[Federal Register: September 17, 2007 (Volume 72, Number 179)]
[Rules and Regulations]
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[DOCID:fr17se07-5]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 2006P-0487]

Food Labeling; Health Claims; Dietary Noncariogenic Carbohydrate Sweeteners and Dental Caries

AGENCY: Food and Drug Administration, HHS.

ACTION: Interim final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing this interim final rule to amend the regulation authorizing a health claim on noncariogenic carbohydrate sweeteners and dental caries, i.e., tooth decay, to include isomaltulose, a noncariogenic sugar. FDA is taking this action in response to a health claim petition submitted on behalf of Cargill, Inc. Based on the totality of publicly available scientific evidence, FDA now has determined that the nutritive sweetener isomaltulose, like other noncariogenic carbohydrate sweeteners listed in the dental caries health claim regulation, 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, FDA has concluded that isomaltulose does not promote dental caries, and it is amending the regulation authorizing a health claim relating certain noncariogenic sweeteners and the nonpromotion of dental caries to include isomaltulose as a substance eligible for the claim.

DATES: This interim final rule is effective September 17, 2007. Submit written or electronic comments by December 3, 2007.

ADDRESSES: You may submit comments, identified by Docket No. 2006P-0487, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following ways:

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.
Written Submissions
Submit written submissions in the following ways:
FAX: 301-827-6870.
Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]: Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described previously, in the ADDRESSES portion of this document under Electronic Submissions.
Instructions: All submissions received must include the agency name and Docket No. 2006P-0487 for this rulemaking. All comments received may be posted without change to http://www.fda.gov/ohrms/dockets/default.htm , including any personal information provided. For

additional information on submitting comments, 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 the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Jillonne Kevala, 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) (Pub. L. 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.

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In 1993, FDA issued a regulation to implement the health claim provisions of the 1990 amendments entitled ``Food Labeling: General

Requirements for Health Claims for Food'' (58 FR 2478, January 6, 1993), 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 (21 CFR 101.70). This regulation became effective on May 8, 1993.

The final rule that established Sec. 101.80 (21 CFR 101.80) (61 FR 43433, August 23, 1996) (the 1996 final rule), relating sugar alcohols to the nonpromotion of dental caries, completed the first rulemaking that FDA conducted in response to a health claim petition (Docket No. 1995P-0003). Section 101.80 (the dental caries health claim) 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) (the 2002 amendment). Section 101.80(a) describes the role of fermentable carbohydrates, (i.e., most 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 some carbohydrate sweeteners, such as sugar alcohols, are relatively noncariogenic because they are fermented by oral microorganisms more slowly than are fermentable carbohydrates and consequently, the rate of acid production is lower than that from fermentable carbohydrates. Noncariogenic carbohydrate sweeteners, when used in place of fermentable sugars, are 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'' (Sec. 101.80(c)(2)(iii)(A)). Section 101.80(c)(2)(ii) also lists 11 noncariogenic carbohydrate sweeteners (xylitol, sorbitol, mannitol, maltitol, isomalt, lactitol, hydrogenated starch hydrolysates, hydrogenated glucose syrups, erythritol, D-tagatose, and sucralose) that are eligible for the claim. 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,' * * *.''

FDA noted in the 1996 final rule that it would consider adding other noncariogenic carbohydrate sweeteners in the list of sweeteners eligible for the health claim based on a petition to amend the regulation that would show how the substance conforms to the requirements of Sec. Sec. 101.14(b) (21 CFR 101.14(b)) and 101.80 and that provides evidence that the additional noncariogenic carbohydrate sweetener will not lower dental plaque pH below 5.7 (61 FR 43433 at 43442). Section 101.80 was first amended in 1997 to list the sugar alcohol erythritol as an additional noncariogenic carbohydrate sweetener eligible for the claim (62 FR 63653, December 2, 1997). The

