71.1. The jet routes listed in this document will be published subsequently in the Order.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E, AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9K, Airspace Designations and Reporting Points, dated August 30, 2002, and effective September 16, 2002, is amended as follows:

Paragraph 2004 Jet Routes

* * * * *

J–211 [Revised]

From Youngstown, OH; Johnstown, PA; INT Johnstown 130° and Westminster, MD, 292° radials; to Westminster.

* * * * *

Issued in Washington, DC, on November 22, 2002.

Reginald C. Matthews,

Manager, Airspace and Rules Division.

[FR Doc. 02–30326 Filed 11–29–02; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 5 and 16

[Docket No. 02N–0251]

Presiding Officers at Regulatory Hearings; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA) is confirming the effective date of January 2, 2003, for the direct final rule that appeared in the **Federal Register** of August 15, 2002 (67 FR 53305). The direct final rule amends the administrative regulations governing who may act as a presiding officer at a regulatory hearing. This document confirms the effective date of the final rule.

DATES: Effective date confirmed: January 2, 2003.

FOR FURTHER INFORMATION CONTACT: Peter C. Beckerman, Office of the Chief Counsel (GCF–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7144.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 15, 2002 (67 FR 53305), FDA solicited comments concerning the direct final rule for a 75-day period ending October 29, 2002. FDA stated that the effective date of the direct final rule would be 30 days after the publication of this confirmation document in the **Federal Register**, unless any significant adverse comment was submitted to FDA during the comment period. FDA did not receive any significant adverse comments.

Therefore, under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321 et al.), and under the authority delegated to the Commissioner of Food and Drugs, the amendments issued thereby will go into effect on January 2, 2003.

Dated: November 26, 2002.

Margaret M. Dotzel,

Assistant Commissioner for Policy.

[FR Doc. 02–30483 Filed 11–29–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 02P–0177]

Food Labeling: Health Claims; D-tagatose and Dental Caries

AGENCY: Food and Drug Administration, HHS.

ACTION: Interim final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulation authorizing a health claim on sugar alcohols and dental caries, i.e., tooth decay, to include the sugar D-tagatose, a novel food ingredient. Similar to the sugar alcohols currently listed in § 101.80 (21 CFR 101.80), D-tagatose is a carbohydrate sweetener that is slowly fermented by oral microorganisms, thus producing less acid than more fermentable carbohydrates. We (FDA) are taking this action in response to a petition filed by Arla Foods Ingredients amba. We 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, we now have determined that the sugar D-tagatose, like the sugar alcohols, is not fermented by oral bacteria to an extent sufficient to lower dental plaque pH to levels that would cause the erosion of dental enamel. Therefore, we have concluded that D-tagatose does not promote dental caries, and we are amending the regulation authorizing a health claim relating certain sugar alcohols and nonpromotion of dental caries to include D-tagatose as a substance eligible for the claim. Moreover, because D-tagatose is a sugar, we are denying the petitioner's request to exclude D-tagatose from the definition of ''sugars,'' and instead are exempting foods containing D-tagatose from the requirement that foods bearing a health claim about nonpromotion of dental caries be sugar-free. Accordingly, although products containing D-tagatose will not be permitted to be labeled as ''sugar-free,'' they will be authorized to say that D-tagatose sugar does not promote, or may reduce the risk of, tooth decay.

DATES: This rule is effective December 2, 2002. Submit written or electronic comments by February 18, 2003.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: James Hoadley, Food and Drug Administration, Center for Food Safety and Applied Nutrition (HFS–832), Harvey W. Wiley Federal Bldg., 5100 Paint Branch Pkwy., College Park, MD, 20740–3835, 301–436–1450.

SUPPLEMENTARY INFORMATION:

I. Introduction

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 ways. One aspect of the 1990 amendments was that they confirmed FDA's authority to

regulate health claims on food labels and in food labeling.

We issued several new regulations in 1993 that implemented the health claim provisions of the 1990 amendments. Among these were § 101.14 (21 CFR 101.14), Health Claims: General Requirements, (58 FR 2478, January 6, 1993) and § 101.70 (21 CFR 101.70), Petitions for Health Claims (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. These regulations became effective on May 8, 1993.

The final rule for § 101.80 (61 FR 43433, August 23, 1996), relating sugar alcohols and 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. 95P–0003). 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 on the surface of teeth produces organic acids, which contribute to the development of dental caries through erosion of tooth enamel. Section 101.80 (b) explains that sugar alcohols are fermented by oral microorganisms more slowly than fermentable carbohydrates. Thus, the rate of acid production is lower than that from fermentable carbohydrates. Consequently, sugar alcohols, when used in place of fermentable carbohydrates, are useful as sweeteners that do not promote dental caries. 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'' as defined by § 101.60(c)(1)(i) (21 CFR 101.60(c)(1)(i)). Section 101.80 (c) also specifies the sugar alcohols that are eligible for the claim: xylitol, sorbitol, mannitol, maltitol, isomalt, lactitol, hydrogenated starch hydrolysates, hydrogenated glucose syrups, erythritol, or a combination of these (§ 101.80(c)(2)(ii)(B)). Section 101.80(c)(2)(ii)(C) further states that:

> When fermentable carbohydrates are present in the sugar alcohol-containing food, the food shall not lower plaque pH below 5.7 by bacterial fermentation either during consumption, or up to 30 minutes after consumption, as measured by the indwelling plaque pH test found in ''Identification of Low Caries Risk Dietary Components,'' * * * which is incorporated by reference * * *.

In the dental caries health claim final rule, the agency stated that for other sugar alcohols to be listed in § 101.80(c)(2)(ii)(B), a petitioner must show how the substance conforms to the requirements of §§ 101.14(b) and 101.80 and must provide evidence that the new sugar alcohol will not lower dental plaque pH below 5.7 (61 FR 43433 at 43442).

In 1997, the agency received a health claim petition (Docket No. 97P–0206) requesting that we amend the dental caries health claim regulation to include erythritol among the sugar alcohols listed in § 101.80(c)(2)(ii)(B). The petition met the requirements in §§ 101.14(b) and 101.80, including evidence from clinical studies using the indwelling plaque pH test cited in § 101.80(c)(2)(ii)(C), demonstrating that erythritol-containing foods do not lower plaque pH below 5.7. Therefore, we amended § 101.80(c)(2)(ii)(B) to include erythritol as one of the sugar alcohols that is eligible to bear a dental caries health claim (62 FR 63653, December 2, 1997).

