



AUG - 8 2001

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

Dear Ms. Scandurra:

This is in response to your letters to the Food and Drug Administration (FDA), dated July 9, 2001, 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 claims, among others, for the following products:

**Butcher's Broom supplements:**

"...affecting the valves and causing a backup of fluid"

**White Willow Bark supplements:**

"Helps treat occasional pain"

"...helps alleviate minor pain, especially occasional...joint aches"

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 statements that you are making for these products suggest that they are intended to treat, prevent, or mitigate diseases, namely edema associated with vein disorders and pain associated with joint disorders. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are 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.


975-0163

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Please contact us if we may be of further assistance.

Sincerely,



*for* Robert M. Foret

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

Copies:

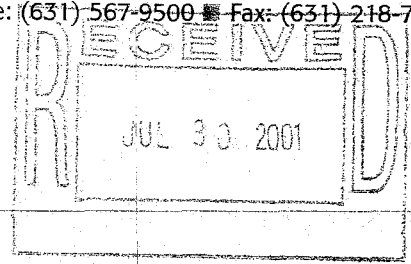
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200

FDA, New York District Office, Compliance Branch, HFR-NE140



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



Office of Nutritional Products/Labeling & Dietary  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C Street, SW (HFS-810)  
Washington, D.C. 20204

July 9, 2001

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 Butcher's Broom supplements under one or more of the following brand names: American Health, Bioenergy Nutrients, Body Fortress, Good 'N Natural, Health's Finest, Heartland, HealthSmart Vitamins, HealthWatchers, Herbal Authority, Hudson, Life's Finest, Natural Wealth, Nature's Bounty, Nutrition Headquarters, Nutrition Warehouse, Physiologics, Precision Engineered, Puritan's Pride, US Nutrition, Vitamin City and Vitamin World:

- Promotes Leg Vein Health
- Supports Leg Vein Health
- The system of veins in your legs is active and dependent on tone.
- As we age, the connective tissue in the vein wall can stretch, affecting the valves and causing a backup of fluid.
- *Ruscus* extracts enhance venous tone by promoting smooth muscle contraction in veins.
- Used for centuries to promote leg vein health, studies indicate that Butcher's Broom (*Ruscus aculeatus*) helps relieve the itching, tingling and cramping caused by occasional discomfort occurring in the lower extremities, especially during mid-life.

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

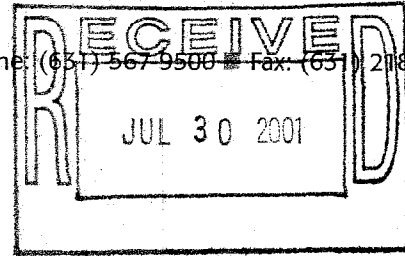
Director of Nutrition Communications

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July 9, 2001

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 White Willow Bark supplements under one or more of the following brand names: American Health, Bioenergy Nutrients, Body Fortress, Good 'N Natural, Health's Finest, Heartland, HealthSmart Vitamins, HealthWatchers, Herbal Authority, Hudson, Life's Finest, Natural Wealth, Nature's Bounty, Nutrition Headquarters, Nutrition Warehouse, Physiologics, Precision Engineered, Puritan's Pride, US Nutrition, Vitamin City and Vitamin World:

- Helps Treat Occasional Pain
- White Willow Bark contains important constituents, including salicin, a natural substance that provides a holistic solution to today's physical lifestyles.
- Used as a supplement, White Willow Bark helps alleviate minor pain, especially occasional muscle and joint aches.

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/lt

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