



NOV 19 2003 8 58 3 '03 NOV 21 P2:05

Mr. Martin J. Hahn
Columbia Square
555 Thirteenth Street, NW
Washington, DC 20004-1109

RE: Petition for a qualified health claim on omega-3 fatty acids and coronary heart disease.

Dear Mr. Hahn:

This letter acknowledges receipt on November 4, 2003 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)) on behalf of Martek Biosciences Corporation. You request FDA to exercise its enforcement discretion concerning a qualified health claim regarding the relationship between omega-3 fatty acids (specifically eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA)) and coronary heart disease. We also acknowledge that, in addition to submitting the petition to our office, you have submitted your petition (without attachments) as a comment to a similar petition that has already been filed in dockets (Docket No. 2003Q-0401).

New qualified health claim petitions normally undergo initial FDA review and decision to either file the petition for comprehensive review or to deny the petition, but we have decided not to process your petition as a new petition. You have submitted your petition to the existing docket (Docket No. 2003Q-0401) as a comment to the qualified health claim petition submitted by Mr. Jonathan W. Emord. The substance and disease identified in your petition is the same as that identified in Mr. Emord's petition. Therefore, we have decided to consolidate your petition with Mr. Emord's petition in the same docket in accordance with procedures set forth in FDA's guidance entitled "Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements" (<http://www.cfsan.fda.gov/~dms/nuttf-e.html>) and to take into consideration the issues you have raised in your petition. A final decision regarding Mr. Emord's qualified health claim petition will be made by April 15, 2004. Since your petition has been consolidated with Mr. Emord's existing petition, you will be notified of our decision by this date as well.

2003 Q-0401

ACK 3

Page 2 - Martin J. Hahn

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

Sincerely yours,

A handwritten signature in cursive script that reads "Tomoko Shimakawa".

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