DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20704-3835

APR 26 2002

184 '03 JUN 27 P2:02

Jonathan W. Emord
Andrea G. Ferrenz
Emord & Associates, P.C.
5282 Lyngate Court
Burke, VA 22015

RE: Health Claim Petition – Phosphatidylserine and Cognitive Dysfunction; Phosphatidylserine and Dementia

Dear Mr. Emord and Ms. Ferrenz:

This letter acknowledges receipt on April 19, 2002 by the Food and Drug Administration (FDA) of your petition submitted on behalf of Doctor Kyl Smith pursuant to Section 403(r)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(r)(4)). You requested that the FDA approve two health claims concerning, respectively, the relationship between the consumption of phosphatidylserine and cognitive dysfunction and the relationship between the consumption of phosphatidylserine and dementia.

Your petition is undergoing initial FDA review. In accordance with Section 403(r)(4)(A)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(r)(4)(A)(i)) and 21 CFR 101.70(j)(2), within 100 days of receipt of your petition, the petition will either be filed for comprehensive review or denied. The 100-day period ends on July 28, 2002, and FDA will notify you by letter on or before that date of the disposition of your petition.

Please feel free to contact me at 301-436-1450 if you have questions concerning your petition.

Sincerely yours,

Lynn A. Larsen, Ph.D.
Director
Division of Nutrition Science and Policy
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

02P-0413

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