petition to list erythritol in Sec. 101.80 (Docket No. 1997P-0206) presented scientific data from a rodent cariogenicity study and from a human in vivo indwelling plaque pH test of erythritol. The agency was satisfied that this evidence was consistent with the results of the studies that investigated the cariogenic potential of the substances previously listed in Sec. 101.80(c)(2)(ii)(A) and that erythritol met the requirements of Sec. 101.14(b). Therefore, erythritol was added to the list of sugar alcohols eligible as a noncariogenic carbohydrate sweetener. Section 101.80 was again amended in the 2002 amendment 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 D-tagatose is a sugar, not a sugar alcohol, the 2002 amendment also changed the title of the regulation from ``sugar alcohols'' to ``noncariogenic carbohydrate sweeteners.'' The most recent amendment of Sec. 101.80 was to list sucralose, a non-nutritive sweetener, as an eligible noncariogenic sweetener (71 FR 15559, March 29, 2006).

II. Petition and Grounds

A. The Petition

On August 31, 2006, FDA received a health claim petition (Ref. 1) from Hyman, Phelps & McNamara, P.C., submitted on behalf of Cargill, Inc. (petitioner), under section 403(r)(4) of the act (21 U.S.C. 343(r)(4)). The petition requested that FDA amend Sec. 101.80 to authorize a noncariogenic dental health claim for isomaltulose. FDA notified the petitioner on December 8, 2006, that the initial review of the petition had been completed 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 21 CFR 101.70(j)(3)(iii)). On March 5, 2007, FDA and the petitioner mutually agreed to extend the deadline for the agency's decision on the petition until September 5, 2007. The petitioner requested that FDA consider exercise of its authority under section 403(r)(7) of the act to make the amendment to Sec. 101.80 effective upon publication.

B. Nature of the Substance

The petitioner identified the substance, which is the subject of the petitioned health claim, to be isomaltulose. Isomaltulose (CAS Reg. No. 13718-94-0) (6-O-[alpha]-D-glucopyranosyl-D-fructose) is a disaccharide sugar. The petitioner identified the intended food use of isomaltulose as a nutritive sweetener. A 2005 generally recognized as

safe (GRAS) notification to FDA (Ref. 2) identified use of isomaltulose as a nutritive sweetener in a variety of foods to have been determined to be GRAS for food use. For the purpose of a health claim, the term ``substance'' has been defined as ``* * * a specific food or component of food * * *'' (Sec. 101.14(a)(2)). An ingredient added to a food as a sweetener is a component of food. As such, FDA concludes that isomaltulose is a ``substance'' as defined in Sec. 101.14(a)(2) for the purpose of food labeling, 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

Dental caries continues to affect a large segment of the U.S. population, notwithstanding its decline in recent years (Ref. 3). The U.S. Department of Health and Human Services' Healthy People 2010 Objectives recognizes dental caries as the single most common chronic disease during childhood, and states that 30 percent of adults have untreated dental decay (Ref. 4). Based

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on these facts, FDA concludes that, as required in Sec. 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 Sec. 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 (Sec. 101.14(b)(3)(i)). The petitioner stated that the intended use of isomaltulose in food is as a nutritive sweetener. Isomaltulose contributes taste (sweetness), nutritive value (source of calories), and a technical effect (nutritive sweetener) listed in Sec. 170.3(o)(21) to the food and retains these attributes when consumed at levels that are necessary to justify a claim. Thus, the agency concludes that the preliminary requirement of Sec. 101.14(b)(3)(i) is satisfied.

3. The Substance Is Safe and Lawful

Section 101.14(b)(3)(ii) requires that for a substance to be eligible for a health claim, it must be a food or a food ingredient or a component of a food ingredient whose use at the levels necessary to justify a claim has been demonstrated by the proponent of a claim, to FDA's satisfaction, to be safe and lawful under the applicable food safety provisions of the act. FDA evaluates whether the substance is ``safe and lawful'' under the applicable food safety provisions of the act. For conventional foods, this evaluation involves considering

whether the ingredient that is the source of the substance is GRAS, approved as a food additive, or authorized by a prior sanction issued by FDA (see Sec. 101.70(f)).

