



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

NOV 21 2000

Ona Scandurra, MS, RD
Director of Nutrition Communications
NBTY, Inc.
90 Orville Drive
Bohemia, New York 11716-2510

0198 '00 DEC -7 P3:07

Dear Ms. Scandurra:

This is in response to your letter of October 30, 2000 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that NBTY Inc. is making the following claim, among others, for the product **GarliChrome**:

“...helps retain normal cholesterol levels.”

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to treat, prevent, or mitigate disease. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if you require further assistance.

Sincerely,

John B. Foret
Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

975-0163

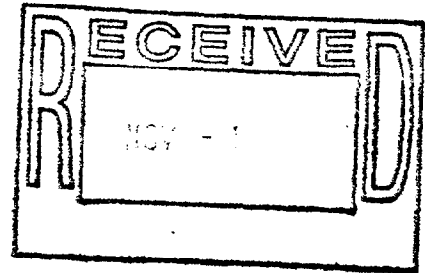
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90 Orville Drive, Bohemia, NY 11716-2510 ■ Phone: (631) 567-9500 ■ Fax: (631) 218-7480

October 30, 2000

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



Dear Sir or Madam:

This letter will serve as a 30 day notification pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994 that NBTY Inc. is using the following statements on our GarliChrome supplement under one or more of the following brand names: American Health, Body Fortress, Good 'N Natural, Health's Finest, Heartland, Herbal Authority, Herbal Harvest, Herbal Sure, Hudson, Life's Finest, Natural Wealth, Nature's Bounty, Nutrition Headquarters, Nutrition Warehouse, Precision Engineered, Puritan's Pride, Select Herbal, US Nutrition, Vitamin World:

- Ginkgo Biloba helps maintain healthy circulation.
- Garlic helps retain normal cholesterol levels.

The above statements are accompanied by the required disclaimer pursuant to Section 6 of the Dietary Supplement Health and Education Act.

Sincerely,

Ona Scandurra, MS, RD
Director of Nutrition Communications

OS/ab

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