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JAN 0 9 2002

January 9, 2002

Food and Drug Administration
Office of Nutritional Products, Labeling and Dietary Supplements (CPK1)
Harvey W. Wiley Federal Building
5100 Paint Branch Parkway
College Park, MD 20740-3835

To Whom It May Concern:

On behalf of Arla Foods Ingredients amba, we hereby submit the enclosed health claim petition (original and one copy) to amend 21 C.F.R. § 101.80 to authorize a noncariogenicity dental health claim for d-tagatose.

Please date stamp a copy of this letter of transmittal and return for our files. If you need additional information or would like to schedule a meeting to discuss the enclosed petition, please do not hesitate to contact me.

Sincerely,

Diane B. McColl

Diane B. McColl
Counsel to Arla Foods Ingredients amba

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02P-0177

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**Date:** January 9, 2002

**Name of Petitioner:** Arla Foods Ingredients amba
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**Subject of the Petition:** To amend 21 C.F.R. § 101.80 to authorize a noncariogenicity dental health claim for tagatose

Food and Drug Administration
Office of Nutritional Products, Labeling and Dietary Supplements (CPK1)
Harvey W. Wiley Federal Building
5100 Paint Branch Parkway
College Park, MD 20740-3835

On behalf of our client, Arla Foods Ingredients amba, we submit this petition pursuant to Section 403(r)(4) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 343(r)(4), requesting that the Food and Drug Administration (FDA) amend 21 C.F.R. § 101.80 to authorize a noncariogenicity dental health claim for tagatose. Attached, and constituting a part of this petition, Arla Foods Ingredients amba provides the following:

A. Explanation of 21 C.F.R. § 101.14(b) Compliance.
B. Summary of Scientific Data.
C. Analytical Data.
D. Model Health Claim and Corresponding Regulatory Amendments.
E. Appendices.
F. Claim for a Categorical Exclusion per 21 C.F.R. § 25.32(p).
G. Representative and Balanced Submission Statement.
H. Compliance Statement for GLP, IRB and Informed Consent Requirements.

As counsel to Arla Foods Ingredients amba, the undersigned will serve as the contact person for all communications with FDA concerning this petition.

Yours very truly,
Arla Foods Ingredients amba

By: Diane B. McColl

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A. EXPLANATION OF 21 C.F.R.§ 101.14(b) COMPLIANCE.

All requirements set forth in 21 C.F.R. § 101.14(b) are satisfied as provided below:

1. Significance of relationship between disease and substance (21 C.F.R. § 101.14(b)(1)).

Dental caries continues to affect a large segment of the United States population, notwithstanding its decline in recent years. The relationship between dietary fermentable carbohydrates, such as sucrose, and dental caries is well-established. As evidenced by the existing dental health claim approval, FDA recognizes the public health benefit resulting from use of non-fermentable sweeteners in place of fermentable sugars. See 21 C.F.R. § 101.80(a), (b).

2. Consumption at decreased dietary levels (21 C.F.R. § 101.14(b)(2)).

Tagatose will not be consumed as a component of a conventional food at decreased dietary levels, so this requirement is inapplicable.

3. Consumed at other than decreased dietary levels, the substance contributes taste, aroma, nutritive value or other technical effect, and maintains such effect at levels that justify the health claim (21 C.F.R. § 101.14(b)(3)(i)).

Tagatose is intended for use in foods in place of fermentable sugars as a nutritive sweetener, humectant, texturizer or stabilizer. Tagatose is consumed for its sweet taste and nutritive value (1.5 kcal/gram). See Appendix 1 for a letter from FDA confirming that the Agency does not object to the 1.5 kcal/gram caloric value of tagatose. Tagatose is a sugar that, like sugar alcohols, is slowly metabolized by oral bacteria to produce a small amount of acid and plaque that contribute to the development of dental caries. Tagatose maintains its nonfermentability, sweetness and nutritive value properties at all food use levels.

