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Barbara Levenstein, M.S.
Director of New Product Development
Arkopharma, LLC
dba Health From The Sun
19 Crosby Drive
Suite 300
Bedford, Massachusetts 01730

Dear Ms. Levenstein:

This is in response to your letter of February 2, 2006 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)).

Your letter states that the following statement will be made for the product PFO™ Pure Fish Oil - CardiA-spirin with Nattokinase:

“[P]romote healthy blood pressure.”

In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1018), FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims. We stated, however, that because “many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease,” in order to avoid implying that the product prevents or treats heart disease, a cholesterol maintenance claim would have to clarify that the product is only for maintenance of cholesterol levels that are already within the normal range. The same principle applies to claims about the control of blood pressure; that is, claims that do not establish that the claims are about blood pressure that is already within normal limits imply that the product is intended to treat elevated blood pressure (hypertension), which is a disease. Therefore, because the claim you are making for this product represents that the product is intended to affect blood pressure but does not also include a statement about it being intended to affect blood pressure that is already in the normal range, it is an implied disease claim.

The product is also the subject of the following claim:

“Nattokinase is a special enzyme (protein) that maintains healthy blood flow by supporting the body’s natural ability to respond to and manage blood coagulation (clot formation).”

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In the January 6, 2000 final rule (65 FR 1000 at 1016), FDA stated that "[I]nhibiting or decreasing platelet aggregation is a well-recognized therapy for the prevention of stroke and recurrent heart attack" and that claims to inhibit normal platelet function are implied disease claims to treat or prevent these disease conditions. The claim above implies that your product will "maintain" healthy blood flow by inhibiting clot formation or dissolving clots that do form. Therefore, it is a disease claim.

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product suggest that it is intended to treat, prevent, or mitigate diseases. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely yours,



Susan J. Walker, M.D.
Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

FDA, New England District Office, Office of Compliance, HFR-NE340



February 2, 2006

Notification of statements on Dietary Supplement Labels

Division of Compliance and Enforcement
Office of Nutritional Products, Labeling and Dietary Supplements
Food and Drug Administration
(HFS-810)
5100 Paint Branch Parkway
College Park, MD 20740-3835

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Dear Sir/Madam:

Reference is made to PFO™-Pure Fish Oil-CardiA-spirin with Nattokinase, marketed by Arkopharma, LLC.

Pursuant to Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act, as codified in 21 U.S.C. 343(r)(6), notification is submitted for structure/function statements made on the following dietary supplement product.

Product Name: Health From The Sea – PFO™ Pure Fish Oil – CardiA-spirin with Nattokinase
Ingredients: Fish Oil, EPA, DHA, Nattokinase NSK-SD™, Lipase Vitamin B₆, Folic Acid, Vitamin B12, Potassium
Company Name/ Address: Arkopharma, LLC
19A Crosby Drive
Suite 300
Bedford, MA 01730-1401

Text of Claims:

1. Health From The Sea CardiA-spirin is a one-of-a-kind formulation combining omega-3 EPA and DHA from molecularly distilled pure fish oil, B vitamins and nattokinase to support healthy heart and cardiovascular function. Nattokinase is a special enzyme (protein) that maintains healthy blood flow by supporting the body's natural ability to respond to and manage blood coagulation (clot formation). Nattokinase also helps maintain healthy blood pressure.
2. The B vitamins help maintain normal homocysteine levels, an important factor for a healthy heart. They, along with the mineral potassium, also help promote healthy blood pressure.
3. Omega-3 Healthy Heart Maintenance

In accordance with 21 CFR 101.93, the disclaimer statement is bolded and boxed on all panels of the label where structure/function claims appear.

The undersigned certifies that the information contained in this notice is complete and accurate and that Arkopharma, LLC, has substantiation that the statements are truthful and not misleading.

As required, the original and two copies of this notification are enclosed. If you have any questions regarding this information, please contact the undersigned at (781) 276-0505.

Sincerely,

Barbara Levenstein, M.S.
Director of New Product Development
Arkopharma, LLC

ARKOPHARMA, LLC dba HEALTH FROM THE SUN
SALES, MARKETING & FINANCE OFFICE
19 Crosby Drive, Suite 300, Bedford, MA 01730 Tel: 781-276-0505 Fax: 781-276-7334/7335
WAREHOUSE & DISTRIBUTION CENTER
22 North Main Street, Newport, NH 03773 Tel: 603-863-8075 Tel: 800-447-2229 Fax: 603-763-9159