II. Petition for Health Claim on D-tagatose and the Nonpromotion of Dental Caries

A. The Petition

On January 9, 2002, Arla Foods Ingredients amba, DK–8260 Viby, Denmark, (the petitioner) submitted a petition under section 403(r)(4) of the act (21 U.S.C. 343(r)(4)). The petition requested that we: (1) Amend § 101.80 to include the sugar D-tagatose as one of the substances eligible to bear the dental caries health claim; (2) amend § 101.9 (21 CFR 101.9), the nutrition labeling regulation, to exclude D-tagatose from the definition of ''sugars'' (§ 101.9(c)(6)(ii)), thereby allowing a ''sugar free'' nutrient content claim; and (3) modify the wording of § 101.80 because D-tagatose is not a sugar alcohol. On April 19, 2001, we notified the petitioner that we had completed our initial review of the petition and that the petition had been filed for further action (Docket No. 02P–0177, Let 1) in accordance with section 403(r)(4) of the act. The April 19, 2001, letter stated that consistent with our strategy for implementation of the 1999 Pearson court decision (see 65 FR 59855, October 6, 2000), the agency would consider using its interim final rule authority under section 403(r)(7)(A)(iii) of the act to allow use of the health claim immediately upon publication of the proposal. 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, 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 July 11, 2002, FDA and the petitioner agreed to extend the deadline to publish a proposed regulation until December 2, 2002 (Docket No. 02P–0177, Let 2).

B. Nature of the Substance

As noted by the petition, D-tagatose, the subject of this health claim, is a sugar (see Ref. 1 at page 2). D-tagatose is a monosaccharide ketohexose sugar.[1] There are four different ketohexose sugars, differing only in the orientation of the hydroxyl groups attached to the carbon atoms in positions 3, 4, and 5; the other three ketohexoses are D-fructose, D-sorbose, and D-psicose. D-fructose is the only abundant ketohexose in nature; D-tagatose occurs naturally in the human food supply at only trace amounts. D-tagatose and D-fructose differ in the orientation of the hydroxyl group at the carbon atom at position 4. The Chemical Abstracts Service Registry Number (CAS No.) for D-tagatose is 87–81–0. It has a sweetness of about 75–92 percent that of sucrose.

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

At the time that the dental caries health claim initially was proposed, 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 a substantial burden throughout the U.S. population (60 FR 37507 at 37509, July 20, 1995). 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 U.S. population is at risk.

2. The Substance Is a Food

Under § 101.14(b)(3)(i), the substance that is the subject of a health claim must contribute taste, aroma, or nutritive value, or any other technical effect

[1] All of the common monosaccharides are six-carbon sugars, i.e., hexoses. All sugars have a carbon-oxygen double bond at either the carbon atom in position 1 (aldose) or at the carbon atom in position 2 (ketose). Sugar alcohols differ from sugars in that the double-bonded oxygen of sugars is reduced to a hydroxyl group (-OH) in the sugar alcohols.

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. The petition states that the intended use of D-tagatose in foods is as a nutritive sweetener, humectant, texturizer or stabilizer (§ 170.3(o)(16), (o)(21), (o)(28), (o)(32)). D-tagatose used as a sweetener contributes taste to the food. Existing § 101.80 does not specify the levels in foods of sugar alcohols necessary to justify the health claim and the current petition does not propose a qualifying level for D-tagatose. As a substitute for dietary sugars, D-tagatose will be used in foods at levels necessary to provide the desired level of sweetness in the finished product. Because D-tagatose contributes taste and other technical effects listed in § 170.3(o) to food, the agency concludes that the preliminary requirement of § 101.14(b)(3)(i) is satisfied.

3. The Substance Is Safe and Lawful

On May 11, 2001, the petitioner notified FDA of its view that D-tagatose is generally recognized as safe (GRAS), through scientific procedures, for use as a bulk sweetener, humectant, texturizer, or stabilizer in a variety of foods. FDA replied to this notice on October 25, 2001, stating that based on the information provided by the petitioner, as well as other information available to FDA, the agency had no questions regarding the petitioner's determination that the intended use of D-tagatose is GRAS (Agency Response Letter to GRAS Notice No. GRN 000078, October 25, 2001) (Ref. 1, Appendix 2). Furthermore, FDA is not aware of any scientific evidence that D-tagatose, under the intended conditions of use, would be harmful. The agency has not made its own determination regarding the GRAS status of D-tagatose, 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.

The petitioner's May 11, 2001 submission reveals significant evidence supporting the safety of the use of D-tagatose as a sweetener. FDA is not aware of any evidence that provides a basis to reject the petitioner's position that the use of D-tagatose as a sweetener is safe and lawful. Therefore, FDA concludes that the petitioner has satisfied the requirement of § 101.14(b)(3)(ii) to demonstrate that the use of D-tagatose as a sweetener is safe and lawful.

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

A. Basis for Evaluating the Relationship Between D-Tagatose 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). 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 will not lower plaque pH below 5.7, and that the substance conforms to the requirements of § 101.14(b) (61 FR 43433 at 43442).

In 1997, the agency amended the dental caries health claim to add erythritol as an additional sugar alcohol eligible for the claim (62 FR 63653, December 2, 1997). The petition to amend § 101.80 to add erythritol (Docket No. 97P–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 sugar alcohols listed in § 101.80(c)(2)(ii)(B) and that erythritol met the requirements of § 101.14(b). Therefore, erythritol was added to the list of eligible sugar alcohols.

The substance that is the subject of the current petition, D-tagatose, is a sugar rather than a sugar alcohol. However, like the sugar alcohols, the intended food ingredient use of D-tagatose is as a nutritive sweetener with reduced caloric value relative to traditional sugars. Also, as is the case with the sugar alcohols, the potential dental health benefit from D-tagatose derives from its reduced 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 D-tagatose to assess whether it qualifies for such a claim. As discussed in section II.C of this document FDA has concluded that D-tagatose satisfies the requirements of § 101.14(b).

B. Review of Scientific Evidence

1. Evidence Considered in Reaching the Decision

In the initial proposal to authorize a health claim relating sugar alcohols and nonpromotion of dental caries (60 FR 37507, July 20, 1995), FDA considered evidence about the cariogenic potential of several specific sugar alcohols from long-term controlled human caries trials, in vivo and in vitro plaque pH measurements, demineralization and remineralization techniques, and rat caries experimental models. FDA's review focused on the scientific evidence from studies evaluating changes in plaque pH, plaque acid production, decalcification or remineralization of tooth enamel, and the incidence of dental caries with sugar alcohols. FDA limited its review to these types of studies because previous Federal Government and other authoritative reviews 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), at the same time forming acids that can demineralize tooth enamel. FDA previously concluded that human studies show sugar alcohols, relative to sucrose, are associated with reduced rate of acid production in dental plaque and, in some studies, a reduced incidence of dental caries (60 FR 37507 at 37523).