4. Consumed at other than decreased dietary levels, the substance is a safe and lawful food or food ingredient. (21 C.F.R. § 101.14(b)(3)(ii)).

Based on a critical review of the scientific evidence, including, e.g., physical and chemical identity information, manufacturing process, publicly available safety data, corroborating unpublished safety data, intended uses and consumption estimates, an independent panel of experts (the "Expert Panel"), qualified by scientific training, and national and international experience to evaluate the safety of food ingredients, concluded that tagatose is generally recognized as safe ("GRAS") based on scientific procedures, under the conditions of intended use in foods. The FDA had no questions in response to Arla Foods Ingredients amba ("Arla Foods") GRAS notice for use of tagatose in foods (GRN 000078). A copy of FDA's response letter is provided in Appendix 2. The use of tagatose in foods is therefore both safe and lawful.

B. SUMMARY OF SCIENTIFIC DATA

A summary discussion of the scientific data, the evidence of significant scientific agreement and the public health benefit are provided below.

1. Indwelling plaque pH data show tagatose is noncariogenic.

To qualify for the existing dental health claim, sugar alcohol-containing foods must 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," T.N. Imfeld, Volume 11, *Monographs in Oral Science*, 1983, Karger AG Publishing Co. See 21 C.F.R. § 101.80(c)(2)(ii)(C). Products that do not lower plaque pH below 5.7 by bacterial fermentation under the conditions of this test are considered noncariogenic.

Applying the indwelling plaque pH test cited by FDA in § 101.80, tagatose was shown to be noncariogenic in repeated tests (Imfeld, 1996 and 1998). Copies of the test reports are provided in Appendix 3.

2. Evidence of significant scientific agreement among experts qualified by scientific training and experience to evaluate dental health claims. (21 C.F.R. § 101.70(f)).

In the dental health claim rulemaking, FDA found significant scientific agreement among qualified experts that the indwelling plaque pH test is the determinative test for evaluating whether a food or food ingredient is noncariogenic. Incorporation of this test into the final dental health claim rule evidences such significant scientific agreement. As described above, tagatose has been subjected to this test and repeatedly found to be noncariogenic.

3. A public health benefit will derive from a dental health claim for tagatose. (21 C.F.R. § 101.70(f)).

FDA recognizes that "[t]o the extent that consumers can select foods that contain fewer fermentable carbohydrates, their chances of reducing their risk of developing dental caries are increased." 61 Fed. Reg. 43,433, 43,442 (Aug. 23, 1996) (preamble to final dental health claim rule). When tagatose is substituted for fermentable carbohydrates, the finished food contains fewer fermentable carbohydrates. A dental health claim for tagatose alerts consumers to the availability of a noncariogenic alternative. A public health benefit will result from a noncariogenicity claim for tagatose just as a public health benefit is derived from the existing noncariogenicity claims for sugar alcohols.

4. There is no optimum level of tagatose beyond which no dental benefit would be expected. (21 C.F.R. § 101.70(f)(B)(1)).

The data summarized above indicate that the noncariogenic properties of tagatose are observed when it is used to replace fermentable sugars in formulating sugarfree products. Petitioner therefore proposes that the requested health claim be permitted when tagatose replaces fermentable sugars in food products that otherwise meet the requirements of 21 C.F.R. § 101.80.

5. There are no adverse health effects associated with tagatose consumption under conditions of intended use in foods. (21 C.F.R. § 101.70(f)(B)(2)).

The Expert Panel critically evaluated the safety of tagatose consumption by all segments of the general population and concluded that tagatose is GRAS under the conditions of intended use in foods. On May 11, 2001, Arla Foods Ingredients amba submitted GRAS Notice (GRN 000078) informing FDA of its determination that under the conditions of intended use in foods, tagatose is GRAS based on scientific procedures. On October 25, 2001, FDA concluded that it had no further questions regarding the GRAS status of tagatose. A copy of FDA's response to the tagatose GRAS notice (GRN 000078) is provided in Appendix 2.

