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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 2004P–0294]

Food Labeling; Health Claims; Dietary Noncariogenic Carbohydrate Sweeteners 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 authorizing a health claim on noncariogenic carbohydrate sweeteners and dental caries, i.e., tooth decay, to include sucralose, a nonnutritive sweetener. Similar to the sweeteners currently authorized to make a health claim, sucralose is used as a sugar substitute that is minimally fermented, relative to sugar, by oral microorganisms and thus does not contribute to production of organic acids by plaque bacteria as do the fermentable sugars for which it is a substitute. FDA is taking this action in response to a health claim petition filed by McNeil Nutritionals. The agency previously concluded that there was significant scientific agreement for the relationship between slowly fermented carbohydrate sugar substitutes, specifically certain sugar alcohols, and the nonpromotion of dental caries. Based on the totality of publicly available scientific evidence, FDA now has determined that the nonnutritive sweetener sucralose, like the sugar alcohols, is not fermented by oral bacteria to an extent sufficient to lower dental plaque pH to levels that would contribute to the erosion of dental enamel. Therefore,

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FDA has concluded that sucralose does not promote dental caries, and it is proposing to amend the regulation authorizing a health claim relating certain noncariogenic sweeteners and nonpromotion of dental caries to include sucralose as a substance eligible for the claim.

DATES: Submit written or electronic comments by [*insert date 75 days after date of publication in the* **Federal Register**]. See section XII of this document for the proposed effective date of a final rule based on this document.

ADDRESSES: You may submit comments, identified by the Docket Number 2004P–0294, by any of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments.* Follow the instructions for submitting comments on the agency Web site.
- E-mail: *fdadockets@oc.fda.gov.* Include Docket No. 2004P–0294 and/or RIN number ___ in the subject line of your e-mail message.
- FAX: 301–827–6870
- Mail/Hand delivery/Courier [for paper, disk, or CD-ROM submissions]: Division of Dockets Management (HFA–305), 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the agency name and Docket Number or Regulatory Information Number (RIN) for this rulemaking. All comments received will be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm*, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the "Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/ohrms/dockets/default.htm* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, room 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: James E. Hoadley, Center for Food Safety and Applied Nutrition (HFS–830), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–1450.

SUPPLEMENTARY INFORMATION:

I. Background

The Nutrition Labeling and Education Act of 1990 (the 1990 amendments) (Public Law 101–535) amended the Federal Food, Drug, and Cosmetic Act (the act) in a number of important respects. One aspect of the 1990 amendments was that they clarified FDA's authority to regulate health claims on food labels and in food labeling.

FDA issued several new regulations in 1993 that implemented the health claim provisions of the 1990 amendments. Among these were § 101.14 *Health claims: general requirements* (21 CFR 101.14) (58 FR 2478, January 6, 1993) and § 101.70 *Petitions for health claims* (21 CFR 101.70) (58 FR 2478), which established a process for petitioning the agency to authorize health claims about substance-disease relationships and set out the types of information that a health claim petition must include. These regulations became effective on May 8, 1993.

The final rule that established § 101.80 (21 CFR 101.80) (61 FR 43433, August 23, 1996), relating sugar alcohols to the nonpromotion of dental caries (the dental caries health claim), completed the first rulemaking that we

conducted in response to a health claim petition (Docket No. 1995P–0003).[1] Section 101.80(a) describes the role of fermentable carbohydrates, i.e., dietary sugars and starches, in the development of dental caries. The fermentation of these carbohydrates by microorganisms produces organic acids on the surface of teeth, which contribute to the development of dental caries through erosion of tooth enamel. Section 101.80(b) explains that noncariogenic carbohydrate sweeteners are fermented by oral microorganisms more slowly than fermentable carbohydrates. Consequently, the rate of acid production is lower than that from fermentable carbohydrates. Noncariogenic carbohydrate sweeteners, when used in place of fermentable sugars, are therefore useful in that they do not promote dental caries as do the sugars they replace. Section 101.80(c) describes the specific requirements of the dental caries health claim, including the requirement that the food bearing the claim be "sugar free" (§ 101.80(c)(2)(iii)(A)). This section also specifies 10 noncariogenic carbohydrate sweeteners (xylitol, sorbitol, mannitol, maltitol, isomalt, lactitol, hydrogenated starch hydrolysates, hydrogenated glucose syrups, erythritol, and D-tagatose) that are eligible for the claim (§ 101.80(c)(2)(ii)). Section 101.80(c)(2)(iii)(C) further states that:

> When carbohydrates other than those listed in paragraph (c)(2)(ii) of this section are present in the 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 * * *."

In the dental caries health claim final rule, the agency stated that for other noncariogenic carbohydrate sweeteners to be included in the list of sweeteners

[1]Section 101.80 was subsequently amended, to expand the substances which are the subject of the claim, to include noncariogenic carbohydrate sweeteners other than sugar alcohols (67 FR 71461, December 2, 2002).

eligible for the health claim, a petitioner must show how the substance conforms to the requirements of §§ 101.14(b) and 101.80 and must provide evidence that the new noncariogenic carbohydrate sweetener will not lower dental plaque pH below 5.7 (61 FR 43433 at 43442).

