



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740-38

JAN 21 2004

Mr. Edward A. Steele
Vice President
Food, Dietary Supplement & Cosmetic Consulting
AAC Consulting Group
7361 Calhoun Place
Suite 500
Rockville, MD 20855-2765

RE: Petition for a qualified health claim on eggs with enhanced omega-3 fatty acid content and a balanced 1:1 ratio of omega-3/omega-6 fatty acids

Dear Mr. Steele:

This letter acknowledges receipt on January 8, 2004, by the Food and Drug Administration (FDA) of the petition you submitted pursuant to Sections 403(r)(4) and 403(r)(5)(D) of the Federal Food Drug and Cosmetic Act (FFD&C Act) (21 U.S.C. § 343(r)(4) and § 343(r)(5)(D)) and in accordance with the July 10, 2003 of the Task Force Final Report on the Consumer Health Information for Better Nutrition Initiative, on behalf of Belovo, Inc. The petition requests a qualified health claim for the relationship between eggs with enhanced omega-3 fatty acid content and a balanced 1:1 ratio of omega-3/omega-6 fatty acids and reduced risk of heart disease and sudden, fatal heart attack.

This petition is undergoing initial FDA review. In accordance with interim procedures set forth in the aforementioned Task Force Final Report, within 45 days of receipt of your petition, you will be notified of FDA's decision to either file the petition for comprehensive review, or to deny the petition. A denial may be by either FDA action within the initial 45-day period, which ends on February 22, 2004, or by a lack of action by FDA within the initial 45-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.

In our preliminary review of your petition, we noticed that the right side of the text of the following articles were cut off.

Reference 72. Harper CR, Jacobson TA. Beyond the Mediterranean Diet: The Role of Omega-3 Fatty Acids in the Prevention of Coronary Heart Disease. *Prev. Cardiol.* 2003;6(3): 136-146.

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Reference 74. Hu FB, Willett WC. Optimal Diets for Prevention of Coronary Heart Disease. *J. Am. Med. Assoc.* 2002;288:2569-2578.

Please send us two complete legible copies of each of these articles.

We also noticed that your petition contains a few deviations from the petition format specified in 21 CFR 101.70(f). The regulation specifies attachment section headings labeled A. B. C., submitted on separate pages, suitably identified. Some of your sections did not start on separate pages. Also, some of your section heading labels did not correspond with the section heading labels specified in the regulation. Complete submissions and correct format facilitate the FDA review of petitions. We request that any future petitions you may submit follow all the requirements specified in 21 CFR 101.70, including format.

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

Sincerely yours,



Tomoko Shimakawa, Sc.D.
Nutrition Programs and Labeling Staff
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

CC: Stanley M. Tarka, Jr., Ph.D., AAC Consulting Group