



MAY 22 1997

8 3 8 8 '97 AUG 12 10:05

Peter S. Liebert, M.D.
270 White Plains Road
Eastchester, NY 10709

Dear Dr. Liebert:

This is in response to your letter of March 31, 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 statement in the labeling of the product "Zinc Lozenges":

Scientific studies indicate that zinc lozenges reduce the duration of symptoms caused by the common cold.

This claim does not come within the coverage of section 403(r)(6) of the act. We would point out that section 403(r)(6) of the act 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 statement that you are making for "Zinc Lozenges" suggests that this product is intended for at least one of these purposes, in that it claims to reduce the duration of symptoms caused by the common cold. Therefore, this claim does not meet the requirements of section 403(r)(6) of the act. This claim suggests that this product is intended for other than food use within the meaning of section 201(g) of the act and that it is 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.

975-0163

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Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in cursive script that reads "James Tanner".

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, New York District Office, Office of Compliance, HFR-NE100

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

cc:

HFA-224 (w/incoming)

HFS-22 (CCO, KCarson)

HFS-456 (r/f, Ross, Moore)

HFS-450 (r/f)

HFD-304 (Aronson)

HFS-600 (Reynolds)

r/d: Sross:5/9/97:d:\sharon\30day\52047

f/d: Sross:5/13/97: DocName:52047.osn: Disc2

Rx Vitamins™

PHYSICIAN FORMULATED

RECEIVED BY THE
OFFICE OF SPECIAL
NUTRITIONALS, HFS-450

March 31, 1997

'97 APR 14 A10:58

Elizabeth Yetley, Ph.D.
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 "C" Street, S.W. (HFS-455)
Washington, D.C. 20204

Dear Dr. Yetley,

Pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994, Rx Vitamins™ wishes to notify the Food and Drug Administration that it has, within the past 30 days, commenced marketing two dietary supplements which bear a statement of nutritional support.

The dietary supplement for which the statements are made is **THE OCULAR FORMULA**. The statement of nutritional support reads as follows:

- Each capsule provides a combination of antioxidants, a rich botanical blend, and essential cofactors for eye health.*
- Nutrients such as lutein, zeaxanthin, bilberry, vitamin C, zinc, beta carotene, selenium and CoQ10 make **THE OCULAR FORMULA** one of the most scientifically advanced formulas ever developed to help maintain normal vision.*

The dietary supplement for which the statements are made is **ZINC LOZENGES**. The statement of nutritional support reads as follows:

- Scientific studies indicate that zinc lozenges reduce the duration of symptoms caused by the common cold.*

These statements are accompanied by the required disclaimer which is prominently displayed in bold-faced type.

These statements of nutritional support are based on a large body of data which, in our judgment, renders these statements substantiated, truthful and non-misleading.

Sincerely,



Peter M. Liebert, M.D.
Chairman

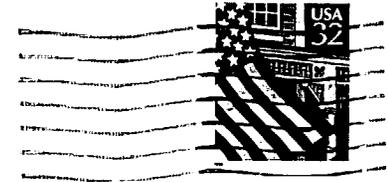
52049

OPTIMAL NUTRITIONAL SUPPORT

270 White Plains Road Eastchester, NY 10709
PH: 914-771-9607 FAX: 914-337-4006 1-800-Rx2-2222

Rx VitaminsTM
PHYSICIAN FORMULATED

270 White Plains Road
Eastchester, NY 10709



Elizabeth Yetley, Ph.D.
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 "C" Street, S.W. (HFS-455)
Washington, D.C. 20204