In 1997, the agency amended the dental caries health claim to include erythritol as an additional noncariogenic carbohydrate sweetener eligible for the claim (62 FR 63653, December 2, 1997). The health claim petition to add erythritol to § 101.80 (Docket No. 1997P–0206) presented scientific data from a rodent cariogenicity study and from a clinical indwelling plaque pH test of erythritol. The agency was satisfied that the results of these two studies were consistent with the results of the studies that investigated the cariogenic potential of the substances previously listed in § 101.80(c)(2)(ii)(A) and that erythritol met the requirements of § 101.14(b). Therefore, erythritol was added to the list of sugar alcohols eligible as a noncariogenic carbohydrate sweetener. In 2002, the agency again amended § 101.80 (67 FR 71461) to add D-tagatose, a non-fermentable sugar, to the list of substances eligible for the health claim. This action was based upon clinical evidence that ingestion of D-tagatose would not lower plaque pH below 5.7 as measured by the indwelling plaque pH method. Because the sweetener added to the health claim in the 2002 amendment was not a sugar alcohol, the 2002 amendment also changed the substance in the title of the regulation from "sugar alcohols" to "noncariogenic carbohydrate sweeteners."

II. Petition and Grounds

A. The Petition

On April 2, 2004, McNeil Nutritionals, of New Brunswick, NJ (petitioner) submitted a petition under section 403(r)(4) of the act (21 U.S.C. 343(r)(4)) (Ref.

1). The petition requested that we amend § 101.80 to include the nonnutritive sweetener sucralose as one of the substances eligible to bear the dental caries health claim. On July 9, 2004, we notified the petitioner that we had completed our initial review of the petition and that the petition had been filed for further action in accordance with section 403(r)(4) of the act. If the agency does not act, by either denying the petition or issuing a proposed regulation to authorize the health claim, within 90 days of the date of filing for further action, the petition is deemed to be denied unless an extension is mutually agreed upon by the agency and the petitioner (section 403(r)(4)(A)(i) of the act and § 101.70(j)(3)(iii)). On April 5, 2005, FDA and the petitioner mutually agreed to extend the deadline to publish a proposed regulation until October 7, 2005.

B. Nature of the Substance

The petition has identified the substance, which is the subject of the petitioned health claim, to be sucralose (CAS Reg. No. 56038–13–2), a substituted carbohydrate in which there is a selective replacement of three hydroxyl groups on a sucrose molecule with chlorine atoms. The food additive use of sucralose is as a general purpose sweetener in both conventional foods and dietary supplements (§ 172.831 (21 CFR 172.831)). Sucralose, used as a general purpose sweetening food additive, is a specific component of food. The term "substance" within the meaning of a health claim includes "* * * a specific food or component of food * * *" (§ 101.14(a)(2)). As such, FDA concludes that sucralose is a "substance" as defined in § 101.14(a)(2) for the purpose of a food label statement which characterizes the relationship of any substance to a disease or health-related condition.

C. Review of Preliminary Requirements for a Health Claim

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

The petition noted that the scientific literature establishing the relationship between dental caries and fermentable carbohydrates is described and referenced in the final rule for the dental caries health claim (61 FR 43433). When authorizing the health claim relating noncariogenic carbohydrate sweeteners and dental caries, the agency recognized that, although the prevalence of dental caries among children in the United States had been declining since the early 1970s, the overall prevalence of dental caries remained widespread throughout the U.S. population (§ 101.80(a)(3)). Currently, the Department of Health and Human Services' Healthy People 2010 Objectives recognizes dental caries as the single most common chronic disease of childhood, and states that 30 percent of adults have untreated dental decay (Ref. 2). Based on these facts, FDA concludes that, as required in § 101.14(b)(1), dental caries is a disease for which the general U.S. population is at risk.

2. The Substance is a Food

When a health claim involves consumption of a substance at other than decreased dietary levels, the substance that is the subject of the health claim must contribute taste, aroma, or nutritive value, or any other technical effect listed in § 170.3(o) (21 CFR 170.3(o)) to the food, and must retain that attribute when consumed at the levels that are necessary to justify a claim (§ 101.14(b)(3)(i)). As noted by the petition, the use of sucralose as a nonnutritive sweetener in conventional foods and dietary supplements is prescribed by the food additive regulation under § 172.831. The sweetness intensity of sucralose is approximately 600 times that of sucrose (Ref. 3), as

such the amount of sucralose used as a sugar substitute is in milligrams per serving and the caloric contribution of sucralose to a food is insignificant. The food additive use of sucralose is as a "non-nutritive sweetener," one of the technical effects listed in § 170.3(o) for which human food ingredients may be added to foods. Because sucralose contributes to food taste, one of the technical effects listed in § 170.3(o), the agency concludes that the preliminary requirement of § 101.14(b)(3)(i) is satisfied.

