Inspector, who may add comments and then send it to the Manager, Los Angeles ACO.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Los Angeles ACO.

(c) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Issued in Renton, Washington, on July 2, 1997.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 97–17848 Filed 7–8–97; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 97P–0206]

Food Labeling: Health Claims; Dietary Sugar Alcohols and Dental Caries

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the regulation that authorized a health claim on sugar alcohols and dental caries to include the sugar alcohol erythritol. FDA is proposing this action in response to a petition filed by the Cerestar Holding B.V., Mitsubishi Chemical Corp., and Nikken Chemicals Co. The agency has tentatively concluded that, based on the totality of publicly available scientific evidence presented in the petition, erythritol does not promote dental caries. Therefore, FDA is proposing to amend the sugar alcohol and dental caries health claim to include erythritol.

DATES: Written comments by September 22, 1997. The agency is proposing that any final rule that may issue based upon this proposal become effective upon its publication in the **Federal Register**.

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

FOR FURTHER INFORMATION CONTACT: Joyce J. Saltsman, Center for Food Safety and Applied Nutrition (HFS–165), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5483.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of August 23, 1996 (61 FR 43433), the agency adopted a final rule to authorize the use, on food labels and in food labeling, of health claims on the association between sugar alcohols and dental caries (hereinafter referred to as the sugar alcohol final rule) (§ 101.80 (21 CFR 101.80)). FDA adopted this regulation 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 (and, by delegation, FDA) shall issue 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) (21 CFR 101.14(c))).

The sugar alcohol final rule sets out the circumstances in which a sugar alcohol is eligible to be the subject of a health claim (§ 101.80(c)(2)(ii)). Section 101.80(c)(2)(ii)(A) states that the food must meet the requirement for a sugar free food defined in 21 CFR 101.60(c)(1)(i). Section 101.80(c)(2)(ii)(B) lists the sugar alcohols that are eligible to bear the claim, xylitol, sorbitol, mannitol, maltitol, isomalt, lactitol, hydrogenated starch hydrolysates, hydrogenated glucose syrups, or a combination of these. Section 101.80(c)(2)(ii)(C) states that:

> [W]hen 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,'' * * * which is incorporated by reference * * *.

In the sugar alcohol final rule, the agency stated that for other sugar alcohols to be included in § 101.80(c)(2)(ii)(B), a petitioner must show how the substance conforms to the requirements of §§ 101.14(b) and 101.80 (61 FR 43433 at 43442). FDA stated:

> 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)). Likewise, the petitioner would need to provide evidence that the sugar alcohol will not lower plaque pH below 5.7. Therefore, before a claim can be made for a new sugar alcohol, it must be shown to meet the requirements for § 101.80. When this is demonstrated, 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).

The present rulemaking is in response to a petition to amend § 101.80(c)(2)(ii)(B) to include erythritol as one of the sugar alcohols that is eligible to bear the sugar alcohol and dental caries health claim.

II. Petition for Health Claim on Erythritol and the Nonpromotion of Dental Caries

A. The Petition

On April 4, 1997, the petitioners submitted a petition to FDA requesting that the agency amend § 101.80(c)(2)(ii)(B) to authorize a claim to authorize a noncariogenicity dental health claim for the sugar alcohol erythritol. On May 16, 1997, the agency sent the petitioner a letter stating that it had completed its initial review of the petition, and that the petition would be filed in accordance with section 403(r)(4) of the act (see Docket 97P–0206, Letter 1). The following is a review of the health claim petition and of whether erythritol satisfies the requirements of §§ 101.80(c)(2)(ii) and 101.14(b) and (c) of FDA's regulations.

B. Preliminary Requirements

1. The Substance That Is the Subject of the Petition

Erythritol is a 4-carbon, monosaccharide polyhydric alcohol. It occurs naturally in a wide variety of plants (e.g., watermelons, melons, grapes, and mushrooms) and animals (e.g., humans, dogs, and cows). Erythritol is also a product of the fermentation by yeasts and molds of sugars (Ref. 1, p. 27).

