



Body Wise International, Inc.
2802 Dow Avenue
Tustin, California 92780

Tel: 714-505-6121
Fax: 714-832-5315

6932 '03 REC 10 12:06

NOV 13 2003

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, Enhance-Rx™.

October 23, 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 Enhance-Rx™. Formula which includes statements of nutritional support in it's labeling.

The following statements are being made for the dietary supplement known as Enhance-Rx™.

- Enhance-Rx™ Enhancing human intimacy. (Addressed by the ingredients: Niacin, Muira Puama Root Extract, L-Arginine, Ashwagandha Root Extract, Ginkgo Biloba Leaf Extract, Oat Straw Concentrate, Damiana Leaf Extract, Mucuna Pruriens Seed Extract, Nettle Root Extract, Tribulus Terrestris Fruit Extract, Korean Ginseng Root Extract, Horny Goat Weed Aerial Parts, Catuaba Bark, and Siberian Ginseng Root Extract.)
- Enhance-Rx™ is the preferred herbal combination available for men and women with low-desire or sexual dysfunction. Herbs such as Muira puama and Tribulus terrestris can support sexual health and function. Korean and Siberian ginseng promote energy levels, increase stamina, and reduce stress. Ginkgo biloba helps promote blood flow to all extremities. Damiana-traditionally used as an aphrodisiac-is another important addition to any libido enhancement formula. It is believed to support the male and female hormonal system and maintain a healthy mood. Arginine and horny goat weed are included in the formula to help support libido.
- Enhance-Rx™ helps maintain a healthy sex life by supporting healthy

975 0162

LET

13300

hormone and energy levels, blood flow, and sexual desire and enjoyment. (Addressed by the ingredients: Niacin, Muira Puama Root Extract, L-Arginine, Ashwagandha Root Extract, Gingko Biloba Leaf Extract, Oat Straw Concentrate, Damiana Leaf Extract, Mucuna Pruriens See Extract, Nettle Root Extract, Tribulus Terrestris Fruit Extract, Korean Ginseng Root Extract, Horny Goat Weed Aerial Parts, Catuaba Bark, and Siberian Ginseng Root Extract.)

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.