



JUN 25 2004

Food and Drug Administration  
College Park, MD 20740

Jeffrey R. Prince  
Vice President  
American Institute for Cancer Research  
1759 R Street, NW  
Washington, DC 20009

Dear Mr. Prince;

This is in response to your letter to Dr. Robert E. Brackett, dated May 3, 2004, concerning nutrient content and health claims for omega-3 fatty acids. You urged the agency to move quickly to permit nutrient content claims for specific omega-3 fatty acids, which will facilitate the selection of foods containing nutrients that are believed to be protective.

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.

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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.

Sincerely,



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