2. The Substance Is Associated With a Disease for Which the U.S. Population Is at Risk

In the preamble to the proposed sugar alcohol and dental caries rule (60 FR 37507 at 37509, July 20, 1995) and in the regulation authorizing the claim on sugar alcohols and dental caries (§ 101.80(a)(3)), FDA established that dental caries is a disease for which the U.S. population is at risk. The agency stated:

> Dental caries is recognized in *The Surgeon General's Report on Nutrition and Health* * * * as a disease or health-related condition for which the United States population is at risk * * *. The overall prevalence of dental caries imposes a substantial burden on Americans. Of the 13 leading health

problems in the United States, dental diseases rank second in direct costs * * *.

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 * * *.

Based on these facts, FDA concludes that, as required in § 101.14(b)(1), dental caries is a disease for which the U.S. population is at risk.

3. The Substance Is a Food

In the preamble to the sugar alcohols proposed rule (60 FR 37507 at 37509) and in the final regulation itself (§ 101.80(a)(4)), the agency states 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 certain confectioneries. Therefore, FDA concludes that erythritol satisfies the preliminary requirement in § 101.14(b)(3)(i).

4. The Substance Is Safe and Lawful

The petitioner has submitted a petition requesting that FDA affirm that the use of erythritol is generally recognized as safe (GRAS) (62 FR 10285, March 6, 1997). The agency notes that this GRAS affirmation petition (GRASP 7G0422) is still under review, and that authorization of a health claim should not be interpreted as affirmation that the proposed uses of erythritol are GRAS. Such a determination can be made only after the agency has completed its review of the GRAS petition. A preliminary review of the GRAS affirmation petition, however, reveals that it contains significant evidence supporting the safety of the use of this substance at the levels necessary to justify a health claim.

In the GRAS affirmation petition, the petitioner relied heavily on published animal subchronic and chronic toxicity studies and reproduction studies (GRASP 7G0422, App. IV: C4, C12, D5, D7, D8, D17, D20, D27, and D30), on human toleration and absorption studies (GRASP 7G0422, App. IV: C9, C19, C27, E2, E6, E8, and E11), and on the conclusions about the safety of erythritol by a panel of independent experts qualified by scientific training and experience to evaluate the safety of foods. The panel of independent scientists based their conclusions on their review of various published and unpublished scientific studies which included animal toxicological studies and clinical studies. In their report entitled, ''Erythritol: A Review of Biological and Toxicological Studies'' (GRASP 7G0422, App. I-1), the panel concluded that:

The large body of published data supports the conclusion that the intake of erythritol would not be expected to cause adverse effects in humans under the conditions of use in food and that other qualified food safety experts would agree that erythritol is generally recognized as safe (GRAS) under the conditions of its intended use in food.

The petitioner also asserted that erythritol occurs endogenously and naturally in the diet, and that it has a history of safe use in foods. The petitioner further argued that the safety of erythritol is supported by its chemical structure, i.e., it is positioned in the homologous series of sugar alcohols, between glycerol and xylitol, a series that also includes other common food ingredients such as sorbitol and mannitol.

Based on the totality of the evidence, the agency is not prepared, at this time, to take issue with the petitioner's view that the use of erythritol is safe and lawful. Therefore, FDA tentatively concludes that the petitioner has provided evidence that satisfies the requirement in § 101.14(b)(3)(ii) that use of erythritol at the levels necessary to justify a claim is safe and lawful.

III. Review of Scientific Evidence

The petitioner submitted two scientific studies evaluating the relationship between erythritol and dental caries: A human study and an animal study that included an in vitro evaluation.

The human study included an interdental plaque pH telemetry test, one of the methods described in the text entitled ''Identification of Low Caries Risk Dietary Components,'' which the agency incorporated by reference in the sugar alcohol regulation (see § 101.80(c)(2)(ii)(C)). The test was conducted at the Bioelectronic Unit of the Clinic of Preventive Dentistry, Periodontology, and Cariology of the University Dental Institute of Zurich, Switzerland (Ref. 1, Appendix B-2).

