



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Washington, DC 20204

*Rec'd 3/26/98 jh*

MAR 13 1998

President  
Rx Vitamins, Inc.  
200 Myrtle Boulevard  
Larchmont, New York 10538

Dear Sir:

This is in response to your submission<sup>1</sup> of October 23, 1997 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 Rx Vitamins, Inc. is making the following claim, among others, for the product "Zinc Lozenges:"

"Zinc Lozenges provide nutritional support for the body's natural defense system, helping to keep you at peak performance during the cold and flu season."

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 statement that you are making for this product suggests that it is intended to prevent, treat or mitigate a disease, namely the common cold and influenza. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). The claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), 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.

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<sup>1</sup>Submission made on your behalf by Emord & Associates, P.C., 1050 Seventeenth St., N.W., Suite 600, Washington, D.C. 20036.

975-0163

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Page 2 - President, Rx Vitamins, Inc.

Please contact us if we may be of further assistance.

Sincerely,

James T. 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, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200  
FDA, New York District Office, Office of Compliance, HFR-NE150

cc:

HFA-224 (w/incoming)  
HFA-305 (docket 97S-0163)  
HFS-22 (CCO, JGordon)  
HFS-456 (File)  
HFS-450 (file, r/f)  
HFD-310 (BWilliams)  
HFD-314 (Aronson)  
HFS-600 (Reynolds)  
HFS-605 (Bowers)  
GCF-1 (Nickerson, Dorsey)  
r/d:HFS-456:RMoore:3/12/98  
Init:GCF-1:LNickerson:3/12/98  
f/t:HFS-456:sar:3/13/98:docname:rxvits:disc26

**EMORD & ASSOCIATES, P.C.**

BURKE PROFESSIONAL CENTER  
5282 LYNNGATE COURT  
BURKE, VIRGINIA 22015

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OFFICE OF SPECIAL  
NUTRITIONAL SERVICES

1050 SEVENTEENTH STREET, N.W.  
SUITE 600

WASHINGTON, D.C. 20036 '97 OCT 24 112:35

PHONE: (202) 466-6937 • FAX: (202) 466-6938

E-MAIL: WWW.EMORD.COM

October 23, 1997

**VIA UPS OVERNIGHT**

Dr. Robert J. Moore  
Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C Street, S.W.  
Washington, D.C. 20204

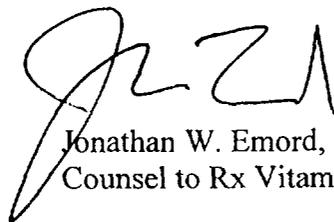
Re: Nutritional Support Statement Notification  
Pursuant to section 403(r)(6) of the Act

Dear Dr. Moore:

Pursuant to Section 403(r)(6) of the Act and 21 C.F.R. § 101.93 et seq., Rx Vitamins, Inc., 200 Myrtle Boulevard, Larchmont, NY 10538, makers of "Zinc Lozenges," hereby file this notification of its intent to use on labels and in labeling the following statement of nutritional support. An original and two copies of this notification are submitted for agency review.

The statement of nutritional support is as follows: "Zinc Lozenges provide nutritional support for the body's natural defense system, helping to keep you at peak performance during the cold and flu season." The name of the dietary ingredient is Zinc Aspartate. The name of the dietary supplement (which is also the brand name of the product) is Zinc Lozenges. Attached hereto is a certification in support of this submission.

Sincerely,



Jonathan W. Emord,  
Counsel to Rx Vitamins, Inc.

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**CERTIFICATION**

I, Craig Kisciras, President of Rx Vitamins, Inc., hereby certify that the information contained in the foregoing notification of statement of nutritional support for Zinc Lozenges is complete and accurate and that Rx Vitamins, Inc. has substantiation that the statement is truthful and not misleading.

Dated: 10/23/97

  
Craig Kisciras