



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration  
College Park, MD

SEP 28 2006

Lore Wiscomb Kolberg, MS, RD, LD  
Manager, Regulatory and Scientific Affairs  
Cargill Health & Food Technologies  
Cargill, Incorporated  
15407 McGinty Road West  
Wayzata, MN 55391

RE: Petition for Health Claim for Barley Betafiber and Coronary Heart Disease

Dear Ms. Kolberg:

This letter is in reference to the subject health claim petition received by the Food and Drug Administration (FDA or the agency) on June 20, 2006, in which Cargill, Inc. requested that the agency amend the health claim entitled "Soluble fiber from certain foods and risk of coronary heart disease" (21 CFR 101.81) to include barley betafiber as an additional substance eligible for the claim. 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, Incorporated.

We have completed our initial review of the petition and are filing it for further action in accordance with section 403(r)(4)(i) of the act (21 U.S.C. 343(r)(4)(i)). The filing date is September 28, 2006. FDA will either publish a proposal to amend § 101.81 in response to your petition, or deny the petition, within 90 days of the filing date, i.e., not later than December 27, 2006. 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.

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

Sincerely yours,

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

2006P-0393

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