



MAR 19 2002

6387 '02 MAR 26 P2:20

Mr. Ed Smith  
CEO  
Herb Pharm  
P.O. Box 116  
Williams, Oregon 97544

Dear Mr. Smith:

This is in response to your letter of February 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)). In your letter, you notified us about a claim you intend to use for your dietary supplement Artichoke Liquid Herbal Extract.

The product Artichoke Liquid Herbal Extract uses the claim "Helps maintain a healthy cholesterol level." In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1018), FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims. We stated, however, that because "many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease," in order to avoid implying that the product prevents or treats heart disease, a cholesterol maintenance claim would have to clarify that the product is only for maintenance of cholesterol levels that are already within the normal range. The claim for your product contains no such clarification, however. Therefore, FDA considers it to be an implied claim to prevent coronary heart disease by preventing the development of elevated cholesterol levels or reducing elevated 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 statement that you are making for this product suggests that it is intended to treat, prevent, or mitigate a disease. 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.

978-0163

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Please contact us if we may be of further assistance.

Sincerely,

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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

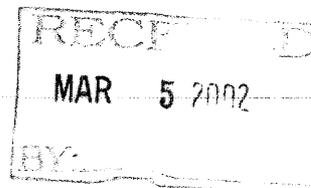
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200

FDA, Seattle District Office, Office of Compliance, HFR-PA340



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Office of Special Nutritionals (HFS-450)  
Center for Food and Safety  
Food and Drug Administration  
200 C. St. SW.  
Washington, DC 20204



2/25/2002

Re: Notice of (a) structure/function statement(s) on a dietary supplement.

(i) Name and address of manufacturer:

HERB PHARM • PO BOX 116 • WILLIAMS, OR 97544

(ii) Text of statement:

"Helps maintain a healthy cholesterol level."

(iii) Dietary ingredient:

Artichoke  
(*Cynara scolymus*)

(iv) Dietary supplement:

Liquid Herbal Extract:  
Artichoke

(v) Brand name:

HERB PHARM

I hereby certify that the information contained in this notice is complete and accurate and that Herb Pharm has substantiation that the statement is truthful and not misleading.

Ed Smith  
CEO of Herb Pharm

CC: 2/FDA, 1/FILE