The current petition to amend the dental caries health claim requires FDA to consider the effects of a sugar, D-tagatose, on the rate of acid production in dental plaque and thus on the incidence of dental caries. To determine whether there is an association between D-tagatose and the nonpromotion of dental caries, FDA compared scientific evidence regarding the cariogenic potential of D-tagatose from two human studies investigating the rate of acid production in dental plaque from D-tagatose relative to that of sucrose with the similar evidence that the agency had previously reviewed regarding the cariogenic potential of certain sugar alcohols. Upon review of this evidence, FDA concluded that, like the sugar alcohols previously authorized for this health claim, D-tagatose is associated with the nonpromotion of dental caries.

2. Review of D-tagatose Studies

The petition included reports (Ref. 1, Appendix 3) from the evaluation of D-tagatose using the indwelling plaque pH test described in ''Identification of Low Caries Risk Dietary Components,'' T. N. Imfeld, Volume 11, *Monographs in Oral Science*, 1983, which is incorporated by reference in the dental caries health claim regulation (§ 101.80(c)(2)(iii)(C)). This evaluation was conducted twice under the same test protocol and with

the same six test subjects. The purpose of the repeat test was to investigate the potential for oral bacteria adaptation to D-tagatose.

Each of the six subjects of these trials had his or her normal dental prosthesis replaced with a mandibular bridge-work that contained a miniaturized telemeterized glass pH-electrode that transmits pH data to an external recording device. Once the telemetric pH prosthesis was inserted into the subject's mouth, the subject was asked not to alter his or her eating habits. The prostheses remained in place throughout the test period to allow an undisturbed growth of plaque over the tips of the pH-electrodes. With the exception of water rinses, the subjects also were asked to refrain from all oral hygiene measures. Following a 3- to 7-day plaque buildup period, the interdental plaque pH telemetry test was conducted. The two tests differed only in that, for the first test, exposure to D-tagatose was limited to a single 2-minute rinse during the pH measurements that followed the plaque buildup period; in the second test, subjects rinsed with D-tagatose five times per day throughout the 3- to 7-day plaque buildup period to determine whether the oral bacteria could adapt to utilize D-tagatose.

For both tests, baseline plaque pH was measured over a 15-minute period after the subjects chewed a piece of paraffin for 3 minutes. The subjects then rinsed with a 10-percent aqueous solution of D-tagatose, followed by plaque pH measurements over a 30-minute period. The same paraffin chew and rinse sequence was then repeated using a 10-percent sucrose rinse. The sucrose rinse served as a positive control to demonstrate the accurate functioning of the pH telemetric equipment and of plaque metabolism.

The results of these tests showed that baseline plaque pH, following the first paraffin chew, ranged from 6.7 to 7.15. The report of these two studies notes that baseline plaque pH in these trials was comparable to that of previous trials of other substances conducted with the same subjects and plaque ages (Ref. 1, Appendix 3). During the D-tagatose rinse and the 30 minutes following the D-tagatose rinse, lowest plaque pH recorded among the six subjects ranged from 5.7 to 6.55. During and after the sucrose rinse, lowest plaque pH recorded among the six subjects ranged from 4.10 to 4.90. Plaque pH measurements during the first test (without exposure to D-tagatose during the plaque build-up period) and the second test (with daily D-tagatose exposure during the plaque buildup period) were substantially the same. The report of these studies concluded that no critical decrease (i.e. below pH 5.7) in the pH of interdental plaque due to bacterial fermentation of D-tagatose occurred; and that dental plaque layers having grown up under repeated exposure to D-tagatose were not more acidified by D-tagatose bacterial fermentation than were nonexposed plaque layers in the same volunteers. Although these two reports of in vivo dental plaque pH tests of D-tagatose constitute a limited body of scientific evidence on the cariogenic potential of D-tagatose, we are satisfied that these reports, 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 D-tagatose should be added to the list of substances eligible for the dental caries health claim.

IV. Decision to Authorize a Health Claim Relating D-Tagatose to the Nonpromotion of Dental Caries

FDA previously concluded that there is significant scientific agreement among qualified experts to support the relationship between certain sugar alcohols and the nonpromotion of dental caries in that the rate and amount of acid production from the metabolism of sugar alcohols by bacteria is significantly less than that produced from the metabolism of sucrose and other fermentable carbohydrates and therefore does not cause the loss of important minerals from tooth enamel (§ 101.80(b)). The petition contains evaluations of the cariogenic potential of D-tagatose from two indwelling plaque pH tests. As discussed previously, the results of the plaque pH tests demonstrate that D-tagatose does not lower plaque pH below 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)(B), and are consistent with the evidence relied upon by the agency when adding erythritol to this list. Therefore, based on the totality of publicly available evidence pertaining to the cariogenicity of D-tagatose and to the relationship between dental plaque pH and dental caries, we conclude that there is significant scientific agreement that D-tagatose does not promote dental caries. Accordingly, we are amending § 101.80 to authorize a dental caries health claim for D-tagatose.

V. Request to Amend the Definition of ''Sugars'' in § 101.9(c)(6)(ii) and Decision to Exempt Foods Containing D-Tagatose From the Sugar-Free Requirement

Section 101.80 (c)(2)(ii)(A) (the dental caries health claim regulation) requires that foods bearing the health claim be ''sugar free'' as defined by (§ 101.60(c)(1)(i) (21 CFR 101.60(c)(1)(i)). D-tagatose is a sugar under the nutrition labeling definition of ''sugars''[2] in 21 CFR 101.9(c)(6)(ii); therefore, by definition, a food containing D-tagatose is not ''sugar free.'' The petition urges FDA to amend § 101.9(c)(6)(ii) to exclude D-tagatose from the ''sugars'' definition, thereby qualifying D-tagatose-containing foods for the ''sugar free'' nutrient content claim, and to provide for a separate declaration of D-tagatose in nutrition labeling. The stated purpose of this request was to assure consistency with other regulations, and to permit D-tagatose-containing noncariogenic foods to inform consumers that the product is ''sugar free'' in accordance with 21 CFR 101.60. (Ref. 1). However, the effect of this request also would be to alter the reported information in the nutrition label for foods containing D-tagatose, because if the request were granted, the amount of D-tagatose in the product would not be recorded under sugars. Thus, products containing D-tagatose and no other sugars would appear to contain zero sugars for purposes of the nutrition label.

