



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

SEP 7 2006

0097 6 DEC -4 P2:08

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

Dear Ms. McColl:

This letter acknowledges receipt on August 31, 2006 by the Food and Drug Administration (FDA) of a health claim petition submitted on behalf of Cargill pursuant to section 403(r)(4) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(r)(4)). You requested that the FDA amend 21 C.F.R. § 101.80 to authorize a noncariogenicity dental health claim for isomaltulose.

The petition is undergoing initial FDA review in accordance with Section 403(r)(4)(A)(i) of the act (21 U.S.C. 343(r)(4)(A)(i)) and 21 CFR 101.70(j)(2). Within 100 days of receipt of a petition, it will be either filed for comprehensive review or denied. A health claim petition may be denied by action taken by FDA or by a lack of action by FDA, in which case the petition will be deemed to be denied unless an extension is mutually agreed upon by the petitioner and FDA. The 100-day period for your petition ends on December 8, 2006 and FDA will notify you by letter on or before that date of the disposition of the health claim petition.

Please feel free to contact me at 301-436-1848 if you have any questions concerning this petition.

Sincerely yours,

Jillonne Kevala, Ph.D.

Nutrition Programs and Labeling
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

2006P-0487

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