

# DSM Nutritional Products, Inc.



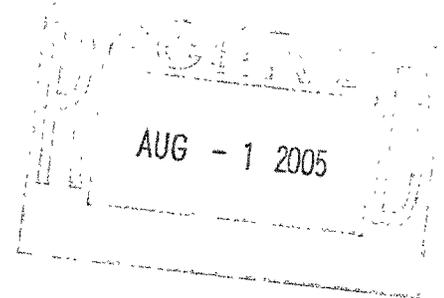
45 Waterview Boulevard, Parsippany, New Jersey 07054-1298

July 22, 2005

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**CERTIFIED MAIL**  
**Return Receipt Requested**

Office of Nutritional Products, Labeling and  
Dietary Supplements, HFS 810  
Center for Food Science and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740



RE: Label claims

Pursuant to Section 403 (r)(6) of the Federal Food, Drug and Cosmetic Act, as codified in 21 U.S.C. 343 (r)(6), notification is herewith submitted for structure/function statements made on the following dietary supplement product.

Product Name: Bonistein™  
Ingredient: Genistein

**Text of Claims:**

In accordance with 21 CFR 101.93, the disclaimer statement is bolded and boxed on all panels of the label where structure/function claims appear.

These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

**Bonistein™ helps maintain bone health.**

**Bonistein™ helps maintain healthy bone density.**

**Bonistein™ helps maintain bone mineral density and bone mineral composition.**

**Bonistein™ is a potent antioxidant.**

**Bonistein™ helps maintain a healthy heart and cardiovascular system function.**

**Bonistein™ helps maintain healthy bones.**

**Bonistein™ helps maintain prostate health.**

**Bonistein™ helps maintain a healthy prostate.**

**Bonistein™ helps maintain bone health in postmenopausal women.**

**Bonistein™ helps maintain bone mineral density and bone mineral composition in postmenopausal women.**

**Bonistein™ helps maintain healthy bone density in postmenopausal women.**

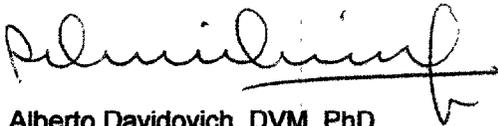
**Bonistein™ helps maintain healthy bones in postmenopausal women.**

975 0162 LET 16566

I certify that the information contained in this notice is complete and accurate and that DSM Nutritional Products, Inc, has substantiation that the statements are truthful and not misleading.

As required, the original and two copies of this notification are enclosed. Please contact the undersigned at (973) 257 8325 if you have any questions regarding this notification

Sincerely,

A handwritten signature in black ink, appearing to read "Al Davidovich", with a horizontal line extending from the end of the signature.

Alberto Davidovich, DVM, PhD  
Director Regulatory Affairs  
DSM Nutritional Products, Inc.