The petition identifies D-tagatose as a sugar but asserts that: (1) There is no compelling health or nutritional reason for D-tagatose to be included in the nutrition labeling ''sugars'' definition and (2) excluding D-tagatose from the ''sugars'' definition will help address public health concerns about tooth decay and will improve the ability of

[2] Simple sugars (monosaccharides) consist of a single polyhydroxy aldehyde or ketone unit. The most abundant simple sugars are six-carbon molecules; i.e., hexoses. Two or more monosaccharides can be combined to form disaccharides (e.g., sucrose and lactose) and polysaccharides; however, in general, polysaccharides of more than two saccharide units are not sweet. For purposes of food labeling, the term ''sugar'' refers only to sucrose (§ 101.4(b)(20)). For nutritional labeling purposes FDA has defined the term ''sugars'' as the sum of all mono- and disaccharides present in a food (§ 101.9(c)(6)(ii)). Although the authorized nutrient content claims that characterize the amount of sugars in a food (e.g., sugar free) use the term ''sugar,'' the criteria for these claims are based on the amount of ''sugars'' as defined in § 101.9(c)(6)(ii); e.g. the criteria for a ''sugar free'' claim is that the food contain less than 0.5 gram of ''sugars'' per reference amount and per labeled serving (§ 101.60(c)(1)(i)). D-tagatose is included within this definition of ''sugars'' as any other monosaccharide sugar would be.

the label to assist consumers in maintaining healthy dietary practices with respect to dental health. The petition asserts that not excluding D-tagatose from the definition of ''sugars'' will frustrate efforts to address the public health concerns about dental caries.

FDA disagrees with these arguments. D-tagatose is a sugar (Ref. 3), unlike sugar alcohols, which are not; therefore, a sugar-free claim for D-tagatose would be neither scientifically accurate nor truthful. Moreover, the petition provides no data to support the assertion that identifying D-tagatose as a sugar in the nutrition label will frustrate efforts to address public health concerns about dental caries. This interim final rule provides the petitioner with an opportunity to use health claim label statements to promote the usefulness of D-tagatose as a sweetener that does not promote dental caries. The agency does not believe that a ''sugar free'' nutrient content claim is essential to the effectiveness of the dental caries health claim in communicating the usefulness of D-tagatose as a sweetener that does not promote dental caries.

The petition also asserts that the metabolic and nutritional characteristics of D-tagatose are sufficiently different from those of dietary sugars to justify excluding D-tagatose from the sugars definition for nutrition labeling purposes. The petition further states that, unlike dietary sugars and similar to sugar alcohols, D-tagatose passes unabsorbed through the small intestine on to the large intestine where it is reduced to short chain fatty acids via fermentation by intestinal bacteria; for this reason, and because D-tagatose is intended to substitute for dietary sugars, the petition argues that D-tagatose should be exempted from the ''sugars'' definition as are the sugar alcohols.

FDA disagrees with these assertions. FDA had proposed to include the sugar alcohols within the nutrition labeling definition of ''sugars'' in the ''Food Labeling; Reference Daily Intakes and Daily Reference Values'' proposed rule (56 FR 60366 at 60369, November 27, 1991). However, as explained in the 1993 final rule, we were persuaded by public comments to revise our ''sugars'' definition to exclude the sugar alcohols in recognition of their usefulness as sugar substitutes in reducing the cariogenic potential of foods, and because of their metabolic differences from dietary sugars, e.g., differences in intestinal digestion and absorption (58 FR 2079 at 2099, January 6, 1993). We agree with the petitioner that these are attributes that the sugar alcohols and D-tagatose have in common. However, a critical difference is that sugar alcohols are sugar-like substances used in foods to substitute for sugars, whereas D-tagatose is a sugar. The current situation, therefore, is distinguishable from our previous decision to exclude sugar alcohols from the nutrition labeling ''sugars'' definition.

We also had considered, in the 1993 mandatory nutrition labeling final rule, public comments urging the exclusion of lactose from the nutrition labeling ''sugars'' definition. These comments argued that lactose, the disaccharide sugar of dairy products, should be excluded from ''sugars'' because, due to its inefficient intestinal digestion and absorption, the metabolism of lactose more closely resembles that of complex carbohydrates than that of simple sugars (58 FR 2079 at 2098). FDA disagreed, stating:

> * * * The agency has been persuaded of the need to define ''sugars'' * * * to be consistent with standard analytical methodologies and in conformity with the traditional usage of the term. Lactose, a di-saccharide, is clearly a sugar by conventional standards and is identified with all other mono- and di-saccharides in routine analytical procedures (58 FR 2079 at 2098).

Thus, although in 1993, FDA cited slow intestinal digestion and absorption among the factors considered in our decision to exclude sugar alcohols from the definition of ''sugars,'' those same factors were rejected as a rationale for excluding lactose because, unlike sugar alcohols, lactose is clearly a sugar within the traditional definition and usage of the term, as well as by conventional standards. Likewise, D-tagatose is clearly a sugar within the traditional definition and usage of the term, as well as by conventional standards (Ref. 3).

The petition asserts that identifying noncariogenic D-tagatose-containing foods as ''sugar free'' is fully consistent with the commonly understood meaning of a ''sugar free'' food and fully consistent with consumer expectations. The petition further argues that to exempt D-tagatose from the ''sugars'' definition, and thereby allow a ''sugar free'' claim, would provide consumers with critical information needed to select noncariogenic foods, reduced calorie foods, and foods that help diabetics follow healthy dietary practices.

FDA is not persuaded by these arguments. The petition contains no consumer survey data with regard to consumer understanding or expectations of ''sugar free'' nutrient content claims. Absent factual support for the petitioner's assertion that a ''sugar free'' claim on a food sweetened with D-tagatose is consistent with consumer understanding and expectations (to which we are open and which we would consider), FDA finds no reason to depart from the accepted scientific classification of D-tagatose as a sugar (Ref. 3). We remain skeptical that a ''sugar free'' claim on the food label is critical information needed for consumers to select D-tagatose-containing noncariogenic foods when such foods will be permitted to bear the dental caries health claim to identify them as noncariogenic. Neither are we convinced that a ''sugar free'' claim is critical information required for consumers to be able to select reduced calorie foods. The ''calories per serving'' declaration in the nutrition label, not a ''sugar free'' claim, is the primary food label information that identifies the energy content of the food. Further, if a food meets the criteria for a ''reduced calorie'' food (described in § 101.60(b)), the food may bear such a claim regardless of the sugar content of the food. Finally, the subject of this health claim petition is D-tagatose and nonpromotion of dental caries. A consideration of labeling information useful to identify foods that help diabetics follow healthy dietary practices is clearly outside the scope of this petition. This health claim petition contains no scientific data regarding the appropriateness of recommending D-tagatose for use by diabetics, and FDA has not evaluated any such information.

