Innovation



Marketing

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Quality

Science

June 4, 2001

Food and Drug Administration Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition 200 C Street, SW Washington, DC 20204

Dear Sirs:

Notice is hereby given pursuant to Section 403(r)(6) (21 U.S.C. § 343(r)(6)) of the Federal Food, Drug, and Cosmetic Act -that Richardson Labs, Inc. ("Richardson"), located at 6111 Broken Sound Parkway, N.W., Boca Raton, Florida 33487 has marketed a dietary supplement bearing the following statement(s) on the label and/or in the labeling:

<u>TruSoy[™] Soy Menopause Formula</u>: Natural support for hormonal balance.

<u>TruSoy[™] Calcium 600mg + Soy</u>: [It] maintains good bone health. [It] supports hormonal balance. [It] promotes cardiovascular health. TruSoy Calcium + Soy is an advanced formula developed to help women maintain their health during the natural changes associated with menopause. [It] combines optimal levels of: calcium, vitamin D, magnesium and soy isoflavones to promote healthy bones; natural plant estrogens from non-GMO soy and Protykin® transresveratrol to maintain normal hormonal balance; magnesium and Protokyn transresveratrol to promote cardiovascular health.

The undersigned certifies that the information contained in this notice is complete and accurate and that Richardson has substantiation that the statement is truthful and not misleading. Pursuant to 101.93 (a)(1), two copies of this notification are enclosed.

Sincerely,

Debaraa Shew Grinker

Deborah Shur Trinker, Esq. Senior Vice President Regulatory Affairs

Enclosure

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