



APR 14 1999
9 00 3 '99 APR 20 P2:13

Mr. Gordon M. Walker
Regulatory Counsel
Nutrition Professionals, Inc.
1375 N. Mountain Springs Parkway
Springville, Utah 84663

Dear Mr. Walker:

This is in response to your letters of April 9, 1999 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 Nutrition Professionals, Inc. (dba as NUPRO) is making the following statements, among others, for the following products:

Ginger Root

“...eases the discomfort associated with travel...”

Garlic

“...shown to lower serum 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 statements that you are making for these products suggest that they are intended to prevent, treat, or mitigate disease, namely, motion sickness and hypercholesterolemia. 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 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.

978-0163

LET 267

Page 2 - Mr. Gordon M. Walker

Please contact us if we may be of further assistance.

Sincerely,

Lynn A. Larsen, Ph.D.
Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
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, Denver District Office, Office of Compliance, HFR-SW240

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-456 (File)

HFS-450 (file, r/f)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-605 (Bowers)

GCF-1 (Nickerson, Dorsey)

HFV-228 (SBenz)

HFV-232 (ABrown)

f/t:HFS-456:rjm:4/13/99:docname:64633.adv:disc37

N·U·P·R·O™

April 9, 1999

Linda S. Kahl, Ph.D.
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 "C" St. S.W. (HFS-450)
Washington, D.C. 20204

Dear Dr. Kahl:

Nutrition Professionals, Inc. wishes to notify the Food and Drug Administration that it has, within the past 30 days, commenced marketing a dietary supplement which bears a statement under Section(r)(6) of the Federal Food, Drug and Cosmetic Act.

The dietary supplement for which the statement is made is Ginger Root. The dietary ingredient that is the subject of the statement is Ginger. The statement reads as follows:

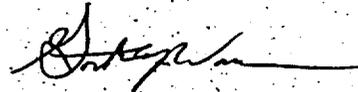
"Ginger Root (*Zingiber officinale*) is an aromatic bitter herb that eases the discomfort associated with travel and stimulates digestion to promote gastrointestinal comfort."

This statement is accompanied by the required disclaimer which is prominently displayed in bold-faced type.

The information contained in this notice is complete and accurate and the above statement is based on data which renders these statements substantiated, truthful and non-misleading.

Sincerely,

NUTRITION PROFESSIONALS, INC.



Gordon M. Walker
Regulatory Counsel

Ire

Gordon\Letter\Kahl; NP-Ginger

375 N. Mountain Springs Parkway
Pringville, IL 64663 USA
Mail P.O. Box 4000
Pringville, IL 64663 USA
OT 489-1500
AX 601-389-1700
or Free 800-805-3436

N·U·P·R·O™

April 9, 1999

Linda S. Kahl, Ph.D.
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 "C" St. S.W. (HFS-450)
Washington, D.C. 20204

RECEIVED
4/13/99

Dear Dr. Kahl:

Nutrition Professionals, Inc. wishes to notify the Food and Drug Administration that it has, within the past 30 days, commenced marketing a dietary supplement which bears a statement under Section(r)(6) of the Federal Food, Drug and Cosmetic Act.

The dietary supplement for which the statement is made is Garlic. The dietary ingredient that is the subject of the statement is Garlic. The statement reads as follows:

"In clinical studies Garlic has been shown to lower serum cholesterol and help maintain circulatory efficiency."

This statement is accompanied by the required disclaimer which is prominently displayed in bold-faced type.

The information contained in this notice is complete and accurate and the above statement is based on data which renders these statements substantiated, truthful and non-misleading.

Sincerely,

NUTRITION PROFESSIONALS, INC.



Gordon M. Walker
Regulatory Counsel

lre

Gordon/Letter/Kahl-NP-Garlic

Mountain Springs Parkway
P.O. Box 34663 USA
Denton, TX 76201
P.O. Box 34663 USA
76201
1-800-305-4435