Finally, the petition asserts that excluding D-tagatose from the nutrition labeling ''sugars'' definition would allow consistency between the dental caries health claim, the ''sugar-free'' nutrient content claim, and nutrition labeling. The petition also asserts that consumers will be thoroughly confused by a nutrition label showing a food to contain sugars when the food label also bears a ''Does not promote tooth decay'' health claim. The petition contains no data to measure the extent of consumer understanding, misunderstanding, or confusion from foods labeled both as noncariogenic and as containing sugars. Therefore, we have no basis, other than the petitioner's subjective views, to evaluate whether or not consumers would be confused. We note that, in the future, it would be helpful to have data like this submitted along with the petition. If such data are submitted, FDA will consider them.

In summary, the petition presents two main arguments for why FDA should omit D-tagatose from the term ''sugars'' as used in the nutrition labeling of foods so as to permit D-tagatose-containing foods to be labeled as ''sugar free'': (1) There is no compelling nutritional or public health reason to include D-

tagatose within the definition of ''sugars,'' and (2) identifying D-tagatose as a sugar will frustrate efforts to communicate the potential dental health benefits of D-tagatose. The agency notes that the dental caries health claim, which is the subject of this health claim petition, is the most direct vehicle for promoting the dental health benefits of the substance. Should there be some potential misunderstandings on the part of consumers regarding the health claim, such problems can be addressed by refining the wording of the health claim. The declaration of ''sugars'' in the nutrition label and the use of ''sugar free'' nutrient content claims are not label information intended to communicate the specific disease-related health benefits (e.g., nonpromotion of dental caries) of a food. Moreover, this situation is not analogous to FDA's decision to exclude sugar alcohol, a nonsugar substance, from the ''sugars'' declared in nutrition labeling. To grant the petitioner's request would be to allow a labeling claim identifying a sugar as a nonsugar. Such a claim would be both false and misleading. For these reasons, FDA is not amending § 101.9(c)(6)(ii) to exclude D-tagatose, a sugar, from the definition of ''sugars.''

The dental caries health claim regulation requires that a food bearing the health claim meet the requirements of § 101.60(c)(1)(i), the ''sugar free'' nutrient content claim (§ 101.80(c)(2)(ii)(A)). As discussed earlier, we are satisfied that the scientific evidence presented in the petition demonstrates that the cariogenic potential of D-tagatose, like that of certain sugar alcohols, is significantly lower than the cariogenic potential of sucrose. However, because D-tagatose is a sugar, we believe that it would be false and misleading to allow D-tagatose containing foods to bear a ''sugar free'' claim. Consequently, rather than granting the petitioner's request and allowing a sugar to declare itself to be ''sugar free,'' we instead are exempting D-tagatose from the ''sugar free'' requirement for the dental caries health claim by amending redesignated § 101.80(c)(2)(iii)(A) to provide that a food bearing the claim be ''sugar free'' except for D-tagatose.

We do recognize that there is a potential incongruity in declaring D-tagatose as a sugar in the nutrition label of a D-tagatose-containing food bearing the dental caries health claim stating that foods high in sugars promote tooth decay. To address this concern, we are adding a new provision in the ''Nature of the Claim'' paragraph to inform consumers about the uniqueness of D-tagatose as a noncariogenic sugar. New § 101.80(c)(2)(i)(H) will provide that where D-tagatose is the substance referred to by the dental caries health claim, the claim must identify D-tagatose as a sugar that, unlike other sugars, does not promote tooth decay or dental caries.

VI. First Amendment Analysis

This interim final rule affects speech because it grants the petitioner's request to authorize a health claim for D-tagatose and dental caries, while denying the petitioner's request to permit a ''sugar free'' nutrient content claim for foods containing D-tagatose. Because Government regulation of food labeling and other commercial speech has constitutional implications, we are providing an analysis explaining why our decision is consistent with the first amendment.

Speech that is inherently misleading is not protected by the first amendment and may be prohibited. (*Central Hudson Gas & Electric Corp.* v. *Public Service Comm'n*, 447 U.S. 557, 563–64 (1980)). The Supreme Court has labeled as misleading, and thus not protected, both speech that is inherently likely to deceive and that ''experience has proved * * * is subject to abuse.'' (*In re R.M.J.*, 455 U.S. 191, 203 (1982)). The agency believes that a sugar-free nutrient content claim for D-tagatose would be inherently likely to deceive, because it is simply untrue. D-tagatose is a sugar and thus, by definition, cannot be sugar-free.

However, even if a sugar-free nutrient content claim for D-tagatose would be only potentially misleading, FDA's decision not to permit such a claim, but to authorize a dental caries health claim for D-tagatose by making an exception to the sugar-free requirement, is constitutional. The Government may place restrictions on commercial speech that is merely potentially misleading as long as the Government interest is substantial, the restrictions directly advance the Government interest, and the restrictions are no more extensive than necessary to serve that interest. (*Central Hudson*, 447 U.S. at 566). FDA's authorization of the dental caries health claim by making an exception to the sugar-free requirement for foods containing the sugar D-tagatose, rather than allowing such foods to be considered ''sugar free'' and to bear a sugar-free claim as the petitioner requested, passes this test.

First, the Government has a substantial and compelling interest in ensuring that food labels are truthful, nonmisleading, and scientifically valid. More specifically, FDA's interest in preventing deceptive nutrient content claims from being made is clearly substantial. The food labeling regulations seek to ensure that consumers have access to information about food that is scientifically valid, truthful, reliable, understandable, and not misleading. (58 FR 2478 at 2526, January 6, 1993). Consumers have a first amendment interest in obtaining information on which to base a decision regarding whether to buy a product, and this interest is ''served by insuring that the information is not false or deceptive.'' (*National Comm'n on Egg Nutrition* v. *FTC*, 570 F.2d 157, 162 (7th Cir. 1977), *cert. denied*, 439 U.S. 821 (1978)).

Second, this interim final rule regulating D-tagatose claims in food labeling directly advances the Government interest. It allows the petitioner and other marketers of D-tagatose to publicize the benefits of D-tagatose in not promoting dental caries, without causing the product to carry a false nutrient content claim (i.e., calling itself sugar-free when it is actually a sugar). Thus, the interim final rule reasonably and effectively ensures that claims for D-tagatose on food labels will be scientifically valid, informative, and not misleading.

