

December 19, 2002

Office of Nutritional Products, Labeling and

JAN 23

Dietary Supplements (HFS-810)

Food and Drug Administration

Center for Food Safety and Applied Nutrition

5100 Paint Branch Pkwy College Park, MD 20740

Dear Sirs:

Notice is hereby given pursuant to the requirements of section 403(r)(6) (21 U.S.C. 343(r)(6)) of the Federal Food, Drug and Cosmetic Act and in accordance with the requirements of 21 CFR 101.93 that Millennium Biotechnologies, Inc., 665 Martinsville Road, Suite 219, Basking Ridge, New Jersey 07920 has commenced marketing a dietary supplement bearing the following statements on the label:

Name of Supplement:

**PROSURGEXTM** 

Structure/Function Claims: Increases Energy

Maintains Lean Muscle Reduces Oxidative Stress Immune Function Support

Name of Ingredients That Are Subject of Claim: Vitamin A, Vitamin C, Thiamin, Riboflavin, Niacinamide, Calcium, Magnesium, Vitamin D, Vitamin E, Vitamin B6, Folic Acid, Vitamin B12, Iodine, Zinc, Copper, Biotin, Pantothenic Acid, Chromium, Selenium, Ornithine Ketogluterate, Leucine, Ribose, Glutamine, Lecithin, Isoleucine, Valine, Lysine, I-Carnitine, Medium Chain Triglycerides, Superoxide Dismutase, Beta Glucans, Nucleotides, Coenzyme Q 10, Fruit Polyphenols, Undenatured Whey Protein, Oat Bran, Rice Fiber, Cereal Solids, Soy Oil, Canola Oil, Casein, Milk Protein, Black Bean Powder, Flax Oil

The undersigned certifies that the information contained in this notice is complete and accurate and that Millennium Biotechnologies, Inc. has substantiation that the statements are truthful and not misleading.

Sincerely,

Carl Germano, RD, CNS, CDN

Sr. VP Research & Product Development

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