



September 30, 2005

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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

OCT 17 2005

Dear Sir/Madam:

Reference is made to The Total EFA for PMS 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 PMS Support

Ingredients: Organic Flaxseed Oil, Evening Primrose Seed Oil, Fish Oil Concentrate, Indole-3 Carbinol, Flaxseed lignan extract, Vitex Agnus, Vitamin B6 and E, Magnesium

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

Text of Claims:

1. The Total EFA Special Formula for PMS Support helps balance hormones and provides the essential fatty acids that the body needs daily.
2. The Total EFA Special Formula for PMS Support contains organic flaxseed oil, evening primrose oil and molecularly distilled fish oil concentrate to provide an ideally balanced fatty acid profile for whole body health and a healthy mood.
3. Indole-3 Carbinol helps maintain healthy breast tissue by promoting proper estrogen metabolism, while flaxseed lignans (SDG) and vitex agnus (chaste tree) help the body adjust to hormonal fluctuations.
4. The addition of magnesium and vitamin B6 and E make the Total EFA Special Formula for PMS Support a true all-in-one supplement for diminishing the unpleasant symptoms of PMS.
5. Hormonal Balance

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.

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

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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,

A handwritten signature in cursive script that reads "Barbara Levenstein".

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