For this test, each subject had a mandibular telemetric prosthesis incorporating a miniaturized glass pH-electrode placed directly opposite the interproximal area of an adjacent abutment tooth. Once the prosthesis was inserted into the subject's mouth, the subject was asked not to alter his or her eating habits. The prostheses were worn throughout the 3-to 4-day test period to allow an undisturbed growth of interdental plaque over the tips of the electrodes. With the exception of water rinses, the subjects were also asked to refrain from all oral hygiene measures.

At the end of the 3-to 4-day plaque buildup period, the interdental plaque pH telemetry test was conducted. Baseline plaque pH was measured over a 15-minute period after the subjects chewed a piece of paraffin for 3 minutes. The subjects then sucked on the sugar-free throat lozenge containing erythritol, followed by plaque pH measurements over a 30-minute period. The same test procedure was then repeated using a 10-percent sucrose rinse as the control substance in place of the erythritol lozenge.

The results of this test showed that after the first paraffin chew, baseline plaque pH measured between 6.9 to 7.0, values that were similar to earlier tests with the same subjects and plaque ages (Ref. 1, Appendix B-2). Following consumption of erythritol, plaque pH measured 6.0 to 6.65. The sucrose rinse caused plaque pH to drop to a range of 4.25 to 4.9, levels that were significantly lower than pH of plaque during the erythritol period and well below the critical pH value of 5.7, the level at which demineralization of enamel occurs. The key finding for this proceeding is that there were no significant differences in plaque pH between the paraffin and erythritol periods.

Kawanabe and coworkers evaluated the cariogenicity of erythritol in vitro and in pathogen-free rats (Ref. 1, Appendix B-3). The authors used microorganisms of various *Streptococcus*, *Lactobacillus*, and *Actinomyces* species to determine whether the organisms could use erythritol as a substrate for lactic acid production and plaque formation. The results of this study showed that erythritol was not utilized as a substrate for lactic acid production or for plaque formation by Streptococcus mutans or certain other oral microorganisms.

In the animal study, the rats were randomly divided into six groups. Three groups of animals were fed modified diets for 5 days. These diets contained either starch alone, with no sugars or sugar alcohol; starch plus sucrose; or starch plus erythritol. Then the animals were infected with *Streptococcus sobrinus*, after which they continued to consume the modified diet for an additional 50 days. In a similar experiment, the other three groups of animals were fed diets that contained starch chocolate; sucrose chocolate, or erythritol chocolate, and the animals were infected with *Streptococcus mutans*. Mandibular caries scores were determined at 70 days of age in all groups.

The results of this study showed that the group fed starch plus erythritol experienced significantly fewer caries compared to the starch and starch plus sucrose groups. The total caries scores for groups fed diets of starch, starch

plus sucrose, and starch plus erythritol were 12.5, 60.5, and 3.1, respectively. Similarly, the group consuming erythritol chocolate experienced significantly fewer caries compared to the starch chocolate and sucrose chocolate groups. The caries scores for the starch chocolate, sucrose chocolate, and erythritol chocolate groups were 18.5, 82.8, and 6.7, respectively. There were no significant differences in the body weights of the rats between groups.

The authors stated that, although the group fed starch usually experienced the least dental caries, the caries score for the group fed starch was significantly higher than that of the group fed starch plus erythritol. The same trend was reported in the animals consuming the chocolate diets. The authors suggested that the cariogenicity of starch in these experiments may be explained by the contamination of mono- and disaccharides. The main conclusion from this study is that erythritol did not induce dental caries.

IV. Decision to Propose a Health Claim Relating Erythritol to the Nonpromotion of Dental Caries

The petition set out the results of an indwelling plaque pH test and the results of an in vitro and animal study that evaluated the cariogenicity of erythritol. FDA reviewed this information and has tentatively concluded that there is significant scientific evidence to demonstrate that erythritol does not promote dental caries. The results of the plaque pH test clearly demonstrate that erythritol does not lower plaque pH below 5.7, and that, therefore, it does not promote the demineralization of dental enamel. The results of the in vitro and animal study are consistent with the results of the indwelling plaque pH study and show that erythritol does not support the growth of oral microorganisms responsible for producing the acid in plaque and has little to no cariogenic potential. The results of these studies are consistent with the results of the studies that investigated the cariogenic potential of the sugar alcohols listed in § 101.80(c)(2)(ii)(B). Therefore, FDA tentatively finds that erythritol has satisfied the requirements set forth in §§ 101.14(d) and 101.80, and the agency is proposing to add erythritol to the list of eligible sugar alcohols.

