



SEP 13 2002

Food and Drug Administration  
College Park, MD 20740

Jonathan W. Emord  
Emord & Associates, P.C.  
Burke Professional Center  
5282 Lyngate Court  
Burke, VA 22015

RE: Health Claim Petition – Phosphatidylserine and risk of cognitive dysfunction and dementia

Dear Mr. Emord:

This letter is in reference to the subject health claim petition that you submitted on April 19, 2002, on behalf of Kyl Smith, D.C. In accordance with section 403(r)(4)(A)(i) of the Federal Food, Drug, and Cosmetic Act (the Act) and 21 CFR 101.70(j)(2), the Food and Drug Administration (FDA) must either issue a final decision denying the petition, or file the petition for further action, not later than 100 days after the petition is received. If FDA does not act within 100 days of receiving the petition, the petition is deemed to be denied unless an extension is mutually agreed upon by the FDA and the petitioner. The 100 day date from receipt of your petition was July 28, 2002. However, by mutual agreement of the petitioner and FDA, the 100-day deadline was extended until September 13, 2002. FDA has filed your petition for comprehensive review as of this date.

In accordance with section 403(r)(4)(A)(i) of the Act and 21 CFR 101.70(j)(3), FDA will notify you by letter, within 90 days of filing your petition, either that a proposed regulation to provide for the requested use of the health claim will be published in the Federal Register, or that your petition is being denied. In addition, under our interim enforcement strategy for dietary supplement health claims that do not meet the significant scientific agreement standard of evidence (65 Federal Register 59855, October 6, 2000), we will consider permitting use of the petitioned health claim under certain conditions by exercising enforcement discretion. If FDA does not take one of the aforementioned actions within 90 days of the date of filing, the petition is deemed to be denied unless an extension is mutually agreed upon by FDA and the petitioner. We have calculated this date to be December 12, 2002.

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

Sincerely,

A handwritten signature in black ink that reads "Kathleen Ellwood". The signature is written in a cursive style with a large, sweeping initial 'K'.

Kathleen Ellwood, Ph.D.  
Acting Director  
Division of Nutrition Science and Policy  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition