



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration  
College Park, MD 20740

JUL 5 2006

Lore Kolberg  
Manager, Regulatory and Scientific Affairs  
Cargill, Incorporated  
15407 McGinty Road West  
Wayzata, MN 55391

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

Dear Dr. Kolberg:

This letter acknowledges receipt on June 20, 2006 by the Food and Drug Administration (FDA or the agency) of your health claim petition submitted on behalf of Cargill, Incorporated, pursuant to Section 403(r)(4)(A)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(r)(4)(A)(i)). You requested that the agency expand 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.

Your petition is undergoing initial FDA review. In accordance with Section 403(r)(4)(A)(i) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. 101.70(j)(2), within 100 days of receipt of your petition, the petition will be filled for comprehensive review or denied. The 100-day period ends on September 28, 2006.

You had previously submitted this petition earlier in 2006, but due to your concerns about the timing of making some material contained in the petition public, Cargill and FDA had a mutual agreement that the petition would be withdrawn and resubmitted after the matter was resolved. The agency does not anticipate requiring the full 100 day period for initial FDA review of the resubmitted petition because the agency had already begun the initial review of the petition well before June 20, 2006, which is the acknowledgement date for this petition.

If you have any questions concerning this petition, my phone number is 301 436-1848 and my email address is [Jillone.Kevala@fda.hhs.gov](mailto:Jillone.Kevala@fda.hhs.gov).

Sincerely yours,

Jill Kevala, Ph.D.

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

2006P-0393

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