



FEB 13 2003

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Ms. Deborah Papillo
Assistant Sales Manager
FoodScience Corporation
20 New England Drive
Essex Junction, Vermont 05453

Dear Ms. Papillo:

This is in response to your letter of January 22, 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)).

The products **FoodScience of Vermont "Cardio-DMG," "DaVinci Laboratories of Vermont "Cardio-DMG,"** and **Mountain Naturals of Vermont "Cardio-DMG"** use the claims "...support...Healthy Management of...Cholesterol Levels." 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 same principle applies to claims about control of blood glucose levels; that is, a claim that does not establish that the claims are about blood glucose levels that are already within normal limits implies that the product is intended to treat elevated blood glucose or diabetes, which is a disease. Therefore, because the claims you are making for the products identified above represent that the products are intended to affect blood cholesterol and glucose levels but do not also include a statement about them being intended to affect blood levels of these substances that are already in the normal range, they are implied disease claims.

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 statements that you are making for these products suggest that they are intended to treat, prevent, or mitigate a disease. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they

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are 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.

Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Susan Walker', written in a cursive style.

Susan J. Walker, M.D.
Acting Director
Division of Dietary Supplement Programs
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, New England District Office, Office of Compliance, HFR-NE240

FOODSCIENCE OF VERMONT®

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January 22, 2002

FEB - 3 2003

Food and Drug Administration
Office of Special Nutritionals (HFS-45)
Center for Food Safety and Applied Nutrition
200 C Street, SW
Washington, DC 20204

Dear Sirs:

Notice is hereby given pursuant to the requirements of section 403(r)(6)(21 U.S.C.343(r)(6)) of the Federal Food, Drug and Cosmetic Act and in accordance with the requirements of 21 CFR 101.93, that FoodScience Corporation, 20 New England Drive, Essex Junction, Vermont 05453 within the past 30 days commenced marketing a dietary supplement bearing the following statement(s) on the label and/or in the labeling:

TEXT OF CLAIM:

"A Dietary Supplement to Support Heart and Circulatory Functions and Healthy Management of Homocysteine and Cholesterol Levels"

NAME OF PRODUCT(s): FoodScience of Vermont "Cardio-DMG"
DaVinci Laboratories of Vermont "Cardio-DMG"
Mountain Naturals of Vermont "Cardio-DMG"

The undersigned certifies that the information contained in this notice is complete and accurate and that FoodScience Corporation has substantiation that the statement is truthful and not misleading.

Sincerely,



Deborah Papillo
Assistant Sales Manager
FoodScience Corporation

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