



1 19 01 13 01 15

AUG 28 2001

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 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 **Cardio CholestaMax**:

“Cholesterol Protection Formula”  
“...to help control normal cholesterol...”

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 hypercholesterolemia and coronary artery disease. 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

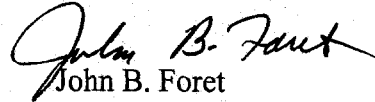
LET 543

Page 2 - Mr. Michael A. Pelton

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:

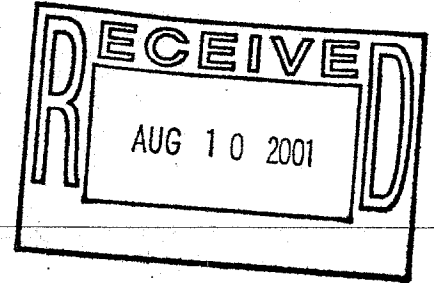
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

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

FDA, New England District Office, Office of Compliance, HFR-NE240



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., Cardio CholestaMax™ 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 Cardio CholestaMax bears the following statements:

"Cholesterol Protection Formula"

"... to help control normal cholesterol and homocysteine levels and protect your heart muscle"

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

*The Nutraceutical Product Leader*

77259