The petitioner asserts that there is general recognition of safety, based upon scientific procedures, for the use of isomaltulose as a nutritive sweetener in food. FDA previously received a notice on November 1, 2005, informing FDA that S[Uuml]DZUCKER AG, Mannheim/ Ochsenfurt, had determined through scientific procedures that use of isomaltulose as a nutritive sweetener in a variety of foods is GRAS (the 2005 GRAS notification). FDA issued a letter on March 20, 2006 (Ref. 2), in response to this notice stating that the agency had no questions at the time regarding S[Uuml]DZUCKER's conclusion that isomaltulose is GRAS under the intended conditions of use. The intended conditions of use for isomaltulose stated in the 2005 GRAS notification include use as a nutritive sweetener in the following food categories: Baked goods and baking mixes (Sec. 170.3(n)(1)); beverages (Sec. 170.3(n)(2) and (n)(3)); cereal-based products (Sec. 170.3(n)(4)); chewing gum (Sec. 170.3(n)(6)); confectionery and frostings (Sec. 170.3(n)(9)); frozen dairy desserts and mixes (Sec. 170.3(n)(20)); fruit and water ices (Sec. 170.3(n)(21)); gelatins, desserts, and puddings, etc. (Sec. 170.3(n)(22)); jams, jellies, and spreads (Sec. 170.3(n)(28)); milk products (Sec. 170.3(n)(31)); nuts and peanut spreads (Sec. 170.3(n)(32)); processed fruit and fruit juices or vegetable juices (Sec. 170.3(n)(35)) and (n)(36)); snack foods (Sec. 170.3(n)(37)); sugar substitutes (Sec. 170.3(n)(42)); and sweet sauces, toppings, and syrups (Sec. 170.3(n)(43)). Other categories include nutritive formulas at 5 to 20 percent, energy-reduced foods at 5 to 40 percent, and meal replacements/slimming foods at 5 to 20 percent. Furthermore, FDA is not aware of any scientific evidence that isomaltulose, under the intended conditions of use, would be harmful. The agency has not made its own determination regarding the GRAS status of isomaltulose, however, and notes that authorization of a health claim for a substance should not be interpreted as affirmation that the use of the substance is GRAS. FDA concludes that the use of isomaltulose in food as a nutritive sweetener at levels necessary to justify the claim and in accordance with the 2005 GRAS notification demonstrates to FDA's satisfaction that such use is safe and lawful under applicable food safety provisions of the act. Therefore, FDA concludes that the preliminary requirements in Sec. 101.14(b)(3)(ii) are satisfied.

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

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

As recognized in Sec. 101.80, certain carbohydrate sweeteners are relatively noncariogenic compared to fermentable carbohydrates such as

starch and most sugars. The relationship between noncariogenic sweeteners and dental caries involves slower fermentation by oral bacteria than that of the dietary sugars they replace. Noncariogenic sweeteners do not promote the development of dental caries because the amount and rate of organic acids resulting from their metabolism by oral bacteria is sufficiently less than that of the fermentable carbohydrates, and they do not cause the loss of minerals from tooth enamel. (Sec. 101.80(b)) The agency noted in the preamble to the 1996 final rule that it would take action to add additional sugar alcohols to Sec. 101.80 when presented, in part, with evidence that the additional sugar alcohols would not lower plaque pH (i.e., raise plaque acidity) below 5.7 (61 FR 43433 at 43442). FDA has subsequently amended Sec. 101.80 on three occasions to list additional noncariogenic sweeteners in the regulation. The three added noncariogenic sweeteners include a sugar alcohol (erythritol), a sugar (D-tagatose), and a non-nutritive sweetener (sucralose). Although the noncariogenic sweeteners that were initially the subject of the health claim were all sugar alcohols, FDA has amended Sec. 101.80 to list additional noncariogenic sweeteners that are not sugar alcohols. When doing so, FDA also changed the title of the health claim from ``Dietary Sugar Alcohols and Dental Caries'' to ``Dietary Noncariogenic Carbohydrate Sweeteners and Dental Caries.''