6. No segment of the general population requires special consideration with respect to a dental health claim for tagatose. (21 C.F.R. § 101.70(f)(B)(3)).

All Americans, regardless of age, sex, and other factors, are susceptible to dental caries. Acknowledging this, FDA's regulation states that "Although there has been a decline in the prevalence of dental caries among children in the United States, the disease remains widespread throughout the population, imposing a substantial burden on Americans." 21 C.F.R. § 101.80(a)(3). A dental health claim in the labeling for foods containing tagatose would therefore provide important information to all Americans.

7. Other nutritional or health factors that are important to consider with respect to tagatose consumption. (21 C.F.R. § 101.70(f)(B)(4)).

The noncariogenic property of tagatose is one of its most important health attributes. The fact that tagatose is not associated with a glycemic response and has a low caloric value (1.5 calories/gram) are additional health factors of importance to consumers with diabetes or those on restricted caloric intake diets.

8. Potential effect of use of tagatose on food consumption.

FDA recognizes that the existing dental health claim for sugar alcohols does not promote "consumption of a particular nutrient rather than focusing on a balanced diet." 61 Fed. Reg. at 43,435. Likewise, a dental health claim for tagatose would not encourage consumers to focus solely on a single nutrient. Rather, it would provide public health information enabling consumers to make alternative food choices that can help reduce their risk of dental caries.

9. Tagatose conforms to the definition of the term "substance." (21 C.F.R. § 101.14(a)(2)).

Section 101.14(a)(2) of FDA's health claim regulation defines the term "substance" as "a specific food or component of food." For purposes of nutrition labeling, FDA defines "sugars" as "the sum of all free mono- and disaccharides (such as glucose, fructose, lactose, and sucrose)." 21 C.F.R. § 101.9(c)(6)(ii). As one such "sugar" intended for use as a component of conventional foods, tagatose is a "substance" eligible for a health claim. As discussed below, Petitioner proposes that FDA amend § 101.9(c)(6)(ii) to exclude tagatose from the definition of "sugars." Nevertheless, even if excluded from the definition of "sugars," tagatose is still a "substance" eligible for a health claim, as per proposed § 101.9(c)(6)(iv), set forth below in Section D.

C. ANALYTICAL DATA.

There is no Association of Official Analytical Chemists (AOAC) method for assaying the tagatose content in representative foods that would be eligible to bear the dental health claim. However, Arla Foods has developed a validated assay method for such purpose. The assay method and data establishing the validity of the method for assaying tagatose in food are provided in Appendix 4. The validation data include a statistical analysis of the analytical and product variability.

D. MODEL HEALTH CLAIM AND CORRESPONDING REGULATORY AMENDMENTS.

1. Amendment to 21 C.F.R. § 101.80.

The model dental health claim proposed for tagatose would be the same as that provided for sugar alcohols and dental caries in 21 C.F.R. § 101.80(e). Specifically, § 101.80 would be amended as follows:

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

(a) . . .

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

(b) *Significance of the relationship between sugar alcohols and tagatose, and dental caries.* Sugar alcohols and tagatose do not promote dental caries. Sugar alcohols and tagatose are slowly metabolized by bacteria to form some acid. The rate and amount of acid production is significantly less than that from sucrose and other fermentable carbohydrates and does not cause the loss of important minerals from tooth enamel.

(c) *Requirements.* (1) All requirements set forth in § 101.14 shall be met, except that sugar alcohol- and tagatose-containing foods are exempt from section § 101.14(e)(6).

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

(A) . . .

(B) The claim shall state that the sugar alcohol or tagatose 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 sugar alcohols, e.g., "sorbitol," or "tagatose."

(D) . . .

(E) The claim shall not attribute any degree of the reduction in risk of dental caries to the use of the sugar alcohol- or tagatose-containing food.

