



September 30, 2005

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

OCT 17 2005

Dear Sir/Madam:

Reference is made to Organic Flax Oil plus Lignans, 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 Sun® – Organic Flax Oil plus Lignans

Ingredients: Organic Flaxseed Oil, Flax Lignan Complex

Company Name/ Address: Arkopharma, LLC
19A Crosby Drive
Suite 300
Bedford, MA 01730-1401

Text of Claims:

1. SDG (secoisolariciresinol diglycoside) is the principal lignan in flax and is recognized for its highly potent antioxidant properties and health benefits.
2. For the richest source of vegetarian omega-3 fatty acids plus concentrated plant lignans, Organic Flax Oil plus Lignans soft gels offer a simple and convenient way for anyone to add a heart-healthy and immune-supporting boost to their diet.
3. Whole Body Health

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.

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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

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,

A handwritten signature in cursive script that reads "Barbara Levenstein".

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