Isomaltulose, the subject of the current petition, is a sugar. As is the case with the noncariogenic sweeteners now listed in the dental caries health claim, the potential dental health benefit from isomaltulose derives from its lower fermentability relative to most sugars used as food ingredients. Consequently, the criteria that FDA used to evaluate the other noncariogenic sweeteners in the existing dental caries health claim can be applied to assess whether isomaltulose also qualifies for the health claim.

B. Review of Scientific Evidence

1. Evidence Considered in Reaching the Decision

The recognized 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., dental plaque), and at the same time to form acids that can demineralize tooth enamel (Ref. 5). FDA initially proposed to authorize a health claim relating noncariogenic carbohydrate sweeteners and nonpromotion of dental caries (60 FR 37507, July 20, 1995), based on 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). FDA concluded that

human studies showing sugar alcohols to be associated with reduced rate of acid production in dental plaque relative to sucrose and, in some studies, a reduced incidence of dental caries, were evidence for the association of sugar alcohols and a reduced risk of developing dental caries (60 FR 37507 at 37523). In the 1996 final rule, 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. However, in order for a food that contains both noncariogenic sweeteners and fermentable carbohydrates to qualify for this health claim, Sec. 101.80(c)(2)(iii)(C) specifies that an indwelling pH electrode method of measuring dental plaque pH is the procedure that the agency will use to verify that a food bearing the health claim does not result in a lowering of dental plaque pH below 5.7. The current petition included a report (Ref. 1, Appendix B) from an assay of the cariogenic potential of isomaltulose which used the indwelling pH electrode method of measuring dental plaque pH specified in Sec. 101.80(c)(2)(iii)(C). This is the same type of evidence FDA considered previously in its decisions to amend Sec. 101.80 to list D-tagatose (67 FR 71461) and sucralose (71 FR 15559).

2. Review of Isomaltulose Noncariogenic Assay Data

The petition included a report (Ref. 1, Appendix B) of an in vivo assay of the cariogenic potential of isomaltulose. This assay was conducted following the protocol described in ``Identification of Low Caries Risk Dietary Components,'' by T. Imfield, vol. 11, Monographs in Oral Science, 1983, which is incorporated by reference in the dental caries health claim (Sec. 101.80(c)(2)(iii)(C)). This protocol provides for the continuous telemetric recording of plaque pH in vivo. The test was conducted for Cerestar R & D Center, Vilvoorde, Belgium, by the University of Zurich, Dental Institute, Clinic of Preventive Dentistry, Periodontology and Cariology, Bioelectric Unit.

The plaque pH telemetry assays were performed with six test subjects in good general health. All test subjects had previously participated in similar studies and their response to positive control procedures was known. Each subject had a miniaturized glass pH-electrode implanted in a dental prosthesis. Once the plaque pH telemetric prosthesis was inserted, it remained in place throughout the test period. Test subjects refrained from all oral hygiene practices, except for water rinses, to allow a 3 to 7 day undisturbed growth of interdental plaque to accumulate over the tips of the pH electrodes.

Baseline plaque pH was measured over a 15 minute period following a 3 minute period of chewing paraffin. Test subjects then rinsed for 2 minutes with 15 milliliters (mL) of a 10 percent aqueous solution of isomaltulose; or alternatively sucking a 1.5 gram (g) tablet of pressed

isomaltulose. Plaque pH response to isomaltulose was recorded for 30 minutes following isomaltulose exposure. The paraffin chew/rinse sequence was then repeated using a 10 percent sucrose rinse instead of isomaltulose. The sucrose rinse serves as a positive control to demonstrate the accurate functioning of the pH telemetric equipment and of plaque metabolism.

