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10/29/03

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, Oxy-G2®.

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 Oxy-G2® which includes statements of nutritional support in it's labeling.

The following statements are being made for the dietary supplement known as Oxy-G2®.

- **Oxy-G2®** A breath of fresh air for your cells. (Addressed by the ingredient: Germanium Sesquioxide-Ge-132.)
- **Oxy-G2®** supplies several nutritional ingredients that have been shown to support the immune system. Ingredients such as Germanium Sesquioxide-Ge-132 may be helpful in supporting cellular health by carrying oxygen and maintaining an alkaline tissue environment. (Addressed by the ingredients: Beta Carotene, Vitamin C, Vitamin E, Pantothenic Acid, Selenium, Molybdenum, Germanium Sesquioxide-Ge-132, Ginkgo Biloba, Milk Thistle Seed Extract, Echinacea Purpurea, Cytochrome C Oxidase, Gamma Oryzanol, L-Glutathione, Ascorbyl Palmitate, L-Cysteine, L-Tyrosine, and Pau D'Arco.)
- **Cytochrome C Oxidase** Increases the oxygen in each cell and retards lactic acid formation.
- **Germanium** Supports the immune system; normalizes body function; exhibits oxygen-sparing effects. (Addressed by the ingredient: Germanium Sesquioxide-Ge-132.)

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

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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,

A handwritten signature in black ink, appearing to read "Alan E. Huffington", written over a horizontal line.

Alan E. Huffington  
Director of Regulatory Affairs

dw/AEH

Enclosures: Two copies of this two-page letter.