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May 30, 2001

Food and Drug Administration  
Office of Nutritional Products Labeling and Dietary Supplements (HFS-810)  
Center for Food Safety and Applied Nutrition  
200 C Street, SW  
Washington, D.C. 20204

Dear Sirs:

Notice is hereby given pursuant to the requirements of section 403(r)(6) (21 U.S.C. 343(r)(6)) of the Federal Food, Drug, and Cosmetic Act and in accordance with the requirements of 21 CFR 101.93, that Arkopharma/Health From The Sun, 22 N. Main St. Newport, NH 03773, within the past 30 days commenced marketing a dietary supplement bearing the following statements on the label and/or in the labeling:

Text of Claims:

1. supports normal menstrual function
2. help your body go through the menstrual period smoothly

Name of Ingredients Subject to Claim: Evening Primrose Oil, Fish Oil, Vitex agnus castus, Vitamin E, Vitamin B6, Calcium, Magnesium

Name of Supplement: BIO-EFA PMS Formula

The undersigned certifies that the information contained in this notice is complete and accurate and that Arkopharma/Health From The Sun has substantiation that the statement is truthful and not misleading.

Sincerely,

Christian Seyrig  
Senior Vice-President

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LET. 8103

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