3. The Substance is Safe and Lawful

The petition notes that FDA has evaluated the use of sucralose in the food supply and has issued a food additive regulation setting out the conditions of its safe use in foods. The safe use of sucralose as a general purpose sweetener in foods in accordance with current good manufacturing practice in an amount not to exceed that reasonably required to accomplish the intended effect is prescribed by the food additive regulation under § 172.831. This food additive regulation establishes the food use of sucralose under conditions prescribed by the regulation to be safe and lawful under section 409 of the act (21 U.S.C. 348). Therefore, FDA concludes that the petitioner has satisfied the requirement of § 101.14(b)(3)(ii) to demonstrate, to FDA's satisfaction, that the use of sucralose as a sweetener is safe and lawful under the provisions of the act.

III. Review of Scientific Evidence of the Substance-Disease Relationship

A. Basis for Evaluating the Relationship Between Sucralose and Dental Caries

In the preamble to the 1996 dental caries health claim final rule, the agency concluded that there was significant scientific agreement among qualified experts to support the relationship between certain sugar alcohols and the nonpromotion of dental caries (61 FR 43433 at 43443). The agency

noted that it would take action to add additional sugar alcohols to this regulation when presented with evidence that the additional sugar alcohols would not lower plaque pH (i.e., raise plaque acidity) below 5.7, and that the substance conformed to the requirements of § 101.14(b) (61 FR 43433 at 43442).

The substance that is the subject of the current petition, sucralose, is a chlorine-substituted sugar rather than a sugar alcohol. However, like the sugar alcohols, the intended food ingredient use of sucralose is as a sugar substitute. Also, as is the case with the sugar alcohols, the potential dental health benefit from sucralose derives from its lower fermentability relative to traditional sugars. Consequently, the criteria that were used to evaluate the sugar alcohols in the existing dental caries health claim can be applied to assess whether sucralose also qualifies for such a claim.

B. Review of Scientific Evidence

1. Evidence Considered in Reaching the Decision

In the initial proposal to authorize a health claim relating noncariogenic carbohydrate sweeteners and nonpromotion of dental caries (60 FR 37507, July 20, 1995), FDA considered evidence from long-term controlled human caries studies, in vivo and in vitro plaque acidity studies, tooth decalcification and remineralization studies, and experimental rat caries studies for the noncariogenic potential of several specific sugar alcohols. FDA's review focused on the scientific evidence from studies evaluating changes in human dental plaque pH, plaque acid production, decalcification or remineralization of tooth enamel, and the incidence of dental caries. FDA limited its review to these types of studies because previous reviews by the Federal Government and other authorities had focused on these areas, and the majority of research efforts have also focused on these areas (60 FR 37507 at 37523). The well

established role of sucrose in the etiology of dental caries is related to the ability of sucrose to be metabolized by oral bacteria into extracellular polymers that adhere firmly to the tooth surfaces (i.e., plaque), and at the same time to form acids that can demineralize tooth enamel. FDA had previously concluded that human studies show sugar alcohols are associated with reduced rate of acid production in dental plaque and, in some studies, a reduced incidence of dental caries, in comparison to sucrose (60 FR 37507 at 37523).

In consideration of the amendment requested in the current petition, FDA compared scientific evidence regarding the cariogenic potential of sucralose from three human studies which investigated the rate of acid production in dental plaque resulting from exposure to sucralose-containing solutions. This is the same type of clinical evidence that the agency previously reviewed regarding the cariogenic potential of certain sugar alcohols and of D-tagatose. As discussed in section II.C of this document, FDA has concluded that sucralose satisfies the requirements of § 101.14(b).

Sucralose is used as a nonnutritive food additive in processed foods. Sucralose is also marketed directly to consumers in several formulations for use in sweetening foods and beverages (Splenda Packet, Splenda Sugar Blend for Baking, and Splenda Granular). Splenda Packet is a formulation of sucralose dispersed in a dextrose/maltodextrin blend containing greater than 0.5 gram (g) dextrose sugar per labeled serving, and packaged in single serving packets for consumer use as a "table top" sweetener. Splenda Sugar Blend for Baking is a formulation of sucralose dispersed in sucrose, containing 2 g sugar per labeled serving, and packaged for consumer use as a sugar replacement in cooking and baking. The dental caries health claim regulation requires that a food bearing the claim be "sugar-free" as defined in the regulations, except

that the food may contain D-tagatose (see § 101.80(c)(2)(iii)(A) and § 101.60(c)(1)(i) (21 CFR 101.60(c)(1)(i)). Neither Splenda Packet nor Splenda Sugar Blend for Baking meet the definition of "sugar-free" as set out in § 101.60(c)(1)(i). Therefore, neither of these two sucralose formulations are eligible for use of the health claim, and the dental plaque pH data provided in the petition for Splenda Packet has not been considered as evidence for amending the health claim regulation. The petition did not include dental plaque pH data for Splenda Sugar Blend for Baking.