Finally, FDA's regulation of D-tagatose claims in food labeling is no more extensive than necessary to serve the Government interest. Under *City of Cincinnati* v. *Discover Network, Inc.*, regulations that are narrowly tailored to serve the government interest will meet this prong of the *Central Hudson* test. (507 U.S. 410, 418n.13 (1993); *see also 44 Liquormart, Inc.* v. *Rhode Island*, 517 U.S. 484, 507–08 (1996)). ''A regulation need not be absolutely the least severe that will achieve the desired end,'' but in determining whether a restriction on commercial speech is reasonable, an agency must consider whether there are ''numerous and obvious less-burdensome alternatives.'' (id.) By exempting D-tagatose from the sugar-free requirement, rather than allowing a sugar to carry a sugar-free claim, FDA has found a reasonable balance between the interest in making information available about the relationship between D-tagatose and dental caries and the interest in ensuring that information about D-tagatose on food labels is truthful, nonmisleading, and scientifically valid. The restriction on ''sugar-free'' claims for foods containing D-tagatose is no more extensive than necessary to serve the Government's interest in preventing the dissemination of false and misleading information through food labeling, and there do not

exist numerous and obvious less-burdensome alternatives in this case.

Moreover, we know of no disclaimer that could cure the deception that would be caused by allowing a sugar to be called ''sugar free.'' (*See Continental Wax Corp.* v. *Federal Trade Comm'n*, 330 F.2d 475 (2d Cir. 1964) (holding that no disclaimer could cure the deception implicit in the name ''Continental Six Month Floor Wax'' where the evidence showed that the wax would not be effective for 6 months)). Where ''the offending deception is caused by a clear and unambiguous false representation implicit in the product's name,'' courts routinely deny the use of disclaimers because ''the addition of a qualifying phrase denying the truth of that representation would lead to a confusing contradiction in terms.'' (id. at 479–80; *see also Bakers Franchise Corp.* v. *Federal Trade Comm'n*, 302 F.2d 258, 261 (3d Cir. 1962) (use of the phrase ''Lite Diet'' with the phrase ''not a low calorie bread'' or ''not low in calories'' would be ''a contradiction in terms and would completely confuse the public'' where the bread at issue contained the same number of calories as other white bread but had thinner slices)). Here, allowing a sugar to be exempted from the definition of ''sugars'' and thus market itself as ''sugar-free'' would be inherently misleading. We are not aware of any evidence that a disclaimer could cure this deception, and common sense counsels against any such conclusion.

Thus, this interim final rule, allowing the dental caries health claim for foods containing D-tagatose but prohibiting ''sugar-free'' claims for such foods, meets the Central Hudson test and does not violate the first amendment.

VII. Description of Modifications to § 101.80

A. Title of the Regulation

Although in this interim final rule we are responding to a specific petition to authorize a claim about D-tagatose and dental caries, we are amending § 101.80 to establish a framework that will allow the agency to readily add to the list of eligible substances additional noncariogenic sugars, as well as additional sugar alcohols. This will provide flexibility for the inclusion of other noncariogenic carbohydrate sweeteners when adequate data are provided to demonstrate that they do not lower plaque pH below 5.7 and, therefore, that they do not promote tooth decay.

We are amending the title of § 101.80 to reflect that the amended regulation includes a noncariogenic sugar, in addition to sugar alcohols, as a substance that is eligible for the health claim about nonpromotion of dental caries. The amended title is: ''Health Claims: dietary noncariogenic carbohydrate sweeteners and dental caries.'' Throughout the regulation references to ''sugar alcohols'' have been changed to ''noncariogenic carbohydrate sweeteners.''

B. Requirements

1. General Requirements

Section 101.80 (c)(1) specifies that all of the requirements set forth in § 101.14 are to be met, except that sugar alcohol-containing foods are exempt from § 101.14(e)(6). Section 101.14(e)(6) specifies that, except for dietary supplements or where provided for in other 21 CFR part 101 regulations, foods making health claims must contain 10 percent or more of the Reference Daily Intake or the Daily Reference Value for vitamin A, vitamin C, iron, calcium, protein, or dietary fiber per reference amount customarily consumed before any nutrient addition. We are amending § 101.80(c)(1) to broaden the exception from the nutrient content requirement in § 101.14(c)(6) to include foods sweetened with any noncariogenic carbohydrate sweetener listed in new paragraph (c)(2)(ii) of this section, including D-tagatose, because of the public health benefit of having a dental caries health claim on the types of foods to which these noncariogenic sweeteners may be added (i.e., chewing gums and confections).

2. Requirements on the Nature of the Claim

Section 101.80 (c)(2)(i) contains requirements on the nature of the claim. For simplicity, we are allowing D-tagatose to be identified in the claim statement as ''tagatose.'' In addition to expanding the coverage of this section from ''sugar alcohols'' to ''noncariogenic carbohydrate sweeteners,'' we are adding new paragraph (c)(2)(i)(H) to require that when a noncariogenic sugar, such as D-tagatose, is the subject of a claim, the claim must explain that the substance is a sugar, but unlike other sugars, does not promote the development of dental caries.

3. Requirements on the Nature of the Substance

As part of establishing a framework to facilitate the addition of other noncariogenic carbohydrate sweeteners to the dental caries health claim, we are adding a new paragraph (c)(2)(ii) to § 101.80 in which to list substances eligible for the claim. This format is consistent with that of most other authorized health claim regulations in which the specific requirements of the claim (§ 101.80 (c)(2)) are divided into three parts: (c)(2)(i) Nature of the claim, (c)(2)(ii) Nature of the substance, and (c)(2)(iii) Nature of the food. Existing § 101.80 (c)(2)(ii) is redesignated as § 101.80 (c)(2)(iii).

The list of sugar alcohols eligible for the dental caries health claim, which is now in the ''Nature of the food'' section, is being moved to new § 101.80 (c)(2)(ii)(A). The noncariogenic sugars currently eligible for the claim, i.e., D-tagatose, are being listed in new § 101.80 (c)(2)(ii)(B).

