

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

February 10, 2005

RE: Dietary Supplement Claims Notification

MAR - 2 2005

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: **B12 - 250 with Folic Acid**

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

"Vitamin B12 has numerous important functions in the human body. Individuals on a vegetarian diet may consider B12 supplementation to increase their intake of this vitamin."

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

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HOME OFFICE:

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

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