

Memorandum

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Date:

SEP 6 2006

From: Consumer Safety Officer, Division of Dietary Supplement Programs , Office of Nutritional Products, Labeling and Dietary Supplements, HFS-810

Subject: 75-Day Premarket Notification of New Dietary Ingredients

To: Dockets Management Branch, HFA-305

Subject of the Notification: **“Omega-3 Phospholipids”**

Firm: Natural ASA

Date Received by FDA: May 23, 2006

90-Day Date: August 21, 2006

In accordance with the requirements of section 413(a) of the Federal Food, Drug, and Cosmetic Act, the attached 75-day premarket notification and related correspondence for the aforementioned substance should be placed on public display in docket number 95S-0316 as soon possible since it is past the 90-day date. Thank you for your assistance.

Victoria Lutwak

19955-0316

RPT 354



Food and Drug Administration
5100 Paint Branch Parkway
College Park, Maryland 20740

AUG 4 2006

Mr. Egil Nilsen
Business Development Manager
Natural ASA
Strandveien 15
N - 1325 Lysaker
Norway

Dear Mr. Nilsen:

This is to inform you that the notification, dated May 15, 2006, that you submitted pursuant to 21 U.S.C. 350b(a)(2)(section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (the Act)) was filed by the Food and Drug Administration (FDA) on May 23, 2006. Additional information was received on June 5, 2006. Your notification concerned the substance that you called "Omega-3 Phospholipids" ("Omega-3 PL") that you intend to market as a new dietary ingredient.

Your notification states that "Omega-3 Phospholipids" will be marketed in liquid form and that "[t]he recommended use of Omega-3 Phospholipids is the consumption of up to 4 g/day." As for conditions of use, your notification states that "[u]sage of Omega-3 PL is not restricted to any target population; the only subpopulations excluded from using Omega-3 PL are individuals allergic to fish and persons taking anticoagulants."

Under 21 U.S.C. 350b(a), the manufacturer or distributor of a dietary supplement containing a new dietary ingredient that has not been present in the food supply as an article used for food in a form in which the food has not been chemically altered must submit to FDA, at least 75 days before the dietary ingredient is introduced or delivered for introduction into interstate commerce, information that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such new dietary ingredient will reasonably be expected to be safe. FDA reviews this information to determine whether it provides an adequate basis for such a conclusion. Under 21 U.S.C. 350b (a) (2), there must be a history of use or other evidence of safety establishing that the new dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe. If this requirement is not met, the dietary supplement is considered to be adulterated under 21 U.S.C. 342(f) (1) (B) because there is inadequate information to provide reasonable assurance that the new dietary ingredient does not present a significant or unreasonable risk of illness or injury.

FDA has carefully considered the information in your submission and the agency has concerns about the evidence on which you rely to support your conclusion that "Omega-3 Phospholipids" will reasonably be expected to be safe.

Your notification states that "Omega-3 Phospholipids" will be marketed in liquid form and the recommended use will be up to 4 g/day. It is unclear how many drops, milliliters, teaspoons or similar units of liquid measure will be used to measure the intended daily serving of 4 g of "Omega-3 Phospholipids".

While your notification contains information about the safety of some of the components of "Omega-3 Phospholipids", the notification does not address the safety of the interesterified components of your ingredient or of the entire mixture that you intend to market. It is therefore unclear how the interesterified components of your ingredient are qualitatively or quantitatively similar to the substances described in the safety information you relied on in your notification or how that information is relevant to evaluating the safe use of the substance that you call "Omega-3 Phospholipids".

For the reasons discussed above, the information in your submission does not provide an adequate basis to conclude that "Omega-3 Phospholipids", when used under the conditions recommended or suggested in the labeling of your product, will reasonably be expected to be safe. Therefore, your product may be adulterated under 21 U.S.C. 342(f)(1)(B) as a dietary supplement that contains a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury. Introduction of such a product into interstate commerce is prohibited under 21 U.S.C. 331(a) and (v).

Your notification will be kept confidential for 90 days after the filing date of May 23, 2006. After the 90-day date, the notification will be placed on public display at FDA's Docket Management Branch in docket number 95S-0316. Prior to that date, you may wish to identify in writing specifically what information you believe is proprietary, trade secret or otherwise confidential for FDA's consideration.

Page -3- Mr. Egil Nilsen

If you have any questions concerning this matter please contact Victoria Lutwak at
(301) 436-1775.

Sincerely yours,

A handwritten signature in cursive script that reads "Linda S. Pellicore". The signature is written in black ink and is positioned above the typed name and title.

Linda S. Pellicore, Ph.D.
Supervisory Team Leader, Senior Toxicologist
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
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