4. Requirements on the Nature of the Food

Redesignated § 101.80 (c)(2)(iii) contains requirements on the nature of the food bearing the dental caries health claim. Current § 101.80 (c)(2)(ii)(A), redesignated as § 101.80 (c)(iii) (A), reads ''The food shall meet the requirement in § 101.60(c)(1)(i) with respect to sugars content.'' This means that a criterion of the health claim is that the food be ''sugar free.'' As previously discussed, we are amending redesignated § 101.80 (c)(2)(iii)(A) to exempt D-tagatose from the ''sugar free'' requirement for a food bearing the dental caries health claim. Amended § 101.80 (c)(2)(iii)(A) will read ''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.'' As discussed in section V of this document we are taking this action as an alternative to the petitioner's recommendation that D-tagatose be excluded from the ''sugars'' definition.

We are amending redesignated § 101.80 (c)(2)(iii)(B) to reflect the addition of D-tagatose as a substance eligible for a dental caries health claim. As amended, the section will state ''A food whose labeling includes a health claim under this section shall contain one or more of the noncariogenic carbohydrate sweeteners listed in paragraph (c)(2)(ii) of this section.'' We also are amending redesignated § 101.80 (c)(2)(iii)(C) to reflect the broadening of the scope of the claim beyond sugar alcohols only. This paragraph now will provide that when carbohydrates other than noncariogenic sweeteners eligible for the claim are present in a food bearing the claim, the food shall not lower plaque pH below 5.7 by bacterial fermentation, as measured by the indwelling plaque test specified in § 101.80 (c)(2)(iii)(C). The address of the Center for Food Safety and Applied

Nutrition also has been updated in this paragraph.

The agency is not specifying a qualifying level of D-tagatose in the food product because, like sugar alcohols, D-tagatose will be used as a substitute for fermentable sugars. Therefore, the amount of the substance required is that needed to achieve a desired level of sweetness.

C. Optional Information

Section 101.80(d) lists the optional information that may be included in the dental caries health claim. We are amending this paragraph to reflect the fact that the claim now includes a noncariogenic carbohydrate sweetener other than sugar alcohols.

D. Model Health Claims

Section 101.80 (e) provides model health claims as examples of statements that meet the requirements to make a claim about nonpromotion of dental caries. FDA emphasizes that these model health claims are illustrative only. These model claims illustrate the required, and some of the optional, elements of the interim final rule. Because the agency is authorizing a claim about the relationship between D-tagatose and the nonpromotion of dental caries, and not approving specific claim wording, manufacturers will be free to design their own claim so long as it is consistent with § 101.80(c) and (d).

Current § 101.80 (e)(1) consists of two model claims as examples of the full claim, and § 101.80 (e)(2) consists of two model claims as examples of the shortened claim for use on packages with less than 15-square inches of surface area available for labeling. We are amending § 101.80(e)(1) and (e)(2) to add model claims for D-tagatose. The first example of the full claim states: ''Frequent eating of foods high in sugars and starches as between-meal snacks can promote tooth decay. Tagatose, the sugar used to sweeten this food, unlike other sugars, may reduce the risk of dental caries.'' (§ 101.80(e)(1)(iii)). The second example of the full claim states: ''Frequent between-meal consumption of foods high in sugars and starches promotes tooth decay. Tagatose, the sugar in [name of food], unlike other sugars, does not promote tooth decay.'' (§ 101.80(e)(1)(iv)). We are amending § 101.80 (e)(2) by adding two shortened model claims (paragraphs (e)(2)(iii) and (e)(2)(iv)) that read ''Tagatose sugar does not promote tooth decay'' and ''Tagatose sugar may reduce the risk of tooth decay.''

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

We are 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 determines that such action is necessary for public health reasons. This authority enables us 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)).

We are satisfied that all three of the criteria in section 403(r)(7)(A) of the act have been met in the petition submitted by Arla Food Ingredients. This health claim will help 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 new knowledge regarding the reduced cariogenic potential of D-tagatose relative to that of other sugars, and will provide consumers with scientifically sound information on the dental health benefits of foods containing D-tagatose . Therefore, we are 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 D-tagatose and 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 Dockets Management Branch (see **ADDRESSES**) written comments regarding this interim final rule by February 18, 2003. Two copies of any comments are to be submitted, except that individuals may submit one copy. Submit electronic comments to http://www.fda.gov/dockets/ecomments. 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 Dockets Management Branch 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.

IX. Analysis of Impacts

A. Regulatory Impact Analysis

We have examined the economic implications of this interim 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: Having an annual effect on the economy of $100 million or more or adversely affecting in a material way a sector of the economy, competition, or jobs. A regulation is also considered a significant regulatory action if it raises novel legal or policy issues. We have determined that this interim final rule is not a significant regulatory action as defined by Executive Order 12866.

FDA has identified three options: (1) Deny the petition; (2) add D-tagatose to the dental caries health claim and amend § 101.80(c)(2)(ii)(A), the ''Nature of the Food'' requirement that the food be ''sugar free'' except for D-tagatose; or (3) add D-tagatose to the dental caries claim and amend § 101.9(c) to exclude D-tagatose from sugars.

Option one: FDA's denial of the petition would mean no change in the dental caries health claim. Therefore, this option generates no new costs and benefits and is the point of comparison for all other options.

Option two: Option two, the option chosen by the agency, permits foods that contain D-tagatose to bear the dental caries health claim under certain conditions. It will generate social benefits because it provides additional information to consumers who wish to avoid dental caries. Treatment of dental caries creates considerable costs. 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. 6). The cost of treating tooth caries includes: The cost of applying an amalgam, maintaining that amalgam for an individual's lifetime, and lost work time for the application of the amalgam. The median life of an amalgam is 9 to 14 years, and so it must be replaced regularly as long as the tooth remains. The estimated average, weighted lifetime cost of a carious surface is 100.62 dollars in 1995 (Ref. 5). This cost estimate includes: The discounted future costs of replacement amalgams and lost work time, and incorporates the incidence of dental caries by age and the age distribution of the U.S. population. With inflation, the cost is 118.37 dollars in 2002. This estimate does not include pain and suffering associated with dental caries, or possible problems associated with failure to treat dental caries, such as tooth losses or root canals. There are a number of risk factors for developing dental caries: Genetic factors, eating behaviors, and types and characteristics of foods eaten (Ref. 4). Specifically, consumption of dietary sugars and starches have been linked to development of dental caries. Substitution of D-tagatose for other sugars in foods, such as gum, candies, and baked goods, can potentially reduce the risk of dental caries. This would lead to benefits in reduced expenditures on dental care, less work time lost for dental visits, and other complications, such as tooth loss.

Option two will not generate any compliance costs relative to option one, because use of the claim is voluntary. No firm will choose to use the claim allowed by this interim rule unless the firm believes that doing so will increase its profits. However, because the interim rule specifies the manner in which a health claim can be made in product labeling, this interim rule imposes restrictions that may lead to greater or smaller social benefits or costs compared with alternative requirements for making the claim. The expected net benefits of option two are positive.

