



a division of Arkopharma

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December 7, 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

41 13 21

Dear Sir/Madam:

Reference is made to The Total EFA for Mature Women (with cod), 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 - The Total EFA for Mature Women (with Cod)

Ingredients: Organic Flaxseed Oil, Flaxseed lignan extract, Black Currant seed oil, Extra Virgin Olive Oil, Olive Leaf extract, Red Wine extract, Vitamins A & D (from cod liver oil)

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

975 0162

LET 17080

Text of Claims:

- 1. Support a healthy heart and healthy breast tissue, immune function, radiant skin and strong bones with this all-in-one essential fatty acid, vitamin, and antioxidant supplement.
2. The Total EFA Special Formula for Mature Women contains essential omega-3 and 6 fatty acids from organic flaxseed and black currant seed oil plus important, heart-healthy fats from olive oil.
3. Red wine extract and olive leaf extract offer antioxidant benefits while plant estrogens in the form of flaxseed lignans (SDG) support immunity and assist the body when hormone levels normally diminish as women mature.
4. Vitamins A and D, naturally found in cod liver oil, complete this formula by adding additional nutrients that women need for healthy immunity, strong bones and more.
5. 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.

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