



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

8389 '97 AUG 12 10 05

APR 15 1997

Paul Kimbar, R.Ph.
Vice President Sales and Marketing
Mason Vitamins
5105 N.W. 159th Street
Miami Lakes, Florida 33014-6370

Dear Dr. Kimbar:

This is in response to your letter of January 23, 1997 making a submission to the Food and Drug Administration (FDA) pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act). Your submission states that you are making the following statements on the label or in the labeling of your product "Zinc Lozenges 23 mg Lemon Flavored:"

Good for the common cold.
Supports the body's natural defense system.

Section 403(r)(6) of the Act makes it 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 or mitigate a disease, namely, the common cold. This claim does not meet the requirements of section 403(r)(6) of the Act. This claim suggests that this product is intended for use as a drug within the meaning of section 201(g)(1)(B) of the Act, and that it is subject to regulation under the drug

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provisions of the Act. If you intend to make a claim 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,

James Tanner, Ph.D.
Acting 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, Florida District Office, Office of Compliance, HFR-SE240
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

cc:

HFA-224 (w/incoming)
HFS-22 (CCO, KCarson)
HFS-450 (w/control slip OSN#50922, r/f)
HFS-456 (Latham, Moore w/cpy incoming)
HFD-304 (Aronson)
HFS-600 (Reynolds)
r/d:HFS-456:JELatham;jel:03/17/97:DocName#50922.OSN:Disc3
Initial:R.Moore:03/20/97



5105 N.W. 159th Street
Miami Lakes, FL 33014-6370

Phone: (305) 624-5557
WATTS: 1-800-327-6005
Fax: 1-800-328-3944

RECEIVED BY THE
OFFICE OF SPECIAL
NUTRITIONALS, HFS-450

A Division of
Mason Distributors, Inc.
Since 1967

The Vitamin Experts

'97 JAN 31 P12:18

January 23, 1997

Dr. Elizabeth Yetley
Director of the Office of Special Nutritionals
Division of Programs and Enforcement Policy
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street
HFS-455
Washington, D.C. 20204

Dear Dr. Yetley:

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 of statements of nutritional support which have been made on the label and/or in the labeling in connection with the marketing of the dietary supplement **ZINC LOZENGES 23 MG LEMON FLAVORED**. **ZINC LOZENGES 23 MG LEMON FLAVORED** was first marketed with these statements of nutritional support on Tuesday, January 21, 1997. The statements of nutritional support are as follows:

Good for the common cold.
Supports the body's natural defense system.

Very truly yours,

Mason Distributors, Inc.

Paul Kimbar, R.Ph.
VP Sales & Marketing

pk/dl

50922



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Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street
HFS-455
Washington, D.C. 20204

Dear Dr. Yetley:

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 of statements of nutritional support which have been made on the label and/or in the labeling in connection with the marketing of the dietary supplement NATURAL HERBAL DIURETIC. NATURAL HERBAL DIURETIC was first marketed with these statements of nutritional support on Wednesday, January 15, 1997. The statements of nutritional support are as follows:

- Helps you eliminate excess body fluids.

Very truly yours,

Mason Distributors, Inc.

Paul Kimbar, R.Ph.
VP Sales & Marketing

pk/dl



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The Vitamin Experts

'97 JAN 31 P12:17

January 23, 1997

Dr. Elizabeth Yetley
Director of the Office of Special Nutritionals
Division of Programs and Enforcement Policy
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street
HFS-455
Washington, D.C. 20204

Dear Dr. Yetley:

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 of statements of nutritional support which have been made on the label and/or in the labeling in connection with the marketing of the dietary supplement NATURAL VEGETABLE LAXATIVE: SENNA EXTRACT Plus FENNEL SEEDS. NATURAL VEGETABLE LAXATIVE: SENNA EXTRACT Plus FENNEL SEEDS was first marketed with these statements of nutritional support on Tuesday, January 21, 1997. The statements of nutritional support are as follows:

- A safe, natural, mild laxative.

Very truly yours,

Mason Distributors, Inc.

Paul Kimbar, R.Ph.
VP Sales & Marketing

pk/dl