



Dockets Management Branch (HFA-305)
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, Maryland 20852

1028 02P-0177-019

October 10, 2002

Re: Docket 02P-0177: Health Claim: D-tagatose and Noncariogenicity

Dear Sir or Madam,

Kellogg is submitting this comment to the Food and Drug Administration (FDA) in support of Arla Foods Ingredients' (Arla Foods) petition to amend 21 CFR § 101.80 to authorize a noncariogenicity dental claim for D-tagatose ("tagatose"). Kellogg is an international manufacturer of cereal and convenience foods, including cookies, crackers, toaster pastries, cereal bars, frozen waffles, meat alternatives, pie crusts and ice cream cones, and is interested in using tagatose as a sweetener in some of our products.

Kellogg supports Arla Foods' health claim petition for several reasons. First, tagatose has been repeatedly demonstrated to be noncariogenic in two tests by the indwelling plaque pH test, Identification of Low Caries Risk Dietary Components, " T.N. Imfeld, Volume II, Monographs in Oral Science, 1983, Karger AG Publishing Co. See 21 CFR. § 101.80(c)(2)(ii)(C). See also Health Claim Petition for Tagatose, attachment 3 (Imfeld studies of tagatose). As FDA has consistently recognized, "[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, 422, (Aug. 23, 1996) (preamble to final dental health claim rule). Permitting a noncariogenicity dental health claim for tagatose will alert consumers to the additional product choices offered by Kellogg and other food manufacturers for reducing dental caries.

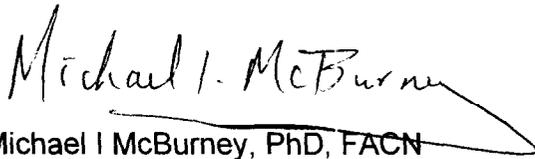
Additionally, tagatose will be useful as a low calorie sweetener given the increase of obesity in the United States. The Surgeon General and other public health agencies in the federal health government have described the increase in obesity levels among Americans as an "epidemic". See The Surgeon General's call to Action to Prevent and Decrease Overweight and Obesity 2001, XIII (2001) (Overweight and obesity ... have reached epidemic proportions in the United States... In 1999, and estimated 61 percent of US adults were overweight or obese, and 13 percent of children and adolescents were overweight.") See also Mokdad, et al., The Continuing Epidemics of Obesity and Diabetes in the United States, JAMA, 1195 (Sept. 2001) (epidemiological study by scientists from Federal Centers for Disease Control and Prevention); Mokdad et al., The spread of the Obesity Epidemic in the United States 1991 - 1998, JAMA 1519 (Oct. 1999) (same). Congress has recently focused on the problem of obesity with the introduction of the Improved Nutrition and Physical Activity Act, S. 2821, a bill that, if enacted, will provide grants to provide health services for improved nutrition, increased physical activity and obesity prevention. Using low calorie sweeteners such as tagatose

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in cereals and convenience foods will provide consumers with more alternatives to sugar sweetened foods, thereby helping to reduce caloric intake.

Because of the increasing rate of obesity in the United States, Kellogg also supports the Arla Foods' request to amend 21 C.F.R. § 101.9(c)(6)(ii) to exclude tagatose from the definition of sugars. This is necessary to avoid confusion that will result if the nutrition labeling lists tagatose as a sugar. Tagatose is fundamentally different than other sugars. Unlike sugar, it is a low-calorie, non-cariogenic sweetener that does not affect glycemic response. Consumers will likely be confused if they see a product that is labeled "low calorie" or "does not promote dental caries," yet has several grams of "sugar" (i.e. tagatose) in the nutritional labeling. Excluding tagatose from the definition of sugars will avoid consumer confusion and increase the likelihood that consumers will choose a product that is low-calorie and non-cariogenic, thereby potentially decreasing risk of obesity and dental caries.

Respectfully submitted:

A handwritten signature in black ink that reads "Michael I. McBurney". The signature is written in a cursive style and is positioned above a horizontal line that extends to the right.

Michael I McBurney, PhD, FACN
Sr. Director of Nutrition & Labeling

Cc: Dr. Susan Thompson
Division of Nutrition Science and Policy
Office of Nutritional Products, Labeling and Dietary Supplements
Center for Food Safety and Applied Nutrition