



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

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

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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, Xtreme™.

October 22, 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 Xtreme™ which includes statements of nutritional support in it's labeling.

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

- Xtreme™ is designed for the X-Generation. It combines high-quality nutrition with adaptogenic herbs. People at younger ages often burn the candle at both ends, combining long hours with late nights. Xtreme helps you deal with these various lifestyle issues while providing a strong foundation of nutritional support. (Addressed by the ingredients: Beta Carotene, Vitamin C Vitamin D, Vitamin E, Vitamin B1, Vitamin B2, Niacin, Vitamin B6, Folic Acid, Vitamin B12, Biotin, Pantothenic Acid, Calcium, Phosphorus, Iodine, Magnesium, Zinc, Selenium, Copper, Manganese, Chromium, Molybdenum, Sodium, Potassium, Ciwujia Root, Trace Minerals, Ginkgo Biloba Leaf, Korean Ginseng Root, Gotu Kola, Ginger Root, Ashwagandha Root Extract, Reishi Mushroom, Suma Root, Codonopsis Root, Wild Yam Root, and Alpha-Ketoglutaric Acid.)
- Korean Ginseng May help increase energy.
- Ashwagandha Shown to support a healthy immune system.
- Xtreme™ was designed to support the health needs of teens and young adults. (Addressed by the ingredients: Beta Carotene, Vitamin C Vitamin D, Vitamin E, Vitamin B1, Vitamin B2, Niacin, Vitamin B6, Folic Acid, Vitamin B12, Biotin, Pantothenic Acid, Calcium, Phosphorus, Iodine, Magnesium, Zinc, Selenium, Copper, Manganese, Chromium,

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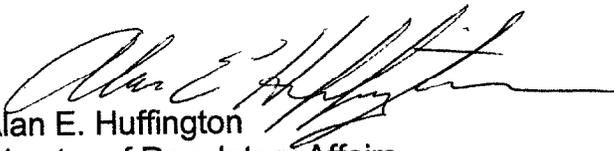
Molybdenum, Sodium, Potassium, Ciwujia Root, Trace Minerals, Ginkgo Biloba Leaf, Korean Ginseng Root, Gotu Kola, Ginger Root, Ashwagandha Root Extract, Reishi Mushroom, Suma Root, Codonopsis Root, Wild Yam Root, and Alpha-Ketoglutaric Acid.)

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.