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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

OCT 17 2005

October 04, 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: **Hawthorn Berries**

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

- *"Hawthorn Berries are rich in bioflavonoids."*
- *"Bioflavonoids are a group of biologically active substances widely found in plants and functioning in the maintenance of the walls of small blood vessels."*
- *"Hawthorn berries can provide some of those ingredients (biologically active substances) to keep the walls of the small blood vessels in perfect maintenance."*
- *"Hawthorn Berries may help support a healthy cardiovascular system."*

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,

  
Dr. Marco Sedelis  
Vice President

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**HOME OFFICE:**

Hillestad Pharmaceuticals U.S.A.  
178 U.S. Highway 51 North  
Woodruff, Wisconsin 54568-1700

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