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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

RE: Dietary Supplement Claims Notification

MAY 25 2005

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: **Dialyvite®**
Dialyvite® with Zinc
Dialyvite® 3000
Dialyvite® 800
Dialyvite® 800 with Zinc
Dialyvite® 800 with Zinc 15
Dialyvite® 800 with Iron

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

- "Supplementing your diet with the right vitamins may help support general health."
- "Renal Multi-vitamins are specifically formulated to suit the nutritional needs of dialysis patients."
- "Folic Acid is good for your cardiovascular system as it helps maintain healthy blood vessels."
- "Supplementation with zinc can also be beneficial to your health."
- "Zinc has antioxidant properties and is involved in normal taste sensitivity. It also plays a vital role in the immune system and may support prostate health in men."
- Dialyvite® 3000: "also contains natural Vitamin E and Selenium, which have antioxidant properties and aid in maintaining a healthy heart and vascular system."

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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,



Dan Hillestad
President

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Hillestad Pharmaceuticals U.S.A.
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