



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

FEB 27 1998

2580 '98 MAR 17 P1:40

Mr. Stephen Holt, M.D.
President
BioTherapies, Inc.
9 Commerce Road
Fairfield, New Jersey 07004

Dear Dr. Holt:

This is in response to your letter to the Food and Drug Administration (FDA), received on February 3, 1998, pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act). Your submission states that BioTherapies, Inc. is making the following claim, among others, for its product **Gugulipid C+™ Dietary Supplement**:

“An adjunct to lowering blood cholesterol with lifestyle change”

Section 403(r)(6) of the act 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, cure, or mitigate disease, in that it claims to treat or prevent hypercholesterolemia by lowering blood cholesterol. This claim does not meet the requirements of section 403(r)(6) of the act. This claim suggests that this product is intended for use as a drug within the meaning of section 201(g)(1)(B) of the act, and that it is subject to regulation under the drug provisions of the act. If you intend to make a claim 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.

Please contact us if we may be of further assistance.

Sincerely yours,

James T. Tanner, Ph.D.
Acting Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition

975-0163

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Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, New Jersey District Office, Office of Compliance, HFR-MA340
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

cc:

HFA-224 (w/incoming)
HFS-22 (CCO, JGordon)
HFS-305 (Docket 97S-0163)
HFS-456 (File)
HFS-450 (r/f)
HFD-314 (Aronson)
HFD-310 (BWilliams)
HFS-600 (Reynolds)
HFS-605 (Bowers)
GCF-1 (Nickerson, Dorsey)
f/t:HFS-456:rjm:2/4/97:docname:56922.adv:Disc25

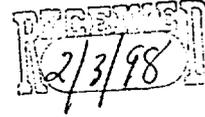


BioTherapies

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Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
200 C Street, S.W.
Washington, D.C. 20204

Re: GUGULIPID C+™

Ladies/Gentlemen:

This is to notify the Food and Drug Administration that our company has begun to market GUGULIPID C+™ Dietary Supplement, with the following statements of nutritional support included on the product's label:

Ayurvedic medicine has used guggulipid to promote cardiovascular health for centuries, with natural Vitamin C as an antioxidant.

An adjunct to lowering blood cholesterol with lifestyle change.

It is hereby certified that the information in this notice is complete and accurate, and that our company has substantiation that the above statements of nutritional support are truthful and not misleading.

Very truly yours,

BioTherapies, Inc.

By Stephen Holt
Stephen Holt, M.D.
President

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