DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

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SEP 17 2001

Mr. Michael A. Pelton
Vice President
Biotech Corporation
107 Oakwood Drive
Glastonbury, Connecticut 06033

Dear Mr. Elton:

This is in response to your letter of July 10, 2001 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 Biotech Corporation is making the following claims, among others, for the product **VenaFit™**:

> "(to) help improve leg vein circulation and...its associated discomfort"
> "Minimize varicose...veins..."

We also are aware that the product label for this product includes the following claim that is subject to the notification requirement in the Act that you did not include in your submission:

> "...help improve leg vein circulation as well as protect against swelling, and its associated discomfort."

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 this product suggest that it is intended to treat, prevent, cure, or mitigate diseases, namely disorders of venous circulation, including varicose veins. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims 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.

975-0163

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Please contact us if we may be of 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 England District Office, Office of Compliance, HFR-NE240

BIOTECH CORPORATION

July 10, 2001

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

Re: Notification of DSHEA nutritional support claim for Biotech Corporation, Inc., VenaFit Dietary Supplement

Dear Sir or Madam:

The purpose of this letter is to provide notification pursuant to section 403 (r)(6) of the Federal Food, Drug, and Cosmetic Act ("the Act") and 7 C.F.R. § 101.93 that Biotech Corporation, Inc., is marketing a dietary supplement that bears a statement of nutritional support as defined in section 403 (r)(6) of the Act.

The labeling for VenaFit bears the following statements:

"Healthy leg formula"

"promotes proper leg circulation and health"

"natural leg health supplement"

"(to) help improve leg vein circulation and . . . its associated discomfort"

"minimize varicose/spider veins and increase venous efficiency for optimal vein health"

"promotes health"

Biotech Corporation, Inc. has on file substantiation that the above statements are truthful and not misleading. To the best of my knowledge, the information contained in this notice is complete and accurate.

Sincerely,

Michael A. Pelton
Vice President

107 OAKWOOD DRIVE
GLASTONBURY
CONNECTICUT
0 6 0 3 3

PHONE 860 633 8111
888 SHEN MIN
FAX 860 682 6863

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The Nutraceutical Product Leader

VenaFit™

Supplement Facts

Serving Size: 1 tablet

	Amount per Serving	% Daily Value
Horse Chestnut Standardized Extract (18%-22% Aescin) (Aesculin Free)	280mg	†
Niacin (As Nicotinic Acid)	20mg	†
Ginkgo Leaf Powder	250mg	†
Garlic 5:1 Standardized Extract	100mg	†
Hawthorne Berries Standardized Extract	100mg	†
Ginger Root Powder	100mg	†
Citrus Bioflavonoids	100mg	†

†Daily Value not established.

DIRECTIONS FOR USE: As a dietary supplement, take (1) tablet (2) times daily. Research shows that effectiveness is reached after 4-6 weeks of use and sustained with continuous use. Always consult your physician before taking any nutritional product.

PRECAUTION: Not for use by pregnant/lactating women.

Store at room temperature.

"These statements have not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent any disease.

Store at room temperature.

Manufactured Exclusively for:

BIOTECH CORPORATION

107 Oakwood Drive
Glastonbury, CT 06033 U.S.A.
800-774-3664 Consumer Hot Line
Visit us on the web at www.Biotechcorp.com

VenaFit™ NEW HEALTHY LEG FORMULA

100% NATURAL LEG HEALTH SUPPLEMENT

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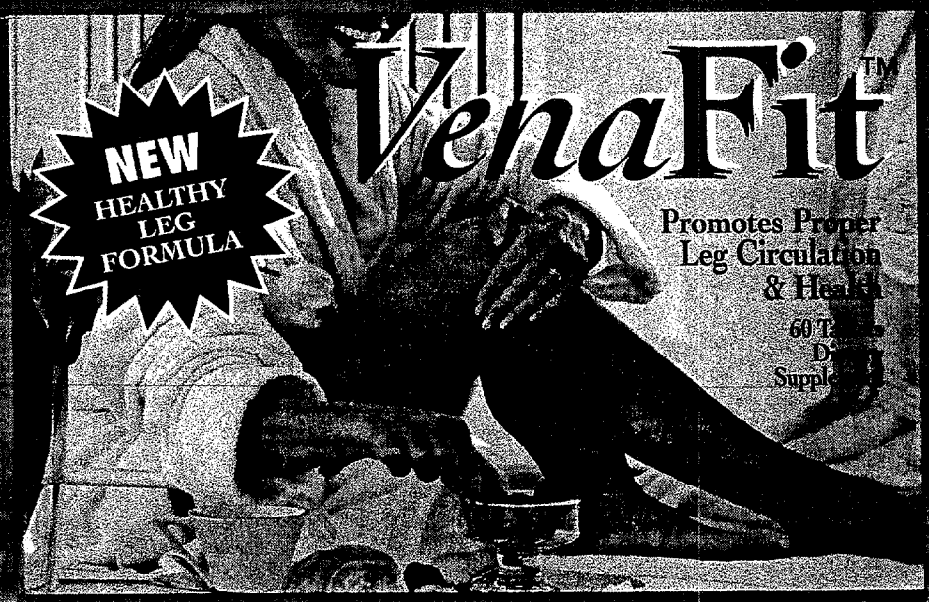
VenaFit™ NEW HEALTHY LEG FORMULA

100% NATURAL LEG HEALTH SUPPLEMENT



VenaFit™

Promotes Proper Leg Circulation & Health

60 T... Di... Suppl...

NEW HEALTHY LEG FORMULA

VenaFit™

LEG HEALTH SUPPLEMENT

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100% NATURAL LEG HEALTH SUPPLEMENT