(F) The claim shall not imply that consuming sugar alcohol- or tagatose-containing foods is the only recognized means of achieving a reduced risk of dental caries.

(G) . . .

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

(B) A food whose labeling includes a health claim under this section shall contain one or more sugar alcohols or tagatose, or a combination of these. The sugar alcohols that may be contained in the food are xylitol . . .or erythritol.

(C) When fermentable carbohydrates are present in the sugar alcohol- or tagatose-containing food . . . .

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

(2) . . .

(3) . . .

(4) The claim may indicate that the sugar alcohol or tagatose serves as a sweetener.

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

(1) Example of the full claim:

(i) Frequent eating of foods high in sugars and starches as between-meal snacks can promote tooth decay. The [sugar alcohol (name, optional) or tagatose] used to sweeten this food may reduce the risk of dental caries.

(ii) Frequent between-meal consumption of foods high in sugars and starches promotes tooth decay. The [sugar alcohols or tagatose] in [name of food] do not promote tooth decay.

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

(i) . . .

(ii) . . .

2. Amendment to 21 C.F.R. § 101.9(c)(6)(ii).

To assure consistency with other regulations, and to permit tagatose-containing noncariogenic foods to inform consumers that the product is "sugar free" in accordance with 21 C.F.R. § 101.60, Arla Foods urges FDA to amend 21 C.F.R. § 101.9(c)(6)(ii) to exclude tagatose from the "sugars" definition as was done for the sugar alcohols. There is precedent for amending other sections of the food labeling regulations in the course of enacting regulations permitting health claims. For example, with regard to the health claim for folate and neural tube defects, FDA amended both 21 C.F.R. § 101.9 (Nutrition labeling for food) and 21 C.F.R. § 101.36 (Nutrition labeling of dietary supplements) to permit alternate uses of terms for folate. See 61 Fed. Reg. 8752, 8779 (Mar. 5, 1996). FDA would be acting well within its authority in amending the definition of "sugars" as part of its response to this health claim petition.

As explained further below, Arla Foods believes that tagatose should be exempted from the § 101.9 "sugars" definition in order to address public health concerns about dental health and provide consumers with the information needed to make decisions about healthy dietary practices. Omitting tagatose from the "sugars" definition will avoid inconsistencies between the health claim, nutrient content claim and nutrition labeling. Tagatose has significantly different metabolic and nutritional properties from other sugars, and, like the sugar alcohols, is intended for use primarily as a substitute for such substances. Most importantly, identifying noncariogenic tagatose-containing foods as "sugarfree" is entirely consistent with the consumers long-standing, traditional understanding of the term. The available validated analytical methodology will also allow full compliance with nutrition labeling requirements.

a. Omitting Tagatose from the "sugars" definition helps address public health concerns about tooth decay.

As a monosaccharide, tagatose falls within the current definition of "sugars" in 21 C.F.R. § 101.9(c)(6)(ii). However, there is no compelling health or nutritional reason to include tagatose in the "sugars" definition for purposes of nutrition labeling. The only public health concern associated with sugar consumption is the promotion of dental caries. See 58 Fed. Reg. 2079, 2097 (Jan. 6, 1993); Glinsmann et al., Report from FDA's Sugars Task Force; Evaluation of Health Aspects of Sugars Contained in Carbohydrate Sweeteners, 116 J. Nutrition S1 (Supp. 11 1986). Since tagatose is clearly noncariogenic, including tagatose in the sugars definition would only frustrate efforts to address the public health concerns about dental caries. As with the sugar alcohols, excluding tagatose from the sugars definition will improve the ability of the label "to assist consumers in maintaining healthy dietary practices with respect to dental health." 58 Fed. Reg. at 2097.

b. The metabolic and nutritional characteristics of tagatose are significantly different from those of other "sugars."

