

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

MAR - 2 2005

February 22, 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: **Hi-Loss**

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

"Hillestad is keeping up with research in offering Hi-Loss, a product that is designed to aid in weight loss. If you intend to lose extra pounds, try adding Hi-Loss to your supplement regimen. Use this product in conjunction with a sensible diet and exercise program."

"weight control"

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:

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