



December 7, 2005

Notification of statements on Dietary Supplement

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

DEC 19 2005

Dear Sir/Madam:

Reference is made to The Total EFA for Joint Support, 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 for Joint Support
Ingredients: Glucosamine (D-Glucosamine HCL), ASU (Avocado Soybean Unsaponifiables)
Fish Oil Concentrate, Black Currant Seed Oil
Company Name/ Address: Arkopharma, LLC
19A Crosby Drive
Suite 300
Bedford, MA 01730-1401

Text of Claims:

1. Health From The Sun The Total EFA for Joint Support is a special combination of omega-3 and 6 essential fatty acids (EFAs) plus specific nutrients shown to support healthy joint function.
2. One of these special nutrients is ASU (Avocado Soybean Unsaponifiables), a unique research-backed natural ingredient shown to promote joint health and integrity.
3. These nutrients all help to maintain healthy cartilage.
4. The daily dose of The Total EFA for Joint Support provides the amounts of glucosamine and ASU shown to support joint flexibility, mobility and comfort.
5. Joint Support

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

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