The mono- and disaccharides are grouped together because they are sweet-tasting, naturally occurring, rapidly absorbed substances that provide a significant source of calories and prompt a serum insulin response. Tagatose resembles other mono- and disaccharides in that it is naturally-occurring and tastes sweet, about 70% to 90% as sweet as sucrose. But this is where the similarity ends. The metabolic and nutritional characteristics that are important for public health distinguish tagatose from the other mono- and disaccharides. Unlike other "sugars," most of ingested tagatose is not absorbed, but passes through to the large intestine where it is reduced to short-chain fatty acids via fermentation by intestinal bacteria, much like the sugar alcohols. Most importantly, tagatose consumption is not associated with a glycemic response nor does it affect insulin levels, whereas other "sugars" typically do. Tagatose also has a much lower caloric value of only 1.5 kcal/gram compared to other "sugars." As determined by FDA, "[s]ugar alcohols are not included in the definition of 'sugars' because they have metabolic effects different than sugars and have a history of being considered to be sugar substitutes rather than sugars." 58 Fed. Reg. 33,731, 33,743 (June 18, 1993). In view of its metabolic effects and intended use in place of sugars, tagatose should similarly be exempted from the "sugars" definition.

c. Identifying noncariogenic tagatose-containing foods as "sugarfree" is fully consistent with the commonly understood meaning of a "sugarfree" food.

Noncariogenic foods containing more than 0.5 grams of "sugars" per "reference amount customarily consumed" ("RACC") cannot bear the "sugarfree" claim if tagatose is included in the "sugars" definition. Excluding "tagatose" from the "sugars" definition so as to allow a "sugarfree" claim on eligible foods containing tagatose is fully consistent with consumer expectations. Consumers search for "sugars" content information on food labels in order to select foods that possess important nutritional and metabolic characteristics: foods that are either noncariogenic, reduced in calories or suitable for diabetics. See 56 Fed. Reg. 60,421 (Nov. 27, 1991). Tagatose is added to food instead of sucrose and other "sugars" precisely because it is noncariogenic, reduced in calories and clearly suitable for diabetics. To omit such material information from the label would mislead the consumer into believing that tagatose –containing foods are cariogenic, high in "empty" calories and not suitable for persons with diabetes. To exempt tagatose from the "sugars" definition, thereby allowing a "sugarfree" claim, and require separate declaration of tagatose content when a "sugarfree" claim is made, as is done with the sugar alcohols, will provide consumers with the critical information needed to select noncariogenic foods, reduced calorie foods and foods that help diabetics follow healthy dietary practices. The nutrition label will not become more "cluttered" by providing such information, since in most applications, tagatose will be listed in place of an added sugar or sugar alcohol.

d. Removing tagatose from the "sugars" definition allows consistency between the health claim, nutrient content claim and nutrition labeling

FDA considers it important for nutrient content claims, such as "sugarfree," to correspond with information on the nutrition label of a food. See 58 Fed. Reg. at 33,743; 56 Fed. Reg. 60,421 (Nov. 27, 1991). Years before it was deemed to be a health claim, the "Does not promote tooth decay" claim appeared on numerous sugarfree foods as a "food for special dietary use" claim. See 60 Fed. Reg. 37,501 (July 20, 1995). Consumers have associated the "Does not promote tooth decay" claim with sugarfree foods for more than a decade. If tagatose is not removed from the "sugars" definition, then tagatose-containing foods bearing the "Does not promote tooth decay" claim would also bear a nutrition label stating that the product contains "sugars." Consumers will be thoroughly confused by a sugars content statement on a tagatose chewing gum or confectionery that "Does not promote tooth decay." Excluding tagatose from the "sugars" definition and requiring tagatose to be declared separately will assure consistency between the "Does not promote tooth decay" health claim, the "sugarfree" nutrient content claim, and the nutrition label. Separate declaration of tagatose avoids consumer confusion and provides meaningful information, thereby allowing consumers to select noncariogenic, sugarfree foods.

e. Compliance with nutrition labeling requirements will not be impeded.

