

Food and Drug Administration
Office of Nutritional Products, Labeling & Dietary Supplements (HFS-810)
5100 Paint Branch Parkway
College Park, MD 20740

February 9, 2005

RE: Dietary Supplement Claims Notification

Dear Sir/Madam:

This letter is to notify the Food and Drug Administration (FDA) that the following product is manufactured, packed and/or distributed by Hillestad Pharmaceuticals at 178 US Highway 51N, Woodruff, WI 54568.

This notification is being provided pursuant to 21 U.S.C. 343(r)(6) and 21 CFR 101.93(a).

Product Name: **PMS Formula**

The following statement(s) are or may be used on the labels or in the labeling of the product:

" Hillestad's PMS Formula provides nutritional support that may help alleviate common symptoms associated with women's normal menstrual cycle."

I certify that the information in this notice is complete and accurate and that Hillestad Pharmaceuticals has substantiation that the statements are truthful and not misleading.

Sincerely,



Dan Hillestad
President

975 0162

LET

15720

HOME OFFICE:

Hillestad Pharmaceuticals U.S.A.
178 U.S. Highway 51 North
Woodruff, Wisconsin 54568-1700

MAILING ADDRESS:

Hillestad Pharmaceuticals U.S.A.
P.O. Box 1700
Woodruff, Wisconsin 54568-1700

(715) 358-2113 • 1-800-535-7742

(715) 358-7812 (FAX)

hill@newnorth.net (E-mail)

www.hillestadlabs.com