V. Description of Modifications to § 101.80

Section 101.80(c)(2)(ii)(B) lists the sugar alcohols that are eligible to be the subject of a dental claim. FDA is proposing to amend § 101.80(c)(2)(ii)(B) to state ''[T]he sugar alcohol in the food shall be xylitol, sorbitol, mannitol, maltitol, isomalt, lactitol, hydrogenated starch hydrolysates, hydrogenated glucose syrups, erythritol, or a combination of these.''

The agency is not specifying a level of erythritol in the food product because, like the other sugar alcohols, erythritol is being used as a substitute for sugars. Therefore, the amount of the substance required is that needed to achieve a desired level of sweetness.

VI. Environmental Impact

The agency has 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. Therefore, neither an environmental assessment nor an environmental impact statement is required. This finding is based on information submitted by the petitioner in an environmental assessment prepared using the format described in 21 CFR 25.31a(b)(5).

VII. Analysis of Impacts

FDA has examined the economic implications of the proposed rule as required by Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select the regulatory approach that maximizes net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including having an annual effect on the economy of $100 million or adversely affecting in a material way a sector of the economy, competition, or jobs, or if it raises novel legal or policy issues. If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize the economic impact of that rule on small entities. FDA finds that this proposed rule is not a significant rule as defined by Executive Order 12866 and finds under the Regulatory Flexibility Act that the proposed rule will not have a significant impact on a substantial number of small entities.

The establishment of this health claim results in benefits and in costs only to the extent that food manufacturers elect to take advantage of the opportunity to use the claim. This rule will not require that any labels be redesigned, or that any product be reformulated.

Some manufacturers are using FDA's approved health claim regarding the benefits of sugar alcohols. This proposed health claim will allow them to highlight the effects of another sugar alcohol, erythritol. The benefit of establishing this health claim is to provide for new information in the market regarding the relationship of erythritol and dental caries, and to provide consumers with the assurance that this information is truthful, not misleading, and scientifically valid.

Costs will be incurred by small entities only if they opt to take advantage of the marketing opportunity presented by this regulation. FDA cannot predict the number of small entities that will choose to use the claim. However, no firm, including small entities, will choose to bear the cost of redesigning labels unless they believe that the claim will result in increased sales of their product. Therefore, this rule will not result in either a decrease in revenues or a significant increase in costs to any small entity. Accordingly, under the Regulatory Flexibility Act, 5 U.S.C. 605(b), the agency certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities.

VIII. Paperwork Reduction Act

FDA tentatively concludes that this proposed rule contains no reporting, recordkeeping, labeling, or other third party disclosure requirement. Thus, there is no ''information collection'' necessitating clearance by the Office of Management and Budget. However, to ensure the accuracy of this tentative conclusion, FDA is seeking comment on whether this proposed rule to permit health claims on the association between erythritol and the noncariogenicity of dental caries imposes any paperwork burden.

IX. Effective Date

FDA is proposing to make these regulations effective upon publication of a final rule based on this proposal.

X. Comments

Interested persons may, on or before September 22, 1997, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

XI. Reference

The following reference has 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.

1. Cerestar Holding B. V., Mitsubishi Chemical Corp., and Nikken Chemicals Co., ''Petition to amend the regulation for 21 CFR § 101.80 to authorize a noncariogenicity dental health claim for the sugar alcohol erythritol (1,2,3,4-butanetetrol),'' April 4, 1997 [CP1].

List of Subjects in 21 CFR Part 101

Food and Drug Administration, Food labeling, 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, it is proposed that 21 CFR part 101 be amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues 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. Section 101.80 is amended by revising paragraph (c)(2)(ii)(B) to read as follows:

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

* * * * *

(c) * * *

(2) * * *

(ii) * * *

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

* * * * *

Dated: June 17, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–17797 Filed 7-8-97; 8:45 am]

BILLING CODE 4160–01–F

FEDERAL COMMUNICATIONS COMMISSION

47 CFR CHAPTER I

[WT Docket No. 97–150; FCC 97–232]

Competitive Bidding

AGENCY: Federal Communications Commission.

