



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

DEC - 1 2000 0204 '00 DEC -7 P3:08

Ms. Marjorie L. Fine
Vice President and General Counsel
Shaklee Corporation
Hacienda Campus
4747 Willow Road
Pleasanton, California 94588-2740

Dear Ms. Fine:

This is in response to your letter to the Food and Drug Administration (FDA) dated November 8, 2000. In your letter, you stated that Shaklee Corporation disagrees with FDA's view that the claim "...retaining normal blood cholesterol levels" suggests that the Shaklee product "Corenergy" is intended to treat, prevent, cure, or mitigate disease. You stated that your 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 that not all claims related to cholesterol are disease claims under the Federal Food, Drug, and Cosmetic Act (the Act). In the preamble to the final rule, 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 making a cholesterol maintenance claim into an implied claim, a cholesterol maintenance claim would have to explicitly disclaim the implied ability of the product to prevent the development of elevated cholesterol levels or to reduce an elevated cholesterol. Therefore, 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."

In a September 20, 2000, letter to Christopher Jensen of Shaklee, we informed you that we consider a claim about "retaining normal cholesterol levels" to be an implied claim to treat, prevent, cure, or mitigate hypercholesteremia. Your November 8 letter does not change our view. We do not believe that the meaning of "to retain" differs materially from the meaning of "to maintain" with respect to the meaning it conveys when used in a claim about the effect

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of a product on blood cholesterol. For this reason, we are not persuaded that the conclusion expressed in our September 20, 2000 letter is incorrect and we stand by our original determination that the claim proposed in your original submission is a disease claim that subjects your 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:

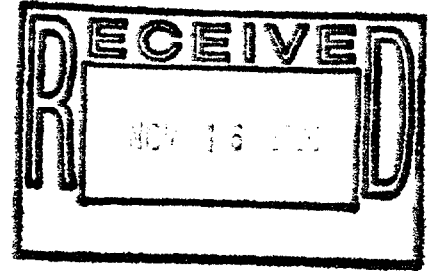
HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO)
HFS-800 (file, r/f)
HFS-811 (r/f, file)
HFD-40 (Behrman)
HFD-310
HFD-314 (Aronson)
HFS-605
HFV-228 (Betz)
GCF-1 (Nickerson, Dorsey)
r/d:HFS-811:RMoore:11/16/00
Revised per GCF-1:LNickerson:11/27/00
f/t:rjm:HFS-811:11/27/00:docname:shaklee.adv:disc52

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Marjorie L. Fine
Vice President and
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Shaklee Technica

November 8, 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
U.S. Food and Drug Administration
Department of Health & Human Services
Public Health Service #FS-811
200 C Street SW
Washington, D.C. 20204

Dear Mr. Foret:

This is in response to your letter of September 20, 2000, stating that the Food and Drug Administration (FDA) considers the claim "retaining normal blood cholesterol levels" on our CorEnergy product to be a claim suggesting that this product is intended to treat, prevent, cure or mitigate hypercholesterolemia. Based on the Agency's position regarding this claim, you state that this claim suggests that this product is intended for use as a drug.

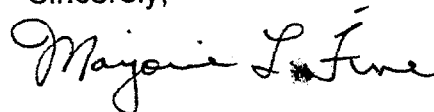
We are aware of the Agency's concern regarding claims that a product "maintains healthy cholesterol levels" as expressed in the preamble to the Final Rule On Statements Made For Dietary Supplements Concerning The Effect Of The Product On The Structure Or Function Of The Body, 65 Fed. Reg. 1000, 1018 (January 6, 2000). While we do not necessarily agree with the Agency's position, we acknowledge that FDA has stated what it believes to be permissible structure/function claims and impermissible disease claims regarding a product's effect on cholesterol. The Agency has stated that an acceptable structure/function claim would be a claim that a product "helps to maintain cholesterol levels that are already within the normal range." *Id.*, at 1019. While our claim is not as verbose as the Agency's suggested claim, we believe it conveys precisely the same meaning.

Mr. John B. Foret
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The dictionary defines "to retain" as "to hold secure or intact (as in a fixed place or condition),"¹; "to hold in place or position,"²; "to keep or hold in a particular place, condition, or position."³ Thus, as a simple matter of plain English, a claim that a product is for "retaining normal cholesterol levels" is simply another way to state that a product is for "keeping or holding normal cholesterol levels intact", which is equivalent to "maintaining cholesterol levels that are already normal." FDA sanctioned such a claim in the preamble language to the January Final Rule, and has reiterated this position in subsequent correspondence with industry. See August 9, 2000 letter from John Foret, Director, Division of Compliance and Enforcement to Tyrie A. Barrott, Assistant General Counsel, Melaleuca, Inc. Because of this, we cannot understand the position regarding this claim taken by the Agency as stated in your September 20 letter, and we respectfully suggest that the claim for our CorEnergy product is an entirely appropriate structure/function claim, based on the Agency's own statements and the plain meaning of the English language.

We look forward to your response.

Sincerely,



Marjorie L. Fine

MLF/

¹ Webster's Third New International Dictionary of the English Language (Unabridged), 1993, p. 1938.

² The Random House Dictionary of the English Language, 1973, p. 1223.

³ American Heritage Dictionary of the English Language, 1980, p. 1109.