There are three primary methods used for measuring the impact of foods on plaque acidity in humans: Plaque sampling, micro-touch, and indwelling electrode methods (Ref. 4). The plaque sampling method involves the scraping of plaque from tooth surfaces, dispersing the collected plaque in distilled water, and in vitro pH measurement of the plaque suspension. The micro-touch method involves measurements of plaque pH in situ, at the plaque surface, by touching a small pH electrode against tooth surfaces. The indwelling electrode method involves mounting a small pH electrode in a removable partial denture such that it is positioned adjacent to a natural tooth crown, allowing in situ pH measurements under the plaque layer that accumulates on the electrode. Since these three methods measure pH at different locations and at different depths in the plaque, they yield somewhat different pH values. Both the micro-touch and indwelling electrode methods have been reported to satisfactorily identify relative differences in acidogenic foods compared to a positive control (Refs. 4 and 5). However, in studies which directly compare the absolute pH values obtained from the different plaque pH measurement methods, the indwelling electrode method consistently yields lower minimum

pH values than do either the plaque sampling or micro-touch methods (Refs. 4 to 6).

When initially authorizing the dental caries health claim, FDA noted that it would take action to add other sweeteners to the list of substances eligible for this health claim when presented with a petition that included, in part, evidence that the substance would not lower plaque pH below 5.7 (61 FR 43433 at 43442). FDA did not specify a specific method to be used in measuring plaque pH for considering the addition of other sweeteners to the list of eligible substances for this health claim. On the other hand, in order for foods that contain both noncariogenic sweeteners and fermentable carbohydrates to qualify for this health claim, § 101.80(c)(2)(iii)(C) specifies that the indwelling electrode method is the procedure that the agency will use.

2. Review of Sucralose Studies

The petition included published reports from three separate randomized, double-blind studies of the effect of sucralose on dental plaque pH in humans (Refs. 7 to 9). Each study was conducted with essentially the same experimental protocol, and in each study interdental plaque pH was measured with a hand-held miniature pH electrode (the micro-touch method). Exposure to sucralose was accomplished by a 1 minute rinsing of the mouth with the test sweetener substances dissolved in water (Ref. 7), hot coffee (Ref. 8), or iced tea (Ref. 9).

Each study recruited subjects older than 18 years of age and with high caries susceptibility as demonstrated by: (1) Greater than seven decayed, missing, or filled teeth, and (2) a plaque pH measurement below 5.7 when challenged with a 4.7 percent sucrose rinse. Subjects refrained from oral hygiene procedures for 48 hours prior to each test and refrained from smoking

and all food and drink, except for water, for at least 4 hours prior to each test to allow for the development of an undisturbed resting plaque layer. At each test session, pre-rinse baseline pH was measured at the mesiobuccal surface of six teeth, after which subjects rinsed with a test sweetener solution for 1 minute, and then pH measurements at the same six sites were repeated at timed intervals over 60 minutes.

Each study included test solutions of: (1) Sucralose alone, (2) sucralose with maltodextrin (Splenda Granular), (3) sucralose with a dextrose-maltodextrin blend (Splenda Packet), and (4) sucrose alone. The sucrose rinse served as a positive control. The sweetness of the sucralose solutions (0.007 percent by weight) and sucrose solution (4.7 percent by weight) were equivalent to 2 teaspoons of sucrose in 6 fluid ounces. A fifth test solution (unsweetened coffee or iced tea) was included in two of the reported studies (Refs. 8 and 9). Test sessions were conducted at 1-week intervals, and at approximately the same time of day for each individual. One sweetener solution was tested per test session and each individual tested all test solutions for the study they were enrolled in.

The reported mean minimum plaque pH values following a sucralose rinse were 6.56 ± 0.23 (water), 6.04 ± 0.44 (coffee), and 6.73 ± 0.34 (iced tea). The reported mean minimum plaque pH values following a Splenda Granular rinse were 6.15 ± 0.36 (water), 5.59 ± 0.35 (coffee), and 6.20 ± 0.31 (iced tea). The reported mean minimum plaque pH values following a Splenda Packet rinse were 5.84 ± 0.47 (water), 5.34 ± 0.29 (coffee), and 6.02 ± 0.42 (iced tea). The reported mean minimum pH values following a sucrose rinse were 5.29 ± 0.30 (water), 5.35 ± 0.37 (coffee), and 5.46 ± 0.33 (iced tea). The reported mean minimum pH values following a rinse with unsweetened beverage were 5.92

± 0.41 (coffee), and 6.79 ± 0.31 (iced tea). These results show that exposure to sucralose alone by an oral rinse did not result in a increase in plaque acidity as measured by the micro-touch pH method. As such, these data are evidence that sucralose will not lower plaque pH below 5.7. However, exposure by an oral rinse to Splenda Granular and Splenda Packet did, in some instances, lower plaque pH below 5.7. For instance, when the oral rinse medium was coffee, mean plaque pH was reduced below pH 5.7 for both Splenda Granular and Splenda Packet.