ACTION: Request for comments.

SUMMARY: On July 2, 1997, the Federal Communications Commission released a public notice requesting comment on the Commission's use of competitive bidding to award licenses to provide wireless services as part of its preparation of a report to Congress, as required by Section 309(j)(12) of the Communications Act, 47 U.S.C. 309(j)(2). The public notice solicits comment from the public on a variety of issues relating to the Commission's spectrum auction program to date, and announces that comments are due on or before August 1, 1997.

DATES: Comments are due on or before August 1, 1997.

FOR FURTHER INFORMATION CONTACT: Mark Bollinger or Alice Elder, Wireless Telecommunications Bureau, Federal Communications Commission, (202) 418–0660.

SUPPLEMENTARY INFORMATION: This is a summary of the public notice released on July 2, 1997. The complete public notice is available for inspection and copying during normal business hours in the FCC Reference Center (Room 239), 1919 M Street, N.W., Washington, D.C., 20554, and also may be purchased from the Commission's copy contractor, International Transcription Services, (202) 857–3800, 2100 M Street, N.W., Washington, D.C. 20037. The complete public notice is also available on the Commission's Internet home page (http://www.fcc.gov).

Summary of the Public Notice

Commission Opens Inquiry on Competitive Bidding Process for Report to Congress

Comment Due Date: August 1, 1997

I. Introduction and Background

The Omnibus Budget Reconciliation Act of 1993 (the ''Budget Act'') added Section 309(j) to the Communications Act of 1934, as amended, 47 U.S.C. §§ 151–713 (the ''Communications Act''). Section 309(j) authorized the Commission to employ competitive bidding to choose from among mutually exclusive applications for initial licenses in services where the licensee receives compensation from subscribers. It requires the Commission to promote the development and rapid deployment of new technologies, products and services for the benefit of the public, including those residing in rural areas, without administrative or judicial delays. It further requires the Commission to promote opportunity and competition by avoiding excessive concentration of licenses and by disseminating licenses among a wide variety of applicants, including small businesses, rural telephone companies, and businesses owned by members of minority groups and women.

In the four years since grant of auction authority, the Commission has completed fourteen auctions. These auctions have resulted in the assignment of over 4,300 licenses for spectrum-based services, which include narrowband Personal Communications Service (PCS), broadband PCS, Interactive Video Data Service (IVDS), Multipoint Distribution Service (MDS), 900 MHz Specialized Mobile Radio Service (SMR), unserved cellular areas, Direct Broadcast Satellite (DBS), Digital Audio Radio Service (DARS) and Wireless Communications Service (WCS). Auctions to date have raised a total of $23.1 billion for the U.S. Treasury. Future auctions being planned include those for licenses to provide Local Multipoint Distribution Service, paging, narrowband PCS, and the 800 MHz SMR and 220 MHz services.

Section 309(j)(12) of the Communications Act requires that the Commission conduct a public inquiry regarding the use of competitive bidding to award licenses and submit a report to Congress by September 30, 1997. Pursuant to the statute, the report must:

(1) Contain a statement of the revenues obtained, and a projection of future revenues, from the use of competitive bidding systems;

(2) Describe the competitive bidding methodologies established by the Commission pursuant to Sections 309(j)(3) and (4) of the Communications Act;

(3) Compare the advantages and disadvantages of the competitive bidding methodologies established by the Commission in terms of attaining the objectives described in Sections 309(j)(3) and (4) of the Communications Act;

(4) Evaluate whether and to what extent:

(i) Competitive bidding significantly improved the efficiency and effectiveness of the process for granting radio spectrum licenses;

(ii) Competitive bidding facilitated the introduction of new spectrum-based technologies and the entry of new companies into the telecommunications market;

(iii) Competitive bidding methodologies have secured prompt delivery of service to rural areas and have adequately addressed the needs of rural spectrum users; and