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: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing its decision to authorize the use of a health claim regarding the association between sucralose and the nonpromotion of dental caries. Based on its review of evidence described in the proposed rule and comments submitted on the proposed rule, the agency has concluded that sucralose does not promote dental caries. Therefore, the agency has decided to amend the regulation that authorizes a health claim regarding noncariogenic carbohydrate sweeteners to include sucralose.

DATES: This final rule is effective [*insert date of publication in the* **Federal Register**].

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

In the **Federal Register** of May 13, 2005 (70 FR 25496), the agency published a proposed rule to amend § 101.80 (21 CFR 101.80), the regulation which authorizes a health claim regarding the relationship between noncariogenic carbohydrate sweeteners and dental caries, to include sucralose, a non-nutritive sweetener food ingredient. Under 403(r)(3)(B)(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(r)(3)(B)(i)), FDA issued this proposed rule in response to a petition filed under section 403(r)(4) of the act (21 U.S.C. 343(r)(4)). Section 403(r)(3)(B)(i) of the act states that the Secretary of Health and Human Services (Secretary) (and, by delegation, FDA) shall issue a regulation authorizing a health claim only if the Secretary 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 21 CFR 101.14(c)). Section 403(r)(4) of the act sets out the procedures that FDA is to follow upon receiving a health claim petition.

On April 2, 2004, McNeil Nutritionals, of Brunswick, NJ (the petitioner) submitted a petition requesting that the agency amend § 101.80 to include the non-nutritive sweetener sucralose as one of the substances eligible to bear the dental caries health claim (Ref. 1). FDA filed the petition for comprehensive review in accordance with section 403(r)(4) of the act on July 9, 2004.

FDA considered the scientific evidence presented in the petition as part of its review of the scientific literature on sucralose and dental caries, as well

as information previously considered by the agency on the etiology of dental caries and the effects of slowly fermentable carbohydrates. The agency summarized this evidence in the proposed rule (70 FR 25496 at 25498 to 25499). Based on the available evidence, FDA concluded that dental caries is a disease for which the U.S. population is at risk; sucralose is a food because it contributes taste and other technical effects listed in 21 CFR 170.3(o) to food; the use of sucralose as a non-nutritive sweetener in food is safe and lawful; and there is significant scientific agreement among qualified experts that sucralose does not promote dental caries (70 FR 25496 at 25499). Consequently, FDA proposed amending § 101.80 (the sucralose proposed rule) to broaden the health claim to include sucralose as an additional noncariogenic carbohydrate sweetener eligible for the health claim.

II. Summary of Comments and the Agency's Response

The agency received four responses, each containing one or more comments, to the sucralose proposed rule. Two responses were from individual consumers, one from an industry trade organization, and the other from the petitioner. One consumer comment had no relevance to the proposed amendment, and the other consumer comment opposed a health claim for this non-nutritive sweetener but provided little specific information. The industry trade organization and the petitioner agreed with the proposed amendment without providing grounds for this support other than those grounds already provided by FDA in the preamble to the sucralose proposed rule. The petitioner also made several comments regarding FDA's evaluation of the evidence, which are discussed in detail in comments 1 to 4 of this section II.

(Comment 1) The petitioner commented that it was inappropriate for FDA to refer to sucralose-based sugar substitute products by brand names in the preamble; specifically in regards to statements about specific SPLENDA sugar substitute products not meeting the eligibility criteria of § 101.80(c)(2)(iii). The petitioner noted that the SPLENDA brand name did not appear in the petition and thus FDA's conclusions should have referred to the eligibility of sucralose-based sugar substitute formulations generically. The petitioner further noted that SPLENDA brand name product formulations can be changed and may in the future meet § 101.80(c)(2)(iii) eligibility criteria.

(Response) The petition cites dental plaque pH studies conducted with sucralose-based formulations representative of commercially marketed SPLENDA sugar substitute products. FDA discussed these products in the preamble to clarify that although the petition included plaque pH data representative of these products, FDA was concluding that the available evidence did not support the eligibility of these sucralose-based formulations for the health claim. FDA referred to these formulations by their specific product names (i.e., SPLENDA Granular, and SPLENDA Packet) for the sake of convenience. The amendment to § 101.80 provides for the use of the dental caries health claim in food labeling of sucralose-containing products in general and does not prohibit the use of the health claim in labeling of any SPLENDA brand name product that meets § 101.80(c)(2)(iii) eligibility criteria.