The study report commented that baseline plaque pH values measured following paraffin chewing coincide with those found in earlier tests with the same test subjects. The study report also commented that the observed decrease of plaque pH subsequent to the sucrose rinse (lowest pH value range was 4.40 to 4.90) demonstrates the accurate functioning of the pH telemetric equipment and of plaque metabolism on the telemetric prosthesis. The lowest interdental plaque pH recorded among the six test subjects during the 30 minutes following the isomaltulose rinse ranged from 6.00 to 6.35 (6.19 0.12, mean standard deviation, n=6). The lowest interdental plaque pH recorded among the six test subjects during the 30 minutes following the isomaltulose tablet ranged from 5.80 to 6.65 (6.38 0.39, mean standard deviation, n=4). The study report concluded that no critical decrease (i.e., below pH 5.7) in the interdental plaque pH due to bacterial fermentation of isomaltulose occurred following either the rinsing with 15 mL of a 10 percent solution of isomaltulose nor the sucking of a 1.5 g tablet of pressed isomaltulose. Although this report of an in vivo dental plaque pH test of isomaltulose constitutes a limited body of scientific evidence on the cariogenic potential of isomaltulose, FDA is satisfied that this report, in conjunction with the information previously considered by the agency on the etiology of dental caries and the effects of slowly fermentable carbohydrates, are sufficient to enable the agency to evaluate whether isomaltulose should be added to the list of substances eligible for the dental caries health claim.

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

FDA previously concluded that there was significant scientific agreement among qualified experts to support the relationship between certain noncariogenic carbohydrate sweeteners (e.g., some sugar alcohols, D-tagatose, and sucralose) and the nonpromotion of dental caries. The principal evidence that substantiates this relationship is in vivo data on the effects of noncariogenic carbohydrate sweeteners on human dental plaque pH (Sec. 101.80(b)). The current petition based its assertion that isomaltulose is noncariogenic on evidence from an indwelling telemetric plaque pH assay of the cariogenic potential of isomaltulose. As discussed in section III of this document, the plaque pH assay demonstrated that isomaltulose did not result in decreases in plaque pH below the critical level of pH 5.7, when introduced as either an aqueous solution or as a tablet, and therefore, would be considered to not promote demineralization of dental enamel. The results of the

isomaltulose plaque pH assay are consistent with the evidence relied upon by the agency when adding other noncariogenic sweeteners to the list of sweeteners eligible for this health claim. Therefore, based on the totality of publicly available evidence pertaining to the cariogenic potential of isomaltulose and to the relationship between dental plaque pH and dental caries, FDA concludes that there is significant scientific agreement that isomaltulose does not promote dental caries. Accordingly, FDA is amending Sec. 101.80 to authorize extending the dental caries health claim to include isomaltulose.

V. Description of Modifications to Sec. 101.80

A. Requirements

Specific requirements for use of the dental caries health claim are provided in Sec. 101.80(c)(2). Section 101.80(c)(2)(ii) lists noncariogenic carbohydrate sweeteners eligible for the health claim. Eligible sugar alcohols, sugars, and non-nutritive sweeteners are listed in Sec. 101.80(c)(2)(ii)(A), (B), and (C), respectively. FDA is amending Sec. 101.80(c)(2)(ii)(B) to include isomaltulose as an additional eligible noncariogenic sugar. Section

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101.80(c)(2)(iii) specifies eligibility criteria for a food to bear the health claim on its label. The first criterion in this paragraph is that the food be ``sugar free,'' as defined in Sec. 101.60(c)(1)(i), except that the food may contain D-tagatose (Sec. 101.80(c)(2)(iii)(A)). FDA is amending Sec. 101.80(c)(2)(iii)(A) to include isomaltulose, in addition to D-tagatose, in the exception to the ``sugar free'' criterion of eligible foods.

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 illustrative only. These model claims illustrate both the elements of the health claim statement required under Sec. 101.80(c)(2)(i) and some of the optional elements permitted under Sec. 101.80(d). FDA is amending Sec. 101.80 to add isomaltulose as an additional noncariogenic carbohydrate sweetener eligible for the health claim, and is not approving specific wording of claim statements. Manufacturers continue to be free to design their own claim so long as it is consistent with agency regulations.

