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Food and Drug Administration  
Office of Nutritional Products, Labeling and Dietary Supplements  
(HFS-810)  
Center for Food Safety and Applied Nutrition  
5100 Paint Branch Pkwy  
College Park, MD 20740

11/15/03

Dear Sir/Madam:

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 within the past 30 days commenced marketing a dietary supplement bearing the following statement(s) on the label and/or in the labeling:

**TEXT OF CLAIM(S):**

The first orally effective, vegetarian form of superoxide dismutase.  
Providing optimum antioxidant defense.

**NAME OF INGREDIENT(S) THAT IS SUBJECT OF CLAIM:**

Superoxide Dismutase

**NAME OF SUPPLEMENT (INCLUDING BRAND NAME):**

Defenzyme™

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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