DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

FEB 9 2006

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

Dear Ms. Hathaway:

The Food and Drug Administration (FDA) is responding to your letter dated January 13, 2006 about the Ocean Nutrition Canada's FDAMA nutrient content notification on EPA and DHA omega-3 fatty acids. Your letter asserts that the receipt date of your notification should be August 26, 2005, and thus the use of the nutrient content claims should be authorized retroactively to December 26, 2005.

In our letter dated December 19, 2005, we have explained our basis for not acknowledging August 26, 2005 as a receipt date of your notification. We have no information that would demonstrate that your notification 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, 2005 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. We consider December 9, 2005 as the receipt date of your notification.

The process for acknowledging the receipt of FDAMA notifications is to send an acknowledgement letter to the notifier within 15 days. We did not receive an inquiry from your office until December 5, 2005.

2006P-0137

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The notification is undergoing FDA review as stated in our December 19, 2005 acknowledgement letter. If you have any questions concerning this notification, please contact Dr. Tomoko Shimakawa at (301) 436-1461.

Sincerely yours,

Kathleen C. Ellwood

Kathleen C. Ellwood, Ph.D.
Director
Division of Nutrition Programs and Labeling
Office of Nutritional Products, Labeling
and Dietary Supplements
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