(Comment 2) The petitioner commented that FDA incorrectly concluded that the use of the dental caries health claim in the labeling of SPLENDA Granular would not be appropriate. The petitioner asserted that the petition contains insufficient information to warrant this conclusion. FDA had concluded that evidence contained in the petition does not demonstrate that

SPLENDA Granular would prevent plaque pH from falling below 5.7 when measured, as specified in § 101.80(c)(2)(iii)(C), by the indwelling electrode method (70 FR 24596 at 25500). The petition included data on the impact of SPLENDA Granular on plaque pH as measured by the micro-touch method, a measurement method different from the indwelling electrode method specified in § 101.80(c)(2)(iii)(C). The petitioner also asserted in this comment that the tests conducted involved the equivalent of two servings of SPLENDA Granular, rather than one, and that this was not taken into consideration by the FDA.

(Response) FDA agrees that a more appropriate conclusion would have been that the submitted evidence is insufficient to establish the eligibility of the sucralose-maltodextrin formulation for the claim, rather than concluding that the available evidence shows the use of the dental caries health claim in labeling of SPLENDA Granular would not be appropriate. However, this discussion does not bear on the amendment to § 101.80 in the final rule because the amendment addresses sucralose, not specific SPLENDA brand products.

(Comment 3) The petitioner objected to FDA specifically identifying SPLENDA Packet as not eligible for use of the dental caries claim because the product does not meet the definition for ''sugar free.'' The petitioner noted that SPLENDA Packet could in the future be reformulated using nonfermentable bulking agents in order to be ''sugar free,'' or to lower the level of dextrose in each packet in order to meet the ''sugar free'' criterion. Furthermore, the petitioner asserted that the plaque pH performance criterion is a more important test than is the ''sugar free'' standard in the health claim requirements, adding that if plaque pH is not lowered below 5.7 by the

indwelling pH method, then it should not matter how much sugar the product contains on a per serving basis.

(Response) The preamble of the proposed rule explicitly stated that this specific sucralose formulation, for which the petitioner submitted plaque pH data, was not being included in our consideration and stated the reason for our decision. FDA believes that we correctly decided to exclude the sucralose formulation in question, but we agree that our comment applies only to that formulation, which was tested in the submitted studies, and not to the SPLENDA Packet brand name. In any case, the petition did not request any amendment to the regulation with respect to the ''sugar free'' requirement. Furthermore, FDA does not rank the importance of the various eligibility criteria in assessing whether the food in question can make the claim, as each of the requirements listed in § 101.80(c), including the ''sugar free'' standard, must be met for the claim to be made.

(Comment 4) The petitioner commented that the evidence submitted in the petition demonstrates that sucralose is not fermented at all, and therefore FDA's conclusion that sucralose is ''minimally fermented'' and ''not fermented by oral bacteria to an extent sufficient to lower dental plaque pH* * *'' is inconsistent with the available evidence.

(Response) FDA considers it a difficult task to demonstrate conclusively that sucralose would not be fermented to any extent by any species of oral bacteria. FDA's decision to add sucralose to the dental caries health claim does not turn on a distinction between ''minimally fermented'' or ''not fermented.'' The amount of sucralose, an intense sweetener, used per serving is in milligram amounts. Even if sucralose were fermented by oral bacteria, considering the amount of sucralose involved, the complete and rapid

fermentation of the amount of sucralose contained in one serving would likely not contribute significantly to a change in plaque pH. Thus, whether sucralose is ''minimally fermented'' or ''not fermented'' does not affect our decision to authorize this amendment to the dental caries health claim.

Given the information discussed in the preamble to the proposed rule and the absence of contrary information in the comments, FDA is adopting as a final rule, without change, the proposed amendment of § 101.80 to include sucralose as a substance eligible for the dental caries health claim.

III. Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the proposed rule. 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.

IV. Analysis of Impacts

A. Regulatory Impact Analysis

FDA has examined the economic implications of this final 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 the following: 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. We have determined that this final rule is not a significant regulatory action as defined by Executive Order 12866.

FDA identified the following 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 final rule will affect the following three sets of stakeholders: Consumers, producers using sucralose, and producers not using sucralose. We 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. 2). 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. The following are several risk factors for developing dental caries: Genetic factors, eating behaviors, types and characteristics of foods eaten, and dental hygiene (Ref. 3). Specifically, consumption of dietary sugars and starches have been linked to development of dental caries.

Option two (final rule): The option chosen by the agency permits producers who use sucralose to place the dental caries health claim in their labeling under certain conditions. If these producers decide to do so they will have to pay to redesign and replace their labels. If they 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 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 make this choice, they reveal that they value the more expensive products more highly than 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 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 now 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 reduce the risk of dental caries. This reformulation would lead to benefits to consumers in reduced costs associated with dental caries. If some producers 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 result 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 previously, 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. Because 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 final rule 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 final rule 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

We have examined the economic implications of this final 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 final 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 final 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 that agencies prepare a written statement of anticipated costs and benefits before issuing any final rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $115,000,000 or more (adjusted annually for inflation) in any 1 year. The Unfunded Mandates Reform Act does not require FDA to prepare a statement of costs and benefits for this rule, because the rule is not expected to result in any 1 year expenditure that would exceed $115,000,000.

