



MAR 16 2004

Cary A. Levitt, Esq.
Solae, LLC
P.O. Box 88940
St. Louis, MO 63188

RE: Health Claim Petition – Soy Protein Containing Products and a Reduced
Risk of Certain Cancers

Dear Mr. Levitt:

This letter acknowledges receipt on March 1, 2004, by the Food and Drug Administration (FDA) of your health claim petition, submitted pursuant to Sections 403(r)(4) of the Federal Food, Drug, and Cosmetic Act (FFD&C Act) (21 U.S.C. § 343(r)(4)) with respect to certain claims about the relationship between soy protein containing products and a reduced risk of certain cancers.

Because your petition is complete it is undergoing initial FDA review. In accordance with Section 403(r)(4)(A)(i) of the FFD&C 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, the petition will either be filed for comprehensive review or denied. A denial may be by either FDA action within the day period, which ends on June 9, 2004, or by a lack of action by FDA within the initial 100-day period in which case the petition shall be deemed to be denied unless an extension is mutually agreed upon by FDA and the petitioner.

If you have any questions please feel free to contact Dr. Tomoko Shimakawa on the Nutrition Programs and Labeling Staff at 301-436-1450.

Sincerely yours,

Shellee Anderson
Team Leader
Nutrition Policy and Labeling Staff
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety

2004Q-0151

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