



DEC 8 2006

Diane B. McColl
Hyman, Phelps & McNamara, P.C.
700 Thirteenth Street, N.W.
Suite 1200
Washington, DC 20005

RE: Health Claim Petition – Isomaltulose and Dental Caries (Docket no.
2006P-0487)

Dear Ms. McColl:

This letter is in reference to the subject health claim petition received by the Food and Drug Administration (FDA or the agency) on August 31, 2006, in which you requested that the agency amend 21 C.F.R. § 101.80 to authorize a noncariogenicity dental health claim for isomaltulose. The petition was submitted pursuant to section 403(r)(4)(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(r)(4)(i)) on behalf of Cargill. On September 7, 2006 we informed you that the petition was undergoing initial FDA review.

We have completed our initial review of the petition and are filing it as specified in section 403(r)(4)(i) of the act (21 U.S.C. 343(r)(4)(i)), on December 8, 2006. Within 90 days of the filing date FDA will either publish a proposed regulation authorizing use of the health claim or deny the petition. We have calculated that date to be March 8, 2007. Denial may be made by FDA action or by lack of FDA action, in which case the petition shall be deemed to be denied unless an extension is mutually agreed upon by FDA and the petitioner.


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Please feel free to contact Dr. Jillonne Kevala at 301-436-1848 if you have questions concerning this petition.

Sincerely yours,

A handwritten signature in cursive script that reads "Barbara O. Schneeman".

Barbara O. Schneeman, Ph.D.
Director
Office of Nutritional Products, Labeling,
and Dietary Supplements
Center for Food Safety
and Applied Nutrition