Under Sec. 101.80(c)(2)(i)(H), there is a requirement that when the substance that is the subject of the claim is a noncariogenic sugar, the claim shall identify the substance as a sugar that, unlike other sugars, does not promote the development of dental caries. This

requirement was added to Sec. 101.80, along with the addition of the sugar D-tagatose as a sweetener eligible for the claim, to address the potential incongruity arising from a sugar-containing food bearing a dental caries health claim stating that foods high in sugars promote tooth decay. The model health claim examples in Sec. 101.80(e)(1)(iii) and (iv) and Sec. 101.80(e)(2)(iii) and (iv) are examples of health claim statements for use with D-tagatose-containing foods. FDA is revising these model health claims to change from the specific sugar ``tagatose'' to ``name of a sugar from paragraph (c)(2)(ii)(B) of this section'' to be inclusive of either tagatose or isomaltulose, or other noncariogenic sugars that may be added to the rule in the future.

Current Sec. 101.80(e)(1) consists of examples of the full claim, and Sec. 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 ``shortened claim'' version provided for in Sec. 101.80(c)(2)(i)(G) may omit: (1) Stating the relationship of frequent between-meal consumption of foods high in sugars and starches and the promotion of dental caries (Sec. 101.80(c)(2)(i)(A)), and (2) identification of the substance by name or as a sugar alcohol (Sec. 101.80(c)(2)(i)(C)). The ``shortened claim'' version, however, does not omit the requirement that when a noncariogenic sugar is the subject of the claim, the substance be identified in the claim statement as a sugar. As such, the model ``shortened claims'' provided by FDA in Sec. 101.80(e)(2) identify by name either tagatose or isomaltulose.

VI. Analysis of Impacts

FDA has examined the impacts of the interim final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). 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). The agency believes that this interim final rule is not a significant regulatory action as defined by the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this interim final rule concerns voluntary claims, the agency certifies that the interim final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ``any rule that includes any 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 one year.'' The current threshold after adjustment for inflation is $122 million, using the most current (2005) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this interim final rule to result in any 1-year expenditure that would meet or exceed this amount.

FDA identified the following three options regarding this petition: (1) Deny the petition, (2) authorize the petition (add only isomaltulose to Sec. 101.80), or (3) add isomaltulose to Sec. 101.80 and also expand the scope of the claim to include all noncariogenic carbohydrate sweeteners. FDA concludes that authorizing the petition by adding only isomaltulose to the dental caries health claim is the best option of those identified.

Option One: Deny the Petition

The agency can only define costs and benefits relative to a baseline, and FDA usually selects the option of taking no action as the baseline because it helps readers identify the costs and benefits of actions that change the status quo. In this case, denying the petition would correspond to taking no action because it would imply no change in the dental caries health claim and thus the continuation of the status quo. By definition, the baseline itself has no costs or benefits. This does not mean that FDA ignores the costs and benefits of the baseline. Instead, it means that the agency expresses the costs and benefits of the baseline in how it calculates the costs and benefits of the other regulatory options.

Option Two: Authorize the Petition (Add Only Isomaltulose to Sec. 101.80)

This option would allow producers who use isomaltulose to use the dental caries health claim on their product labels under certain conditions. Producers would only choose to change product labels or reformulate products if they believe that doing so will increase profits more than the costs of making those changes. Providing this information may increase profits for some producers because some consumers may find this information valuable when choosing products. Some consumers may find this information valuable because it may allow them to reduce their risk of dental carries. 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. Therefore, using the claims will not generate offsetting costs for consumers. The agency does not know how many producers will find it worthwhile to use this claim. However, if this interim final rule is finalized without change, it is sure that to whatever extent producers use the claim, both producers and consumers will be made better off under option two than under option one. The agency can conclude that adding isomaltulose to the dental caries health claim will generate either a net increase in social benefits or, if no producers find it worthwhile to use the claims, no impact on social welfare.

Option Three: Add Isomaltulose to Sec. 101.80 and Also Expand the

Scope of the Claim to Include All Noncariogenic Carbohydrate Sweeteners

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This option would allow producers who use isomaltulose and all other noncariogenic carbohydrate sweeteners to use the dental caries health claim on their product labels under certain conditions rather than just listing specific individual sweeteners. Similar to option two, producers would only choose to change product labels or reformulate products if they believe that the benefits that they will derive from doing so are at least as great as the costs of making those changes. In addition, this option would reduce the future burden on manufacturers of petitioning FDA to use the dental caries health claim for additional noncariogenic carbohydrate sweeteners, and it would also reduce FDA's burden of evaluating each petition for each individual noncariogenic carbohydrate sweetener.