Compliance with nutrition labeling requirements will not be adversely affected if tagatose is excluded from the "sugars" definition because there exists a collaboratively validated analytical method for measurement of tagatose in foods. Using this method, tagatose content is readily and reliably identified. The standardized analytical method will allow FDA to assess industry compliance with nutrition labeling requirements, and manufacturers to provide accurate content information on nutrition labels of tagatose-containing foods. Nutrition labeling compliance will

not be impeded due to the methodological difficulties encountered with tri- and tetra-saccharides. See 58 Fed. Reg. at 2097.

f. Based on the foregoing, Arla Foods requests that 21 C.F.R. § 101.9 be amended as follows:

**§ 101.9 Nutrition Labeling of Food**

(c)(6)(ii) "Sugars": . . . Sugars shall be defined as the sum of all free mono- and disaccharides . . . other than tagatose . . . .

(iii) "Sugar alcohol" . . . .

(iv) "Tagatose" (VOLUNTARY): A statement of the number of grams of tagatose in a serving may be declared voluntarily on the label, except that when a claim is made on the label or in labeling about tagatose or sugars when tagatose is present in the food, tagatose shall be declared. For nutrition labeling purposes, tagatose is defined as a stereo-isomer of D-fructose, and whose use in the food is generally recognized as safe. Tagatose content shall be indented and expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement "Contains less than 1 gram" or "less than 1 gram" may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(v) "Other carbohydrate" . . .

E. APPENDICES.

Appendix 1. Letter from J. Hoadley, Division of Technical Evaluation, Office of Food Labeling, Center for Food Safety and Applied Nutrition (CFSAN), FDA to M. Wertzberger of October 25, 1999.

Appendix 2. Letter from A. Rulis, Director, Office of Food Additive Safety, CFSAN, FDA to D. McColl of October 25, 2001.

Appendix 3. T. Imfeld, Telemetric evaluation of D-tagatose provided by MD Foods Ingredients amba (now Arla Foods Ingredients amba), DK 8260 Viby J, Denmark, with regard to the product's qualification as being "safe for teeth." (unpublished report) (Nov. 1996).

T. Imfeld, Telemetric evaluation of D-tagatose provided by MD Foods Ingredients amba (now Arla Foods Ingredients amba), DK 8260 Viby J, Denmark with regard to the product's qualification as being "safe for teeth," study performed after different plaque-adaption periods. (unpublished report) (Feb. 1998).

Appendix 4. H. Christensen, Analysis of selected foods for D-Tagatose. (unpublished report) (June 18, 1998).

F. CLAIM FOR A CATEGORICAL EXCLUSION PER 21 C.F.R. § 25.32(p).

Petitioner claims that the regulatory amendments requested in this health claim petition are categorically excluded under 21 C.F.R. § 25.32(p) and do not require preparation of an Environmental assessment (EA) or an Environmental impact statement (EIS).

G. PETITIONER STATEMENT OF RESPONSIBILITY.

The undersigned confirms that to the best of his knowledge and belief this petition is a representative and balanced submission that includes unfavorable information as well as favorable information known to him to be pertinent to the evaluation of the proposed health claim.

Petitioner Arla Foods Ingredients amba

By: _____

Kristian Eriknauer
Arla Foods Ingredients amba

## H. PETITIONER STATEMENT OF GOOD LABORATORY PRACTICES, INSTITUTIONAL REVIEW AND INFORMED CONSENT COMPLIANCE

The nonclinical studies described herein were conducted in accordance with good laboratory practices in effect at the time of such investigations.

The indwelling plaque pH test described herein was conducted in compliance with applicable requirements for institutional review and informed consent in effect at the time of such investigation.

Petitioner Arla Foods Ingredients amba .

By: _____

Kristian Eriknauer
Arla Foods Ingredients amba