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

NOV - 4 2005

October 25, 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: **Chewable B12, B6 & Folic Acid**

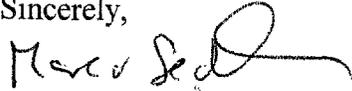
The following statement(s) are or may be used on the labels and in the labeling of the product:

- *"Vitamin B12, B6 and Folic Acid are powerful factors to help maintain cardiovascular health."*
- *"a combination of nutrients, which support healthy heart and blood vessel function"*
- *"Methylcobalamin is active in the body immediately upon absorption while the cyanocobalamin form must be converted to an active form prior to utilization."*
- *"Numerous studies suggest that Vitamin B12, Vitamin B6 and Folic Acid play an important role in regulating homocysteine levels in the body."*
- *Vitamin B12, B6 as well as Folic Acid each are key players in the human body, involved in countless functions, e.g., in the nervous system and the immune system, in the formation of hemoglobin (a crucial component of red blood cells), in the release of energy resources from muscle and liver tissues, in the metabolism of amino acids, and in the synthesis of DNA and proteins.*

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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,



Dr. Marco Sedelis
Vice President

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