



JAN 9 1997

7 8 2 2 '98 MAY 11 P 1 :45

Mr. Sam Beckourt
Advanced Plant Pharmaceutical, Inc.
17 John Street
New York, New York 10038

Dear Mr. Beckourt:

This is in response to your letter of November 21, 1996 to the Food and Drug Administration (FDA) pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act). Your submission states that you are making the following statement for your products, "Lo-Chol" and "Methachol:"

Scientifically proven to lower cholesterol levels, shown is [sic] numerous clinical studies to not only lower total cholesterol and triglycerides, but also increase HDL (good cholesterol) and balance the proportion of HDL to LDL.

This claim does not come within the coverage of section 403(r)(6) of the act. We would point out that 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 these products suggest that they are intended to prevent, treat, or mitigate heart disease, in that they claim that they are "proven to lower cholesterol levels" and "not only lower total cholesterol and triglycerides, but also increase HDL (good cholesterol) and balance the proportion of HDL to LDL.

A product that claims to reduce cholesterol and triglycerides, but is not used in the context of dietary management, is a drug within the meaning of section 201(g)(1)(B) of the act, and 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.

975-0163

LET 174

Page 2 - Mr. Sam Beckourt

Please contact us if we may be of further assistance.

Sincerely yours,

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

Copies:

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

FDA, New York District Office, Office of Compliance, HFR-NE100

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



**ADVANCED PLANT
PHARMACEUTICALS, INC.**

RECEIVED BY THE
OFFICE OF SPECIAL
NUTRITIONALS: HFS-450

'96 DEC -4 A8:45

Nov. 21, 1996

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

SECTION 403 (r) (6) NOTIFICATION

Dear Sir or Madam:

In accordance with the requirements of section 403 (r)(6) of the Federal Food, Drug, and Cosmetic Act, Advanced Plant Pharmaceutical, Inc. notifies FDA that it has begun using the following statements:

Scientifically proven to lower cholesterol levels, shown in numerous clinical studies to not only lower total cholesterol and triglycerides, but also increase HDL (good cholesterol) and balance the proportion of HDL to LDL.

Ingredients: Active- garlic; Other- Foenugreek, Clove, Cinnamon, Costus, Mole Plant

which contain the statutory statement, on the following products:

Lo-Chol and Methachol

I certify that the foregoing is complete and accurate, and that Advanced Plant Pharmaceutical, Inc. has substantiation that the statements are truthful and not misleading.

Very truly yours,

Advanced Plant Pharmaceutical, Inc.

by Sam Berbowitz

17 John Street, New York, N.Y. 10038
Tel (212) 964-5863 Fax (212) 964-6362

50016