



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

APR 21 2000

Ms. Mary E. Helrich, CN
Director of Strategic Planning
FoodScience Corporation
20 New England Drive
Essex Junction, Vermont 05453

Dear Ms. Helrich:

This is in response to your letters of March 29, 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 submissions state that FoodScience Corporation is making the following claim for the products **K-9 Freedom and K-9 Flex**:

“A dietary Supplement for Dogs to Support Connective Tissue and Joint Functions.”

In the April 22, 1996 Federal Register (61 FR 17706; copy enclosed), FDA set forth guidance regarding the inapplicability of the Dietary Supplement Health and Education Act of 1994 (the DSHEA) to products intended for use in animals. Therefore, because the products **K-9 Freedom and K-9 Flex** are for animal use, these products are not subject to regulation under the provisions of the DSHEA.

Because the products are not subject to 21 U.S.C. 343(r)(6), the claims that are made on the label and in the labeling that evidence that these products are intended to affect the structure or function of the body are not subject to the exemption from the coverage of 21 U.S.C. 321(g)(1)(C) that is provided in 21 U.S.C. 343(r)(6). Thus, these claims suggest that the products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(C). If you intend to market these products, or any of your other products, as animal foods, you should contact FDA's Center for Veterinary Medicine, Office of Surveillance and Compliance, Division of Animal Feeds, HFV-220, 7500 Standish Place, Rockville, Maryland 20855-2733.

975-0163

LET 357

Page 2 - Ms. Mary E. Helrich

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 Veterinary Medicine, HFV-228

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

FDA, New England District Office, Office of Compliance, HFR-NE240

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-800 (r/f, file)

HFS-811 (r/f, file)

HFS-605

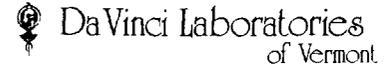
GCF-1 (Dorsey, Barnett, Nickerson)

f/t:HFS-811:rjm:4/13/00:docname:70182.adv:disc46



70182

March 29, 2000



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 05452 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 for Dogs to Support Connective Tissue and Joint Functions"

NAME OF PRODUCT(s): FoodScience of Vermont "K-9 Freedom" and Mountain Naturals of Vermont "K-9 Flex"

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,

A handwritten signature in cursive script that reads "Mary E. Helrich, CN".

Mary E. Helrich, CN
Director of Strategic Planning

MEH:bal