

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration  
College Park, MD 20740

DEC 19 2005

0657 6 MAR 30 P2:22

Carolyn R. Hathaway, Esq.  
LATHAM & WATKINS, L.L.P.  
555 Eleventh Street, N.W.  
Suite 1000  
Washington, D.C. 20004-1304

Dear Ms. Hathaway:

This letter acknowledges receipt on December 9, 2005, by the Food and Drug Administration (FDA) of the nutrient content claim notification you submitted pursuant to Section 403(r)(2)(G) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(r)(2)(G)). The notification is informing FDA that Ocean Nutrition Canada, Ltd intends to make nutrient content claims based upon alleged authoritative statements from the Institute of Medicine. The nutrient content claims are for conventional foods and dietary supplements containing a combination of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA).

The notification is undergoing FDA review. In accordance with Section 403(r)(2)(G) of the act, within 120 days (ending on April 8, 2006) of receipt of your nutrient content claim notification, you will be informed by FDA if the notification does not comply with Section 403(r)(2) of the act. A lack of action by FDA within the 120-day period will deem the proposed nutrient content claims approved and will allow a conventional food or a dietary supplement with a label containing the claims to be introduced into interstate commerce.

The FDA does not agree with your characterization of the history of this notification as outlined in your letter to Kathleen C. Ellwood, Ph.D., dated December 8, 2005. We have no information that would demonstrate that a notification of this nutrient content claim was submitted to or received by the Office of Nutritional Products, Labeling and Dietary Supplements (ONPLDS) or any Division within ONPLDS, on any date prior to December 9, 2005. (The photocopy you attached to your December 8 letter, which bears an illegible signature and a handwritten date on the first page, does not support your claim that this notification was previously submitted and received by ONPLDS.)

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ACK 1

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This letter is being sent to you based on our procedures for acknowledging the receipt of a notification within 15 days. If you have any questions concerning this notification, please contact me at (301) 436-1450.

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