However, FDA does not know the identity of all the sweeteners that may fall under the category of ``all noncariogenic carbohydrate sweeteners.'' Thus, FDA would have to extrapolate the data applicable to the known noncariogenic carbohydrate sweeteners to unknown noncariogenic carbohydrate sweeteners in that category, even though the science may not support such an extrapolation. By expanding the use of the claim to all noncariogenic carbohydrate sweeteners without reviewing the scientific data on each individual sweetener, FDA would not be able to verify that the claim was being used under circumstances where it is truthful and not misleading to consumers. If producers used the expanded claim on a product that was, in fact, not noncariogenic, then the expanded claim could actually result in an increase in the number of dental caries.

Based on these considerations, FDA cannot conclude that the potential cost savings of option three would necessarily outweigh the increased risk of producers making a false or misleading claim under the expanded claim. Therefore, FDA cannot conclude that option three would be better for social welfare than option two.

In addition, the agency notes that it does not believe this option is legally feasible. FDA believes that expanding the dental caries health claim to all carbohydrate sweeteners without reviewing the scientific data supporting such a claim of noncariogenicity for each individual carbohydrate sweetener would be a failure to carry out FDA's statutory responsibility under section 403(r)(3)(B) of the act to issue health claim regulations only when FDA determines that there is significant scientific agreement that the claim is supported by the totality of publicly available scientific evidence.

VII. Environmental Impact

The agency 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.

VIII. Paperwork Reduction Act

FDA concludes that the labeling provisions of this interim 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 consumption of isomaltulose 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'' (see 5 CFR 1320.3(c)(2)).

IX. Federalism

FDA has analyzed this interim final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule has 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)(5) of the act provides that:

* * * 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) * * *

This interim final rule amends existing food labeling regulations to add isomaltulose to the authorized health claim for noncariogenic carbohydrate sweeteners and dental caries. Although this rule has a preemptive effect in that it precludes States from issuing any health claim labeling requirements for isomaltulose and the nonpromotion of dental caries that are not identical to those required by this interim 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 this interim final rule is 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 on August 1, 2007, when FDA's Division of Federal and State Relations provided notice via fax and e-mail transmission to State health commissioners, State agriculture commissioners, food program directors, and drug program directors as well as FDA field personnel of FDA's intent to amend the health claim regulation authorizing health claims for noncariogenic carbohydrate sweeteners and dental caries (Sec. 101.80). It advised the States of FDA's possible action and encouraged the States and local governments to review the notice and to provide any comments to the docket (Docket No. 2006P-0487), until September 1, 2007. FDA received no comments from any States in response to the fax and e-mail transmission. FDA is also providing an opportunity for State and local officials to comment on this interim final rule.

In conclusion, the agency has determined that the preemptive effects of this interim final rule are consistent with Executive Order 13132.

X. Issuance of an Interim Final Rule and Immediate Effective Date

FDA is issuing this rule as an interim final rule, effective immediately, with an opportunity for public comment. Section 403(r)(7) of the act authorizes us to make proposed regulations issued under section 403(r) of the act effective upon publication pending consideration of public comment and publication of a final regulation, if the agency

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determines that such action is necessary. This authority enables the agency to act promptly on petitions that provide for information that is necessary to: (1) Enable consumers to develop and maintain healthy dietary practices, (2) enable consumers to be informed promptly and effectively of important new knowledge regarding nutritional and health benefits of food, or (3) ensure that scientifically sound nutritional and health information is provided to consumers as soon as possible. Proposed regulations made effective upon publication under this authority are deemed to be final agency action for purposes of judicial review. The legislative history indicates that such regulations should be issued as interim final rules (H. Conf. Rept. No. 105-399, at 98 (1997)).

