



a division of
Arkopharma

August 15, 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

AUG 24 2005

Dear Sir/Madam:

Reference is made to The Total EFA Double Action, 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 Double Action

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. The Total EFA Double Action provides the additional health benefits of a super potent fish oil concentrate purified by molecular distillation.
2. The Total EFA Double Action is a comprehensive, complete and well-balanced blend of EFA nutritional oils for your overall health and well-being.
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.

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

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WAREHOUSE & DISTRIBUTION CENTER

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