



December 7, 2005

Notification of statements on Dietary Supplement Labels

JAN -3 P2:29

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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 Organic Flax Oil plus CoQ10, 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 CoQ10

Ingredients: Coenzyme Q10, Organic Flaxseed Oil

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

Text of Claims:

1. Flax oil is one of nature's best vegetarian sources of omega-3 essential fatty acids (EFAs) which are known to support healthy heart function.
2. Coenzyme Q10 is a potent antioxidant and essential nutrient for optimal function of all cell types in the body.
3. It promotes normal heart muscle function and supports a healthy cardiovascular system.
4. Omega-3 Healthy Heart Maintenance

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*

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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