



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

DEC 27 2000

Richard S. Morey, Esq.
Kleinfeld, Kaplan and Becker
1140 Nineteenth Street, N.W.
Washington, D.C. 20036-6601

Dear Mr. Morey:

This is in response to your letter to the Food and Drug Administration (FDA) dated December 7, 2000 on behalf of Pharmavite Corporation. In your letter, you asked that FDA reconsider the position taken in our November 24, 2000 letter to Pharmavite Corporation that the claim "Helps maintain normal cholesterol levels" is a disease claim that suggests that the product "Optimize Hi-Fiber" is intended to treat, prevent, cure, or mitigate disease. You stated that the label claim is equivalent to the claim "helps to maintain cholesterol levels that are already within the normal range," a claim that FDA sanctioned in the preamble language to the January 6, 2000 final rule (65 FR 1000 at 1018).

You are correct that FDA concluded in the January 6, 2000, final rule that not all claims related to cholesterol are disease claims under the Federal Food, Drug, and Cosmetic Act (the Act). However, the final rule also concluded that some health maintenance claims "use terms that are so closely identified with a specific disease" that FDA considers them implied disease prevention claims. As you note, the final rule stated that claims about the maintenance of normal cholesterol levels do not necessarily constitute implied disease claims. Because "many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease," however, we added that an appropriate structure/function claim about maintaining cholesterol should explicitly state that the cholesterol levels that are the subject of the claim are "already within the normal range." See 65 FR 1000 at 1018-19. The agency considers a claim that a product "helps maintain normal cholesterol levels" to be an implied disease claim because it does not make clear that the product is not intended to prevent the development of elevated cholesterol levels or to reduce an elevated cholesterol. Therefore, consumers are likely to interpret the claim as a claim to prevent or treat hypercholesterolemia, heart disease, or both.

In a November 24, 2000, letter to Mr. David Kropp of Pharmavite Corporation, we informed the firm that we consider a claim that the product "helps maintain normal cholesterol levels" to be an implied disease claim. Your December 7 letter does not change our view. In your letter, you assert that there is no difference in meaning or implication between the claims

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“maintaining cholesterol levels already in the normal range” and “maintaining normal cholesterol levels.” We do not agree, for the reasons stated above. Consequently, we are not persuaded that the conclusion stated in our November 24, 2000 letter is incorrect, and we stand by our original determination that the claim proposed in your client’s original submission is a disease claim that subjects its product to regulation under the drug provisions of the Act.

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, Los Angeles District Office, Compliance Branch, HFR-PA240

cc:

HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO)
HFS-800 (file, r/f)
HFS-811 (r/f, file)
HFD-40 (Behrman)
HFD-310
HFD-314 (Aronson)
HFS-605
HFV-228 (Betz)
GCF-1 (Nickerson, Dorsey)
r/d:HFS-811:RMoore:12/12/00
Revised per GCF-1:LNickerson:12/15/00
f/t:rjm:HFS-811:RMoore:12/16/00:docname:pharvit2.adv:disc53

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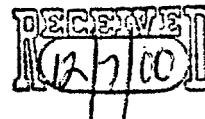
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December 7, 2000



Mr. John B. Foret, Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety and Applied Nutrition

Dear Mr. Foret:

We are writing to ask you to reconsider the enclosed letter of November 24, 2000, addressed to our client Pharmavite Corporation and concerning the claim: "Helps maintain normal cholesterol levels." The letter takes the position that this claim suggests an intention to treat, prevent, cure or mitigate hypercholesterolemia.

We submit that the above position is inconsistent with that taken by the agency in the preamble to its January 6, 2000 rule on Statements Made for Dietary Supplements Concerning the Effect of the Products on the Structure or Function of the Body. On page 1018 of that rule the agency states:

FDA does not agree that claims concerning maintenance of normal cholesterol levels necessarily constitute implied disease claims. Although an elevated cholesterol level is a sign of hypercholesterolemia and an important risk factor for heart disease, a cholesterol level within the normal range is not a sign or risk factor for disease. Moreover, maintaining cholesterol levels within the normal range is essential to the structure and function of the body for reasons other than prevention of disease.

65 Fed. Reg. 1018.

We also note that the agency explicitly approved the claim: "Helps to maintain cholesterol levels that are already within the normal range." See 65 Fed. Reg. 1019. This claim is identical in meaning to the claim objected to. Both claims are to "help

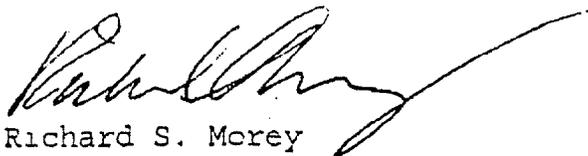
KLEINFELD, KAPLAN AND BECKER

Mr. John B. Foret, Director
December 7, 2000
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maintain cholesterol levels." The only difference in wording is in characterizing the "levels" of cholesterol. However, there is no difference in meaning or implication between maintaining "cholesterol levels already in the normal range" in the explicitly approved claim and maintaining "normal cholesterol levels" in Pharmavite's claim. Pharmavite's claim does not in any way suggest or imply use for cholesterol levels outside the normal range. It would therefore be unreasonable not to recognize that the language used by Pharmavite is synonymous with the explicitly approved claim.

We would appreciate your review of this question as soon as possible.

Yours very truly,



Richard S. Morey

Counsel for Pharmavite Corporation

Enclosure

cc: 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, Los Angeles District Office, Office of Compliance,
HFR-PA140

Catherine Copp, Esq., Associate Chief Counsel of Food,
Office of the General Counsel, GCF-1



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

NOV 24 2000

RECEIVED
NOV 28 2000
D. Kropp

Mr. David Kropp
Acting Director, Regulatory and Consumer Affairs
Pharmavite Corporation
15451 San Fernando Mission Boulevard
P.O. Box 9606
Mission Hills, California 91346-9606

Dear Mr. Kropp:

This is in response to your letter of November 3, 2000 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 Pharmavite Corporation is making the following claim, among others, for the product Optimize Hi-Fiber:

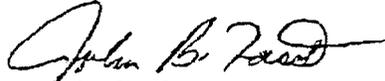
"Helps maintain normal cholesterol levels."

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 suggests that it is intended to treat, prevent, cure, or mitigate disease, namely, hypercholesterolemia. 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 we may be of further assistance.

Sincerely,



John B. Foret

Director

Division of Compliance and Enforcement

Office of Nutritional Products, Labeling

and Dietary Supplements

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and Applied Nutrition

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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, Los Angeles District Office, Office of Compliance, HFR-PA140