The human in situ plaque pH evidence for non-fermentability of sucralose is supported by pre-clinical study evidence submitted with the petition. The petitioner submitted reports from in vitro studies of sucralose metabolism by oral bacteria. These data indicate that sucralose does not support the growth of *Streptococcus mutans* nor of other strains of acidogenic plaque bacteria, nor do the bacteria produce acid from sucralose (Refs. 10 and 11). Studies with experimental rat models for caries development indicate that sucralose is noncariogenic in rats (Refs. 12 and 13). The preclinical data taken in total support a conclusion that sucralose is not a substrate for cariogenic bacteria and is not a contributor to caries development.

IV. Decision to Authorize a Health Claim Relating Sucralose to the Nonpromotion of Dental Caries

FDA previously concluded that there is significant scientific agreement among qualified experts to support the relationship between certain noncariogenic carbohydrate sweeteners (e.g., some sugar alcohols and D-tagatose) and the nonpromotion of dental caries. The principal evidence, which substantiates this relationship, is in situ human plaque pH data showing that the metabolism of sugar alcohols and D-tagatose by oral bacteria is significantly less than the metabolism of sucrose and other fermentable carbohydrates, and

therefore does not contribute to the loss of minerals from tooth enamel (§ 101.80(b)). The current petition evaluated the cariogenic potential of sucralose based on three studies which measured the acidogenic potential of sucralose with in situ plaque pH tests. As discussed previously, these plaque pH tests demonstrate that rinsing of the mouth with sucralose did not result in decreases in plaque pH below pH 5.7 and, therefore, does not promote demineralization of dental enamel. The results of these studies are consistent with the results of the studies that investigated the cariogenic potential of the sugar alcohols originally listed in § 101.80(c)(2)(ii), and are consistent with the evidence relied upon by the agency when adding erythritol (62 FR 63653) and D-tagatose (67 FR 71461) to this list. Therefore, based on the totality of publicly available evidence pertaining to the cariogenicity of sucralose and to the relationship between dental plaque pH and dental caries, we conclude that there is significant scientific agreement that sucralose does not promote dental caries. Accordingly, we are proposing to amend § 101.80 to authorize extending the dental caries health claim to include sucralose.

Section 101.80(c)(2)(iii) contains requirements for the nature of the food bearing the dental caries health claim. Section 101.80(c)(2)(iii)(A) states "The food shall meet the requirement in § 101.60(c)(1)(i) with respect to sugars content, except that the food may contain D-tagatose." That is, one criterion of the health claim is that the food be "sugar free," i.e., the food contains less than 0.5 grams of sugar per reference amount customarily consumed and per labeled serving. The agency notes that "Splenda Packet" contains in excess of 0.5 g of dextrose per serving and as such does not meet the "sugar free" requirement of § 101.80 and thus is ineligible to bear the dental caries health claim. The petition does not request amendments to the "sugar-free"

requirement in § 101.80(c)(2)(iii) in order to accommodate use of the dental caries health claim by Splenda Packet, nor has the agency considered amending this paragraph.

The predominant ingredient, by weight, of Splenda Granular is maltodextrin, a fermentable carbohydrate. The data provided by the petitioner indicates that rinsing with one serving of Splenda Granular (sweetness equivalent to 2 teaspoons of sucrose) resulted in plaque acidity between pH 5.6 and 6.2, depending on the beverage in which it was suspended, as measured by the micro-touch plaque pH measurement method. As mentioned in section III.B.1 of this document, plaque pH values measured by the indwelling electrode pH measurement method are consistently lower than are the pH values obtained by the micro-touch method.

A provision of the § 101.80 health claim regulation requires that when carbohydrates other than those eligible for the claim are present in a food bearing the dental caries health claim, bacterial fermentation of the food must not lower plaque pH below 5.7, either during consumption or up to 30 minutes after consumption, as measured by an indwelling electrode pH method (see § 101.80(c)(2)(iii)(C)). The petitioner's micro-touch pH measurement method data do not satisfy the pH evidence requirement of § 101.80(c)(2)(iii)(C) for Splenda Granular (i.e., plaque pH remains above pH 5.7 as measured by the indwelling electrode method). Therefore, FDA concludes that the use of the dental caries health claim on the label of Splenda Granular would not be appropriate.

V. Description of Modifications to § 101.80

A. Requirements

Specific requirements for use of the dental caries health claim are provided in § 101.80(c)(2). The noncariogenic carbohydrate sweeteners now eligible for the health claim are listed within the nature of the substance paragraph (§ 101.80(c)(2)(ii)). FDA is proposing to amend § 101.80(c)(2)(ii) to include sucralose as an additional eligible noncariogenic carbohydrate sweetener.

