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

Dear Ms. Scandurra:

This is in response to your letter of January 13, 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 **Borage Oil**:

“Gamma-Linolenic Acid is a precursor to prostaglandins which help decrease the stickiness of platelets in blood.”

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, namely stroke and recurrent heart attack¹. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests 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.

¹See the discussion on the claim “inhibits platelet aggregation” in paragraph 41 in the preamble to the final rule published in the January 6, 2000 Federal Register (65 FR 1000 at 1016).

975-0163

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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

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, Office of Compliance, HFR-NE140

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-456 (file)

HFS-450 (r/f, file)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-605

HFV-228 (Benz)

GCF-1 (Dorsey, Barnett, Nickerson)

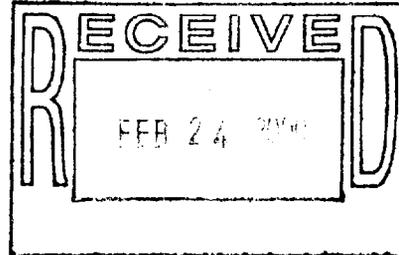
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90 Orville Drive, Bohemia, NY 11716-2510 ■ Phone: (516) 567-9500 ■ Fax: (516) 567-1953

January 13, 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 statement on our Borage Oil supplement under one or more of the following brand names: American Health, Body Fortress, Good 'N Natural, Health's Finest, Heartland, Hudson, Life's Finest, Natural Wealth, Nature's Bounty, Nutrition Headquarters, Nutrition Warehouse, Puritan's Pride, US Nutrition, Vitamin World:

Gamma-Linolenic Acid (GLA) is a precursor to prostaglandins, action-specific bio-molecules that regulate many important functions in cells. Gamma-Linolenic Acid is a precursor to prostaglandins which help decrease the stickiness of platelets in blood.

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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