



JUN 25 2004

Food and Drug Administration
College Park, MD 20740

Barbara J. Moore, Ph.D.
President and CEO
Shape Up America!
15009 Native Dancer Road
N. Potomac, MD 20878

Dear Dr. Moore;

This is in response to your letter, dated April 30, 2004, to Dr. Lester Crawford concerning a FDAMA notification for nutrient content claims for DHA, EPA, and ALA omega-3 fatty acids. You recommended that we favorably consider the notification. You noted that coronary heart disease (CHD) is our nation's leading killer and that the scientific evidence demonstrates that EPA and DHA, and to a lesser degree ALA, can reduce the risk of CHD.

As you are aware, on January 16, 2004, FDA received a notification from Michael J. O'Flaherty of Olsson, Frank and Weeda, on behalf of Alaska General Seafoods, Ocean Beauty Seafoods, Inc., and Trans-Ocean Products, Inc. The notification was submitted pursuant to section 403(r)(2)(G) of the Food, Drug, and Cosmetic Act (the act) for nutrient content claims for foods and dietary supplements containing DHA, EPA, and ALA.

Section 403(r)(2)(G) permits distributors and manufacturers to use claims if such claims are based on current, published, authoritative statements from certain federal scientific bodies, as well as from the National Academy of Sciences (NAS). These provisions are intended to expedite the process by which the scientific basis for such claims is established. Under section 403(r)(2)(G) of the act, any interested person may submit, at least 120 days before introducing the food with a label bearing the claim into interstate commerce, notifications for nutrient content claims based on authoritative statements that includes (1) the exact words to be used in the claim, (2) a concise description of the basis for the claim that was used to determine that the requirements for an authoritative statement have been satisfied, (3) a copy of the authoritative statement, and (4) a balanced representation of scientific literature relating to the nutrient level to which the claim refers.

2004N-0217

LET 3

Page 2 - Barbara J. Moore

The 120 day period passed on May 15, 2004, and the agency has filed the notification in a public docket (Docket No. 2004N-0217). Manufacturers may now lawfully label qualifying foods with the nutrient content claims detailed in the notification. However, because the agency disagrees with basis for the notified nutrient content claims for EPA and DHA, FDA intends to initiate rulemaking to itself define nutrient content claims for EPA and DHA.

We hope this is helpful, if you have additional questions do not hesitate to contact us.

Sincerely,

A handwritten signature in cursive script that reads "Shellee Anderson".

Shellee Anderson
Team Leader
Nutrition Programs and Labeling Staff
Office of Nutritional Products, Labeling
and Dietary Supplements
Center of Food Safety
and Applied Nutrition