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JUN 12 2002

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

Dear Mr. Pelton:

This is in response to your letter of May 29, 2002 to the Food and Drug Administration (FDA) responding to our May 1, 2002 letter concerning the claims being made for the product **Prostate Gold**.

In your letter, you proposed to change the claim being made for your product to:

- “Help support a healthy prostate;”
- “Help maintain normal urinary function;” and
- “Help maintain healthy sexual functioning.”

The replacement of the claim cited in our previous letter with the claims listed above appears to resolve the issues we raised in that letter and we have no further comment on the claims you intend to make for **Prostate Gold**.

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

BIOTECH CORPORATION

May 29, 2002

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6/4/02

John 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
College Park, MD 20740

RECEIVED
JUN 03 2002
BY:

Dear Mr. Foret,

I am in receipt of your letter of May 1, 2002, regarding your objection to our labeling of our Prostate Gold product. The claim you rejected was:

“ . . . Lessen nocturnal urination and help restore normal function . . . “

While we believe the statement to be true and substantiated, we understand your position that the statement could be read as suggesting the product is a treatment of a disease. We have no problem changing the label claim. We would like your opinion on the following to see if you believe any or all of these meet the requirement of DSHEA:

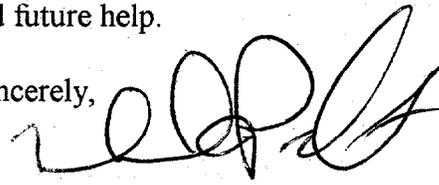
- “Help support a healthy prostate”
- “Help maintain normal urinary function”
- “Help maintain healthy sexual functioning”

As you know, we have always been cooperative with your office on labeling issues. We would like to expedite changes to the label, and would greatly appreciate your help in restoring our Prostate Gold labeling as compliant.

Feel free to call, write, fax, or email at your convenience. We appreciate your past, present and future help.

107 OAKWOOD DRIVE
GLASTONBURY
CONNECTICUT
0 6 0 3 3

Sincerely,



Michael A. Pelton
Vice President

PHONE 860 633 8111
888 SHEN MIN
FAX 860 682 6863

The Nutraceutical Product Leader



MAY - 1 2002

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

Dear Mr. Pelton:

This is in response to your letter of March 25, 2002 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 claim, among others, for the product **Prostate Gold**:

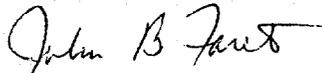
“...lessen nocturnal urination and help to restore normal function....”

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, in the context of other statements that make clear that the product is intended for “prostate support,” suggests that it is intended to treat, prevent, or mitigate a disease, namely benign prostatic hypertrophy. 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.

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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

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