The petitioner requested the agency to consider making any proposed regulation on the petitioned health claim effective upon publication of

an interim final rule. FDA acknowledges that all three of the criteria in section 403(r)(7)(A) of the act have been met in the petition submitted by Hyman, Phelps & McNamara, P.C. on behalf of Cargill, Inc. The health claim will enable consumers to develop and maintain healthy dietary practices, such as limiting snacks that contain fermentable sugars. The health claim also will provide consumers with important knowledge regarding the reduced cariogenic potential of isomaltulose relative to that of other sugars, and will provide consumers with scientifically sound information on the dental health benefits of foods containing isomaltulose. Therefore, FDA is using the authority given to us in section 403(r)(7)(A) of the act to issue an interim final rule authorizing a health claim for isomaltulose and the nonpromotion of dental caries, effective immediately.

FDA invites public comment on this interim final rule. The agency will consider modifications to this interim final rule based on comments made during the comment period. Interested persons may submit to the Division of Dockets Management, in any of the ways noted in the ADDRESSES section at the beginning of this document, comments regarding this interim final rule by December 3, 2007. 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

This regulation is effective upon publication in the Federal Register. The agency will address comments and confirm or amend the interim final rule in a final rule.

XI. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

XII. 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. Cargill, Inc., ``Petition to Amend 21 CFR 101.80 to Authorize a Noncariogenicity Dental Health Claim for Isomaltulose,'' Docket No. 2006P-0487, August 31, 2006.

2. Agency Response Letter to GRAS Notice No. GRN 000184, Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Food Additive Safety, March 20, 2006. Available at: http://www.cfsan.fda.gov/~rdb/opa-g184.html.

3. U.S. Department of Health and Human Services, Oral Health in America: A Report of the Surgeon General--Executive Summary, Rockville, MD, National Institute of Dental and Craniofacial Research, National Institutes of Health, May 2000. Available at: http://www2.nidcr.nih.gov/sgr/execsumm.htm.

4. U.S. Department of Health and Human Services, ``Oral Health,'' chapter 21, Healthy People 2010, vol. II, part B, 2d ed., Washington, DC., U.S. Government Printing Office, November 2000. Available at: http://www.healthypeople.gov/document/html/volume2/21oral.htm .

5. Medline Plus Medical Encyclopedia, ``Dental Cavities.'' Available at U.S. National Library of Medicine and the National Institutes of Health MedlinePlus: http://www.nlm.nih.gov/medlineplus/ency/article/001055.htm .

List of Subjects in 21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

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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

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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.

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2. Section 101.80 is amended by revising paragraphs (c)(2)(ii)(B), (c)(2)(iii)(A), (e)(1)(iii), (e)(1)(iv), (e)(2)(iii), and (e)(2)(iv) to read as follows:

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

* * * * *

(c) * * *

(2) * * *

(ii) * * *

(B) The sugars D-tagatose and isomaltulose.

* * * * *

(iii) * * *

(A) The food shall meet the requirement in Sec. 101.60(c)(1)(i) with respect to sugars content, except that the food may contain D-tagatose or isomaltulose.

* * * * *

(e) * * *

(1) * * *

(iii) Frequent eating of foods high in sugars and starches as between-meal snacks can promote tooth decay. [Name of sugar from paragraph (c)(2)(ii)(B) of this section], the sugar used to sweeten this food, unlike other sugars, may reduce the risk of dental caries.

(iv) Frequent between-meal consumption of foods high in sugars and starches promotes tooth decay. [Name of sugar from paragraph (c)(2)(ii)(B) of this section], the sugar in [name of food], unlike other sugars, does not promote tooth decay.

* * * * *

(2) * * *

(iii) [Name of sugar from paragraph (c)(2)(ii)(B) of this section] sugar does not promote tooth decay.

(iv) [Name of sugar from paragraph (c)(2)(ii)(B) of this section] sugar may reduce the risk of tooth decay.

Dated: September 6, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7-18196 Filed 9-14-07; 8:45 am]

BILLING CODE 4160-01-S