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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

May 20, 2005

MAY 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: **Z23**

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

- *"Zinc is an essential mineral in the prostate gland function."*
- *"In proper dosage, zinc has even been shown to enhance immune response."*
- *"Supports healthy prostate function"*

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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