DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

NOV - 5 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 October 8, 2001 to the Food and Drug Administration (FDA). Your letter responded to our letter of September 17, 2001 concerning claims that you intended to make pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)) for your product **VenaFit™**.

In your letter, you indicated that you intended to change the claim in your product labeling to "help maintain healthy leg vein circulation." This claim appears to be a claim that may be made in the labeling of a dietary supplement pursuant to 21 U.S.C. 343(r)(6) and we have no further comment on it.

You also asked whether the statement "for more attractive legs" would be a claim pursuant to 21 U.S.C. 343(r)(6) or a claim that describes a product defined in 21 U.S.C. 321(i). Based on the information you have provided, this claim does not appear to be a claim defined in 21 U.S.C. 343(r)(6), nor does it appear to be a claim that describes a product defined in 21 U.S.C. 321(i). Such a claim could be made for a dietary supplement if the manufacturer has substantiation that it is truthful and not misleading.

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

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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

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October 8, 2001

John B. Foret
Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling and Dietary Supplements
Center for Food Safety and Applied Nutrition
Food and Drug Administration
Washington DC 20204

Dear Mr. Foret,

We are in receipt of your letter dated September 17, 2001, regarding our product Vena Fit™ and its submitted structure/function claims. We think it first important to note that on the advice of counsel we had already made changes to the labeling of this product to bring it into what we believed to be compliance with DSHEA. Hence, the slight differences in our submission versus your noted awareness of different labeling on a product you saw. I do inquire where you saw that product, as we had made changes to the label version you were aware of. Not that it is of any particularly relevance.

In light of your letter, we agree to change the labeling on VenaFit™ to read the following (or something within the same context given graphic limitations on our packaging):

"Help maintain healthy leg vein circulation"

We also request an advisory opinion on whether the additional phrase, alone or in conjunction with the above, "For more attractive legs", fits within the legal boundaries of DSHEA. We think this particular claim to be truthful and not misleading, and substantiated by the research on the ingredients in VenaFit. However, we are not sure if the FDA would consider this a structure/function claim of the formula, or a cosmetic claim falling under another section of the Act. We believe it to be a fact resultant of the ingestion of the product. Your opinion would be greatly appreciated.

Once again, thank you for your letter and direction. We are always pleased to receive information that makes us a better company.

Sincerely,

Michael A. Pelton
Vice President