



December 7, 2005

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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

Dear Sir/Madam:

Reference is made to The Total EFA New & Improved, 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 New & Improved
Ingredients: Fish Oil, Organic Flax Oil, Borage Oil
Company Name/ Address: Arkopharma, LLC
19A Crosby Drive
Suite 300
Bedford, MA 01730-1401

Text of Claims:

- 1. Rediscover the most balanced, comprehensive and complete EFA formula for your family's overall health and well-being with The Total EFA – the new and improved "multi-vitamin of EFAs."
- 2. 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.

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

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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