B. Model Health Claims

Section 101.80(e) provides examples of statements that meet the requirements to make a health claim about nonpromotion of dental caries. FDA emphasizes that these "model health claims" are only illustrative. These model claims illustrate both the elements of the health claim statement required under § 101.80(c)(2)(i) and some of the optional elements permitted under § 101.80(d). Because the agency is proposing to amend § 101.80 to add sucralose as an additional noncariogenic carbohydrate sweetener eligible for the health claim, and is not approving specific claim wording, manufacturers will be free to design their own claim so long as it is consistent with agency regulations.

Current § 101.80(e)(1) consists of examples of the full claim, and § 101.80(e)(2) consists of examples of the shortened claim for use on packages with less than 15 square inches of surface area available for labeling. The petition recommends amending § 101.80(e) to include examples of both the full claim and the shortened claim specific for sucralose. One of the requirements of the dental caries health claim is that the claim statement specify the substance as "sugar alcohol," "sugar alcohols," or by the name of the substance, e.g., sorbitol or tagatose (§ 101.80(c)(2)(i)(C)). The health claim

regulation provides that packages with less that 15 square inches of surface area available for labeling are exempt from the § 101.80(c)(2)(i)(C) requirement of specifying the substance in the claim statement (§ 101.80(c)(2)(i)(G)). As such, the shortened claim provided for by § 101.80(c)(2)(i)(G) need not specify the substance and therefore FDA is not proposing to amend § 101.80(e)(2) to add examples of the shortened claim specific for sucralose. FDA notes that the lack of a model shortened claim specifying "sucralose" in § 101.80(e)(2) does not preclude a manufacturer from using, on packages with less that 15 square inches of surface area available for labeling, a shortened claim that mentions sucralose specifically, as was proposed by the petition. We are proposing to amend § 101.80(e)(1) to add the model claim for sucralose proposed by the petition. The added example of the full claim will state: "Frequent eating of foods high in sugars and starches as between-meal snacks can promote tooth decay. Sucralose, the sweetening ingredient used to sweeten this food, unlike sugars, does not promote tooth decay." (proposed § 101.80(e)(1)(v)).

VII. Analysis of Impacts

A. Regulatory Impact Analysis

FDA has examined the economic implications of this proposed rule as required by Executive Order 12866. 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, and other advantages, 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,

adversely affecting a sector of the economy in a material way, adversely affecting competition, or adversely affecting jobs. A regulation is also considered a significant regulatory action if it raises novel legal or policy issues. FDA has determined that this proposed rule is not a significant regulatory action as defined by Executive Order 12866.

FDA has identified three options regarding this petition: (1) Deny the petition; (2) add sucralose to the dental caries health claim using the standards previously applied for making that claim; or (3) add sucralose to the dental caries health claim using different standards from those standards previously applied for making that claim, so that the claim could be applied to products such as Splenda Granular and Splenda Packet. This rule will affect three sets of stakeholders: Consumers, producers using sucralose, and producers not using sucralose. The agency will evaluate each of the three options with respect to their effect on each of these three sets of stakeholders.

Option one: FDA's denial of the petition would mean no change in the dental caries health claim. This option generates no new costs and benefits and is the point of comparison for all other options. Producers using sucralose would not change labels to provide more information on sucralose and dental caries. Producers not using sucralose would not be affected by changes in the information given to consumers about sucralose and dental caries or changes in the relative prices of sweeteners or products using sweeteners. Consumers would continue to experience dental caries unaffected by information on sucralose and dental caries.

If we deny the petition, then the state of treatment of dental caries would not be affected. Dental caries is the most common chronic childhood disease and 94 percent of adults have either untreated decay or fillings in the crowns

of their teeth, with an average of 22 affected surfaces, according to the National Oral Health Survey, part of the National Health and Nutrition Examination Survey (Ref. 14). The cost of dental caries includes the costs of dental treatment as well as the value of lost productivity and pain and suffering associated with dental caries. There are several risk factors for developing dental caries: Genetic factors, eating behaviors, and types and characteristics of foods eaten (Ref. 15). Specifically, consumption of dietary sugars and starches have been linked to development of dental caries.

Option two: The option chosen by the agency under certain conditions permits producers who use sucralose to place the dental caries health claim in their labeling. If these producers decide to do so they will have to pay to redesign and replace their labels. If they voluntarily make this choice, then their choice reveals that they value the ability to place the health claim on their products more highly than they value the cost they must bear to make the labeling change. Producers who use sucralose are better off under option two than under option one because under option two they have additional ways to market their products to consumers.

