

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

February 18, 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: **Valerian Root**

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

*"May be effective for the relief of occasional sleeplessness"*

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

97S 0162

LET

15770