


Body Wise International, Inc.
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Office of Nutritional Products
Labeling and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
5100 Paint Branch Pkwy.
College Park, MD 20740

RE: Notification of statements on a dietary supplement known as, Male Advantage™.

October 20, 2003

Dear Ladies/Gentlemen;

Pursuant of 21 C.F.R. Subpart F, section 101.93, Body Wise International, Inc. ("Body Wise" the distributor, which is located at 2802 Dow Avenue, Tustin, CA 92780) wishes to notify the Food and Drug Administration that it has commenced marketing a dietary supplement known as Male Advantage™ which includes statements of nutritional support in it's labeling.

The following statements are being made for the dietary supplement known as Male Advantage™.

- Male Advantage™ is an advanced nutritional supplement that may provide immediate and long-term health benefits. It combines such remarkable ingredients as Saw Palmetto, Bromelain, Damiana Leaf, Korean Ginseng Root, and Eleuthero Root. This formulation is an exciting breakthrough in superior nutritional value. It can help your body manage stress as well as maintain a healthy heart, immune system, and prostate.
- Saw Palmetto Supports prostate health and function.
- Pygeum Extract Helps support healthy prostate tissue.
- Pumpkin Seeds Contains zinc and essential fatty acids, which may help support a healthy prostate gland.
- Echinacea Supports a healthy immune system.
- Male Advantage™ helps support a healthy prostrate, cardiovascular system, and overall male health. (Addressed by the ingredients: Zinc, Saw Palmetto Berry Fruit Extract, Alpha-Ketoglutaric Acid, Flax Seed, Pumpkin Seed, Siberian Ginseng Root, Eleuthero Root, Turmeric Root Extract, Damiana Leaf and Stems, L-Alanine, L-Glutamic Acid, Glycine, Pygeum Africana Bark Extract, Gotu Kola, and Bromelain.)

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The above statements are accompanied by the required disclaimer, which is prominently displayed in a box in boldfaced type.

The information contained in this notice is complete and accurate. Body Wise maintains on file substantiation that these statements are truthful and non-misleading.

An original and two copies of this notification are being submitted.

Sincerely,



Alan E. Huffington
Director of Regulatory Affairs

dw/AEH

Enclosures: Two copies of this two-page letter.