



May 3, 2005

MAY 17 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 Super Potent PFO Pure Fish Oil plus Garlic, 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: Super Potent PFO Pure Fish Oil plus Garlic

Ingredients: Fish oil concentrate, Garlic oil

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

Text of Claims:

1. Omega-3 Healthy Heart Maintenance
2. clinically tested potency of omega-3 EPA and DHA for serious cardiovascular support
3. higher potency omega-3 EPA and DHA nutrition, plus the antioxidant garlic for added cardiovascular support
4. Enteric-coated soft gels prevent aftertaste and promote intestinal absorption for maximum benefit
5. Heart-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

975 0162

LET

16157

**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