



APR 15 2004 10:04 APR 15 22:13

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

RE: Qualified Health Claim (Soy Protein Containing Products and a Reduced Risk of Certain Cancers) (Docket No. 2004Q-0151)

Dear Mr. Levitt:

This letter acknowledges receipt on March 30, 2004, by the Food and Drug Administration (FDA) of your letter regarding the health claim petition that you submitted on March 1, 2004. We understand that you intended to have the petition reviewed under the qualified health claim process rather than under the standard health claim review process described in Section 403(r)(4) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 343(r)(4)). We will follow the interim procedures for qualified health claims described in the FDA publication titled "Consumer Health Information for Better Nutrition Initiative" Task Force Final Report (<http://www.cfsan.fda.gov/~dms/nuttftoc.html>).

Accordingly, today we are filing your qualified health claim petition about the relationship between soy protein containing products and a reduced risk of certain cancers. The petition is posted on Dockets web page (<http://www.fda.gov/ohrms/dockets/dockets/dockets.htm>) and we are requesting comment on it for 60 days. Interested persons may submit comments until June 14, 2004. Within 270 days of the receipt of the petition, we will notify you of our final decision regarding the requested qualified health claim. We have calculated this date to be November 26, 2004.

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

Sincerely yours,

Jugma Z. Wilkening
for Laura M. Tarantino, Ph.D.
Acting Director
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

2004Q-0151

ACK 2