Option 3: Allowing the addition of D-tagatose to the dental caries claim and amending the definition of sugars also would aid consumers in choosing foods that do not promote dental caries. However, D-tagatose is a sugar. Amending the nutrition labeling definition of sugars to exclude D-tagatose would be counter to the commonly understood definition of sugars. To declare D-tagatose not to be a sugar would mislead consumers and undermine the scientific accuracy of the nutritional labeling, which many consumers currently rely on to make healthy food choices. It is not possible to quantify this cost. Amending the definition of sugars to exclude D-tagatose, and therefore, allowing foods containing D-tagatose to be labeled ''sugar free,'' could potentially generate considerable benefits to the petitioner in its efforts to market D-tagatose. However, these benefits would be offset by the costs of providing invalid information to consumers.

B. Regulatory Flexibility Analysis

We have examined the economic implications of this interim 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 interim 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 its profits. Accordingly, we certify that this interim 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 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.'' We have determined that this interim final rule does not constitute a significant regulatory action under the Unfunded Mandates Reform Act.

X. Environmental Impact

We have determined under 21 CFR 25.32(p) that the actions resulting from this interim final rule are categorically excluded. Therefore, neither an environmental assessment nor an environmental impact statement is required.

XI. 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 D-tagatose 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)).

XII. Federalism

We have analyzed this interim final 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, we have concluded that the interim final rule does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.

XIII. References

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

1. Arla Foods Ingredients amba, ''Petition to amend the regulation for 21 CFR Sec. 101.80 to authorize a noncariogenicity dental health claim for D-tagatose,'' CP–1, Docket No. 02P–0177, January 9, 2002.

2. U.S. Department of Health and Human Services, ''Oral Health,'' Chapter 21 in *Healthy People 2010*, vol. II, part B, 2d ed., Washington, DC., U.S. Government Printing Office, (www.health.gov/healthypeople/Document/HTML/Volume2/21Oral.htm), November 2000.

3. Lubert Stryer, ''Carbohydrates,'' Chapter 18 in *Biochemistry*, 4th ed., New York, W. H. Freeman and Co., 1995.

4. 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://www.nidcr.nih.gov/sgr/execsumm.htm), 2000.

5. Susan O. Griffin, Kari Jones, and Scott L. Tomar, ''An Economic Evaluation of Community Water Fluoridation,'' *Journal of Public Health Dentistry*, 61:78–86, 2001.

6. 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 6/11/2002), March 11, 1996.

List of Subjects in 21 CFR Part 101

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

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

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 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 redesignating paragraph (c)(2)(ii) as paragraph (c)(2)(iii); by revising the section heading, paragraph (a)(4), the first two sentences in paragraph (b), paragraphs (c)(1), (c)(2)(i) introductory text, (c)(2)(i)(B), (c)(2)(i)(C), (c)(2)(i)(E), and (c)(2)(i)(F); by revising newly redesignated paragraph (c)(2)(iii); by revising paragraphs (d)(1), (d)(4), and (e) introductory text; and by adding new paragraphs (c)(2)(i)(H), (c)(2)(ii), (e)(1)(iii), (e)(1)(iv), (e)(2)(iii), and (e)(2)(iv) to read as follows:

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

(a) * * *

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

(b) *Significance of the relationship between noncariogenic carbohydrate sweeteners and dental caries.* Noncariogenic carbohydrate sweeteners do not promote dental caries. The noncariogenic carbohydrate sweeteners listed in paragraph (c)(2)(ii) of this section are slowly metabolized by bacteria to form some acid. * * *

(c) *Requirements.* (1) All requirements set forth in § 101.14 shall be met, except that noncariogenic carbohydrate sweetener-containing foods listed in paragraph (c)(2)(ii) of this section are exempt from § 101.14(e)(6).

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

(A) * * *

(B) The claim shall state that the noncariogenic carbohydrate sweetener present in the food ''does not promote,'' ''may reduce the risk of,'' ''useful [or is useful] in not promoting,'' or ''expressly [or is expressly] for not promoting'' dental caries.

(C) In specifying the nutrient, the claim shall state ''sugar alcohol,'' ''sugar alcohols,'' or the name or names of the substances listed in paragraph (c)(2)(ii) of this section, e.g., ''sorbitol.'' D-tagatose may be identified as ''tagatose.''

(D) * * *

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

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

(G) * * *

(H) 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.

(ii) *Nature of the substance.* Eligible noncariogenic carbohydrate sweeteners are:

(A) The sugar alcohols xylitol, sorbitol, mannitol, maltitol, isomalt, lactitol, hydrogenated starch hydrolysates, hydrogenated glucose syrups, and erythritol, or a combination of these.

(B) The sugar D-tagatose.

(iii) *Nature of the food.* (A) 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.

(B) A food whose labeling includes a health claim under this section shall contain one or more of the noncariogenic carbohydrate sweeteners listed in paragraph (c)(2)(ii) of this section.

(C) 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,'' dated 1983, by T. N. Imfeld, in Volume 11, *Monographs in Oral Science*, 1983. The Director of the Office of the Federal Register has approved the incorporation by reference of this material in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from Karger AG Publishing Co., P.O. Box, Ch–4009 Basel, Switzerland, or you may examine a copy at the Center for Food Safety and Applied Nutrition's Library, Harvey W. Wiley Federal Building, 5100 Paint Branch Pkwy., College Park, MD, or at the Office of the **Federal Register**, 800 North Capital St. NW., suite 700, Washington, DC.

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

* * * * *

(4) The claim may indicate that a substance listed in paragraph (c)(2)(ii) of this section serves as a sweetener.

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

(1) Examples of the full claim:

(i) * * *

(ii) * * *

(iii) Frequent eating of foods high in sugars and starches as between-meal snacks can promote tooth decay. Tagatose, 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. Tagatose, the sugar in [name of food], unlike other sugars, does not promote tooth decay.

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

(i) * * *

(ii) * * *

(iii) Tagatose sugar does not promote tooth decay.

(iv) Tagatose sugar may reduce the risk of tooth decay.

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Margaret M. Dotzel,

Assistant Commissioner for Policy.

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PENSION BENEFIT GUARANTY CORPORATION

29 CFR Parts 4011 and 4022

Disclosure to Participants; Benefits Payable in Terminated Single-Employer Plans

AGENCY: Pension Benefit Guaranty Corporation.