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JAN 24 2005

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

January 14, 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: **Opti-Cran**

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

*"Opti-Cran supports a healthy urinary tract, containing freeze-dried cranberries equal to 2.4 grams of harvested fresh cranberries."*

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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