



MAY 23 P2:38

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May 3, 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

Dear Sir/Madam:

Reference is made to Ultra potent EPA plus Lipase, 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: Ultra potent EPA plus Lipase  
Ingredient: Fish oil concentrate, Lipase  
Company Name/ Address: Arkopharma, LLC  
19A Crosby Drive  
Suite 300  
Bedford, MA 01730-1401

Text of Claims:

1. Omega-3 EPA for Mood support & emotional balance
2. provides you with higher potency omega-3 EPA for a healthy mood and emotional balance, with the added benefits of the enzyme lipase for optimum digestion and absorption.
3. Brain Healthy Omega-3

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 statement is 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**  
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