

Hebruary 2, 2001 MAR -8 P12:07



Office of Nutritional Products Labeling and Dietary Supplements Division of Compliance and Enforcement Dietary Supplements Branch (HFS-811) Food and Drug Administration 200 "C" St. S.W. Washington, D.C. 20204

To Whom It May Concern:

Nature's Way Products, Inc. wishes to notify the Food and Drug Administration that it has, within the past 30 days, commenced marketing a dietary supplement which bears a statement under Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act.

The dietary supplement for which the statement is made is Femaprin. The dietary ingredients that are the subject of the statement are Vitex Extract and Vitamin B-6. The statement reads as follows:

"Regulates Menstrual Cycle. Femaprin is the most widely used supplement for balancing a women's monthly cycle and for the avoidance of periodic discomforts. Trusted for over 40 years by European health practitioners, Femaprin's unique formula contains clinically proven standardized Vitex (Chaste Tree) extract with Vitamin B-6 to help alleviate the bloating breast tenderness and mood changes associated with premenstrual syndrome (PMS)."

This statement is accompanied by the required disclaimer which is prominently displayed in bold-faced type.

The information contained in this notice is complete and accurate and the above statement is based on data which renders these statements substantiated, truthful and non-misleading.

Sincerely,

NATURE'S WAY PRODUCTS, INC.

Gordon M. Walker General Counsel

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