V. Paperwork Reduction Act

FDA concludes that the labeling provisions of this final rule are not subject to review by the Office of Management and Budget because they do not

constitute a ''collection of information'' under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). Rather, the food labeling health claim on the association between sucralose and the nonpromotion of dental caries is a ''public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public.'' (5 CFR 1320.3(c)(2)).

VI. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule will have a preemptive effect on State law. Section 4 (a) of the Executive Order requires agencies to ''construe * * * a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.'' Section 403A of the act (21 U.S.C. 343–1) is an express preemption provision. Section 403A(a) of the act (21 U.S.C. 343–1(a)) provides that:

(a)* * * no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce -- * * *

(5) any requirement respecting any claim of the type described in section 403(r)(1) made in the label or labeling of food that is not identical to the requirement of section 403(r). * * *

Currently, this provision operates to preempt States from imposing health claim labeling requirements concerning sucralose and reduced risk of dental caries because no such requirement had been imposed by FDA under section 403(r) of the act. This final rule amends existing food labeling regulations to

add sucralose as an eligible noncariogenic carbohydrate sweetener to the dietary noncariogenic carbohydrate sweeteners and dental caries health claim. Although this rule would have a preemptive effect, in that it would preclude States from issuing any health claim labeling requirements for sucralose and reduced risk of dental caries that are not identical to those required by this final rule, this preemptive effect is consistent with what Congress set forth in section 403A of the act. Section 403A(a)(5) of the act displaces both State legislative requirements and State common law duties. *Medtronic v. Lohr, 518 U.S. 470, 503 (1996)* (Breyer, J., concurring in part and concurring in judgment); *id. at 510* (O'Connor, J., joined by Rehnquist, C. J., Scalia, J., and Thomas, J., concurring in part and dissenting in part); *Cipollone v. Liggett Group, Inc., 505 U.S. 504, 521 (1992)* (plurality opinion); *id. at 548–49* (Scalia, J., joined by Thomas, J., concurring in judgment in part and dissenting in part).

FDA believes that the preemptive effect of the final rule would be consistent with Executive Order 13132. Section 4(e) of the Executive Order provides that ''when an agency proposes to act through adjudication or rulemaking to preempt State law, the agency shall provide all affected State and local officials notice and an opportunity for appropriate participation in the proceedings.'' FDA provided the States with an opportunity for appropriate participation in this rulemaking when it sought input from all stakeholders through publication of the proposed rule in the **Federal Register** on May 13, 2005 (70 FR 25496). FDA received no comments from any states on the proposed rulemaking.

In addition, on December 23, 2005, FDA's Division of Federal and State Relations provided notice by fax and email transmission to State health commissioners, State agriculture commissioners, food program directors, and

drug program directors as well as FDA field personnel of FDA's intended amendment to add sucralose as a sweetener to the noncariogenic carbohydrate sweeteners and dental caries health claim (21 CFR 101.80). The notice provided the States with further opportunity for input on the rule. It advised the States of the publication of the proposed rule and encouraged State and local governments to review the notice and to provide any comments to the docket (docket number 2004P–0294), opened in the May 13, 2005, **Federal Register** notice, by a date 30 days from the date of the notice (i.e., by January 23, 2006), or to contact certain named individuals. FDA received no comments in response to this notice. The notice has been filed in the above numbered docket.

In conclusion, the agency believes that it has complied with all of the applicable requirements under the Executive Order and has determined that the preemptive effects of this rule are consistent with Executive Order 13132.

VII. References

The following references have been placed on display in the Division of Dockets Management, (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. McNeil Nutritionals, ''Petition to Amend the Regulation for 21 CFR Sec. 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, National Institute of Dental and Craniofacial Research, ''Results of National Oral Health Survey Released'' (press release), Rockville MD, *http://www.hhs.gov/news/press/1996pres/960311.html*, March 11, 1996.

3. U.S. Department of Health and Human Services, National Institute of Dental and Craniofacial Research, ''Oral Health in America: A Report of the Surgeon General,'' executive summary (monograph on the Internet), Rockville MD, *http://www.nidcr.nih.gov/AboutNIDCR/SurgeonGeneral/ExecutiveSummary.htm*, May 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 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: March 21, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 06–????? Filed ??–??–06; 8:45 am]

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