This option under certain conditions permits producers who use sucralose to give consumers more information about sucralose and dental carries. Some consumers may find this information valuable to them while choosing products. As stated previously, FDA has determined that this information has sufficient scientific support, and when provided in labeling under certain conditions is truthful and not misleading to consumers. Consumption of products containing sucralose, such as gum and soft drinks, can potentially reduce the risk of dental caries. This would lead to benefits in reduced expenditures and other health costs related to dental caries. It is possible that

the health claim could draw some consumers to choose foods that are more expensive. If they voluntarily make this choice, they reveal that they value the more expensive products more highly than the they value the additional expenditure. It is also possible that the prices of products containing sucralose may rise and cause some consumers to seek other, less expensive products with less protection against dental caries. If they voluntarily make this choice, they reveal that they value the less expensive products more highly than the increased probability of bearing the consequences of dental caries. Regardless of their choices, consumers are better off under option two than under option one because they can have more information related to their health and can make the choices that seem best to them.

If the agency under certain conditions permits producers who use sucralose to place the dental caries health claim in their labeling, products that do not contain sucralose may be affected. Some producers may be hurt if consumers choose to stop consuming their products and instead consume products containing sucralose. Some producers may be helped if changes in the prices of products using sucralose make their products look less expensive to consumers. Producers not using sucralose will be affected differently depending on the type of product that they produce, and it is impossible to tell beforehand how the approval of this health claim will affect different producers.

Some producers not currently using sucralose may decide to reformulate their products to contain sucralose. Substitution of sucralose for sugars in some foods, such as gum and soft drinks can potentially reduce the risk of dental caries. This reformulation would lead to benefits to consumers in reduced costs associated with dental caries. If some producers voluntarily choose to

reformulate their products, they reveal that they value the ability to place the health claim on their products more highly than they value the cost of reformulating their products. Whatever the effects of this option on producers not using sucralose, they will be the results of the product choices made by consumers who respond to the new information and make the choices that seem best to them.

Option three: This option would relax some of the restrictions imposed by the agency in option two so that the claim could be applied to products such as Splenda Granular and Splenda Packet. Option three would use different standards for approving this claim than previously applied to other products.

Option three would give producers using sucralose more opportunities to make the health claim than under option two. If, when given this option, producers decide to make the claims, they would have to pay to redesign and replace their labels, and they could decide to change more labels than under option two. However, if they voluntarily make this choice, they reveal that they value the ability to place the health claim on their product more highly than they value the cost of the label change regardless of how many labels they would change. Therefore, producers who use sucralose are better off under option three than under option two because they have additional opportunities for marketing their products to consumers using the health claim.

Option three makes producers using sucralose better off while making consumers worse off. As stated above, the intended use of Splenda Granular is in the preparation of foods likely to lower plaque pH below 5.7 when measured by the indwelling electrode method. It also is designed to be used

in the cooking and baking of many foods containing starch. Since foods containing starch are associated with increased plaque acidity and thus increased risk of dental caries, consumers would not benefit from seeing the health claim on products such as Splenda Granular. Also, as stated previously, Splenda Packet contains dextrose, and therefore is not "sugar free" and may promote tooth decay. Therefore, consumers would be made worse off under option three than under option two. Having the health claim on these additional types of products may mislead consumers and undo some of the benefit (reduced dental caries) of allowing the claim on products containing sucralose that meet the conditions set forth by the agency.

For producers not using sucralose, the effect of option three is generally the same as for option two, though allowing the claim to appear on more products would likely make for larger effects.

We can conclude that the option chosen by the agency (option two) is better for society than option one because the impact on consumers and on producers using sucralose is positive and the impact on producers not using sucralose is indeterminate and depends only on choices made by better informed consumers. We can also conclude that the option chosen by the agency (option two) is better for society than option three because under option three any advantage to producers using sucralose comes at the disadvantage of consumers.

The petition also raises the issue of the effect the increased use of sucralose could have on weight loss in the U.S. population. We have not addressed that issue here because the products involved and the amounts consumed are so small that a health claim relating sucralose to reduced dental

caries would not have an impact big enough to cause a noticeable change in weight.

B. Regulatory Flexibility Analysis

FDA has examined the economic implications of this proposed rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant impact on a substantial number of small entities, the Regulatory Flexibility Act requires the agency to analyze regulatory options that would minimize the economic impact of the rule on small entities.

As previously explained, this proposed rule will not generate any compliance costs for any small entities, because it does not require small entities to undertake any new activity. No small business will choose to use the dental caries health claim authorized by this rule unless it believes that doing so will increase private benefits by more than it increases private costs. Accordingly, we certify that this proposed rule will not have a significant impact on a substantial number of small entities. Under the Regulatory Flexibility Act, no further analysis is required.

C. Unfunded Mandates

Title II of the Unfunded Mandates Reform Act of 1995 (Public Law 104–4) requires cost-benefit and other analyses before any rulemaking if the rule would include a "Federal Mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year." FDA has determined that this proposed rule does not constitute a significant regulatory action under the Unfunded Mandates Reform Act.

VIII. Environmental Impact

FDA has determined under 21 CFR 25.32(p) 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.

