured product itself.

The basis for listing HFCS in 21 CFR part 182 was that HFCS is made with enzyme preparations that FDA has affirmed as GRAS; the saccharide composition (glucose to fructose ratio) of HFCS is approximately the same as that of honey, invert sugar, and the disaccharide sucrose; and the minor components (primarily higher saccharides of glucose) of HFCS are also found at similar levels in corn syrup and corn sugar which are already on the GRAS list. Therefore, FDA concluded that it was appropriate to list HFCS as GRAS for use in food while the agency fully evaluated it during the

comprehensive safety review of corn sugar, corn syrup, invert sugar, and sucrose.

In the 1983 final rule, the agency gave notice to all interested parties that when the agency completed its comprehensive safety review of corn sugar (dextrose), corn syrup, invert sugar, and sucrose, it would examine the data on these substances to determine whether those data provide an adequate basis to affirm that HFCS is GRAS. In the Federal Register of November 7, 1988 (53 FR 44862), the agency published a final rule affirming that the use of corn sugar, corn syrup, invert sugar, and sucrose in food is GRAS.

II. The Safety Review of High Fructose Corn Syrup

In the Federal Register of November 7, 1988 (53 FR 44904), FDA proposed to affirm that the use of HFCS in food is GRAS (hereinafter referred to as the 1988 HFCS proposal). Included in the 1988 HFCS proposal was the agency's: (1) Evaluation of the data contained in the petitions and of their relationship to the safety of HFCS; (2) discussion of the relevancy of reports by the Select Committee on GRAS Substances of the Federation of American Societies for Experimental Biology entitled "Evaluation of the Health Aspects of Corn Sugar (Dextrose), Corn Syrup, and Invert Sugar as Food Ingredients" (Ref. 1) and "Evaluation of the Health Aspects of Sucrose as a Food Ingredient" (Ref. 2) to the safety assessment of HFCS; and (3) discussion of the relevancy of FDA's Sugars Task Force Report "Evaluation of the Health Aspects of Sugars Contained in Carbohydrate Sweeteners" (Ref. 3) to the safety evaluation of HFCS.

The agency made it clear during its safety evaluation of corn sugar, corn syrup, invert sugar, and sucrose that its exposure estimate for HFCS included exposure to HFCS containing 55 percent fructose (HFCS-55) (Ref. 3). Furthermore, FDA noted that most of the components found in HFCS