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December 7, 2005

Notification of statements on Dietary Supplement Labels

DEC 19 2005

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 Skin & Wrinkle Pearls, 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: Arkopharma – Skin & Wrinkle Pearls

Ingredients: Rice Bran Oil, Soybean Extract (non GMO), Olive Leaf Extract, Sea Buckthorn Berry Extract, Green Tea Leaf Extract

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

Text of Claims:

1. The inactive ingredients in this 'internal cosmetic' help maintain smooth, wrinkle-free skin by protecting against free radical damage which leads to aging of the skin.
2. Supply your skin from the inside out with the nutrients it needs for healthy youthful skin – omega-3 and omega-6 fatty acids, vitamins, minerals, & more.

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

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Barbara Levenstein, M.S.
Director of New Product Development
Arkopharma, LLC

ARKOPHARMA, LLC dba HEALTH FROM THE SUN

SALES, MARKETING & FINANCE OFFICE

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WAREHOUSE & DISTRIBUTION CENTER

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