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December 12, 2006

Dr. Jillonne Kevala
U.S. Food and Drug Administration
Office of Nutritional Products, Labeling and Dietary Supplements (CPK1)
Harvey W. Wiley Federal Building
5100 Paint Branch Parkway
Room 4A035
College Park, Maryland 20740-3835

1207

Re: Isomaltulose Health Claim Petition (Docket 2006P-0487)

Dear Dr. Kevala:

On behalf of our client, Cargill, Inc. (Cargill), we acknowledge that the Food and Drug Administration (FDA) filing date for Cargill's isomaltulose noncariogenicity health claim petition is December 8, 2006.

Additionally, we request that upon approval of the petition, FDA issue an interim final health claim regulation effective upon publication pending consideration of public comment as authorized by 21 U.S.C. § 321(r)(7). Such a regulation would be consistent with FDA precedent regarding the noncariogenicity health claim for tagatose. See 67 Fed. Reg. 71461 (Dec. 2, 2002).

We believe that the statutory criteria for an interim final health claim regulation are clearly satisfied in that the isomaltulose noncariogenicity health claim would promptly educate consumers as to this important dental health property and allow them to adopt healthier diets through better food choices. See 21 U.S.C. § 321(r)(7)(A)(i)-(iii). As FDA concluded for the tagatose noncariogenicity claim, an isomaltulose noncariogenicity health claim will help enable consumers to develop and maintain healthy dietary practices, such as limiting snacks that contain fermentable sugars. The claim will also provide consumers with important new knowledge regarding the reduced cariogenic potential of isomaltulose relative to that of many other sugars and allow dissemination of scientifically sound

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information on the dental health benefits of foods containing isomaltulose. <u>See</u> 67 Fed. Reg. at 71469. We therefore request an interim final health claim regulation regarding noncariogenicity of isomaltulose upon approval of Cargill's petition.

If any questions arise regarding this request, please contact me as soon as possible.

Sincerely,

Diane B. McColl

Diane B. McColl

DBM/dmh