IX. Paperwork Reduction Act

FDA concludes that this proposed rule contains no collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

X. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. We have determined that the rule does not contain policies that have substantial direct effects on the States or on the relationship between the National Government and the States, or on the distribution of power and responsibility among the various levels of government. Accordingly, FDA has concluded that the proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

XI. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments in response to FDA's proposed rule. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Identify comments with the docket number found in brackets in the heading of this

document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

XII. Proposed Effective Date

FDA proposes that any final regulation that may issue based on this proposal become effective 30 days after its date of publication in the **Federal Register.**

XIII. References

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

1. McNeil Nutritionals, "Petition to Amend 21 CFR 101.80 to Authorize a Noncariogenicity Dental Health Claim for Sucralose," CP–1, Docket No. 2004P–0294, April 2, 2004.

2. U.S. Department of Health and Human Services, "Oral Health," chapter 21, *Healthy People 2010*, volume II, part B, 2d ed., Washington, DC: U.S. Government Printing Office (*www.health.gov/healthypeople/Document/HTML/Volume2/21Oral.htm*, visited 03/17/2005), November 2000.

3. G.A. Miller, "Sucralose," *Alternative Sweeteners, 2d ed.* L.O. Nabors and R.C. Gelardi, eds. Marcel Dekker, Atlanta, pp. 173–175, 1991.

4. P. Lingström, T. Imfeld, and D. Birkhed, "Comparison of Three Different Methods for Measurement of Plaque-pH in Humans After Consumption of Soft Bread and Potato Chips," *Journal of Dental Research*, 72:865–870, 1993.

5. D.S. Harper, R. Gray, J.W. Lenke, et al., "Measurement of Human Plaque Acidity: Comparison of Interdental Touch and Indwelling Electrodes," *Caries Research*, 19:536–546, 1985.

6. M.E. Jensen and C.F. Schachtele, "Plaque pH Measurements by Different Methods on the Buccal and Approximal Surfaces of Human Teeth After Sucrose Rinse," *Journal of Dental Research*, 62:1058–1061, 1983.

7. L.M. Steinberg, F. Odusola, J. Yip, et al., "Effect of Aqueous Solutions of Sucralose on Plaque pH," *American Journal of Dentistry*, 8:209–211, 1995.

8. L.M. Steinberg, F. Odusola, J. Yip, et al., "Effect of Sucralose in Coffee on Plaque pH in Human Subjects," *Caries Research*, 30:138–142, 1996.

9. C. Meyerowitz, E.P. Syrrakov, and R.F. Raubertas, "Effect of Sucralose—Alone or Bulked With Maltodextrin and/or Dextrose—on Plaque pH in Humans," *Caries Research*, 30:439–444, 1996.

10. D.A. Young and W.H. Bowen, "The Influence of Sucralose on Bacterial Metabolism," *Journal of Dental Research*, 69:1480–1484, 1990.

11. D.B. Drucker and J. Verron, "Comparative Effects of the Substance Sweeteners Glucose, Sorbitol, Sucrose, Xylitol, and Trichlorosucrose on Lowering of pH by Two Oral *Streptococcus Mutans* Strains In Vitro," *Archives of Oral Biology*, 24:965–970, 1980.

12. W.H. Bowen, D.A. Young, and S.K. Pearson, "The Effects of Sucralose on Coronal and Root-Surface Caries," *Journal of Dental Research*, 69:1485–1487, 1990.

13. W.H. Bowen, S.K. Pearson, and J.L. Falany, "Influence of Sweetening Agents in Solution on Dental Caries in Desalivated Rats," *Archives of Oral Biology*, 35:839–844, 1990.

14. Department of Health and Human Services, Results of National Oral Health Survey Results Released (press release) (*http://www.hhs.gov/news/press/1996pres/960311.html*, visited on 03/17/2005), March 11, 1996.

15. U.S. Department of Health and Human Services, *Oral Health in America: A Report of the Surgeon General*—Executive Summary, Rockville, MD, U.S. Department of Health and Human Services, National Institute of Dental and Craniofacial Research,

National Institutes of Health, (*http://www2.nidcr.nih.gov/sgr/execsumm.htm*, visited on 03/17/2005), 2000.

List of Subjects in 21 CFR Part 101

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, 21 CFR part 101 is proposed to be amended as follows:

PART 101—FOOD LABELING

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

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371; 42 U.S.C. 243, 264, 271.

2. Section 101.80 is amended by adding (c)(2)(ii)(C) and (e)(1)(v) to read as follows:

§ 101.80 Health claims: dietary noncariogenic carbohydrate sweeteners and dental caries.

* * * * *

(c) * * *

(2) * * *

(ii) * * *

(C) Sucralose.

* * * * *

(e) * * *

(1) * * *

(v) Frequent eating of foods high in sugars and starches as between-meal

snacks can promote tooth decay. Sucralose, the sweetening ingredient used to sweeten this food, unlike sugars, does not promote tooth decay.

Dated: 5/4/05
May 4, 2005.

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 05–????? Filed ??–??–05; 8:45 am]

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