



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Washington, DC 20204

Mr. Michael Finamore  
President  
VitaGem, Inc.  
140-2 Keyland Court  
Bohemia, New York 11716

FEB 11 2000 1739 '00 FEB 29 P2:12

Dear Mr. Finamore:

This is in response to your letter of February 1, 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 submission states that VitaGem, Inc. is making the following claim, among others, for the product **Natural Cold Season Dietary Supplement**:

“...defends against a dietary Vitamin C and Zinc deficiency during the cold 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, including the use of the term “cold season in the product name,” suggests that it is intended to treat, prevent, or mitigate disease, namely, the common cold. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest 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.

Please contact us if you require 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

975-0163

LET344

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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-NE140

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-456 (file, r/f)

HFS-450 (r/f, file)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-605

HFV-228 (Benz)

GCF-1 (Dorsey, Barnett, Nickerson)

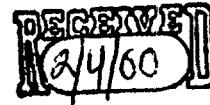
f/t:HFS-456:rjm:2/7/00:docname:69098.adv:disc44

VitaGem, Inc  
140 - 2 Keyland Ct.  
Bohemia, NY 11716  
( 516 ) 218 - 0014

February 1, 2000

69098

Office of Special Nutritionals ( HFS 450 )  
Center for Food Safety and Applied Nutrition  
200 C St. SW.,  
Washington, DC 20204



**Re: Notification of Claim for Nutritional Supplements**

To whom it may concern:

Below please find the necessary information concerning the labeling of a proposed nutritional supplement:

1. This product is being distributed by Vitagem, Inc., Bohemia, NY 11716
2. The statements appearing on the attached label and product carton are identical to eachother, and are as follows:
  - a. Indications: This product is a dietary supplement which defends against a dietary Vitamin C and Zinc deficiency during the cold season and throughout the year, as Zinc and Vitamin C are important elements of the body's natural immune system. These items are combined in a base of Echinacea extract, which historically is the world's most popular seasonal herb, to provide a truly superior product.\*
  - b. ( This Product ) Supports your body's natural defenses\*
3. The product is titled Natural Cold Season Nutritional Supplement.

I certify that the information contained in this notice is accurate, complete and truthful, and not intended to be misleading.

Please feel free to call me if I can be of any further assistance at ( 516 ) 218 - 0014.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael Finamore".

Michael Finamore, President  
VitaGem, Inc.

enc. Three ( 3 ) labels for "Natural Cold Season Nutritional Supplement."  
Three ( 3 ) outer cartons for "Natural Cold Season Nutritional Supplement".

SUPPLEMENT FACTS		
Serving Size: One tablet		
Each Tablet Contains		%Daily Value*
Vitamin C (from ascorbate acid)	240mg	400%
Zinc (from zinc oxide)	15mg	100%
Echinacea areal parts extract, dried (Echinacea purpurea)	50mg	**

\*Daily value based upon 2,000 calorie diet.  
\*\* Daily value not established.

Other Ingredients: Dicalcium Phosphate, Magnesium Stearate, Stearic Acid, Silica, Pharmaceutical Glaze, FD&C Yellow #6, Talc.

LOT#  
EXP. DATE:

VITAGEM PHARMACEUTICAL, INC.

# NATURAL COLD SEASON

## Dietary Supplement

Supports Your Body's Natural Defenses \*      Standardized Echinacea with Vit C & Zinc

Compare to the active ingredient in One-A Day Cold Seasons®      50 Tablets

DO NOT USE IF IMPRINTED FOIL INNER SEAL IS BROKEN.

**INDICATIONS:** This product is a dietary supplement which defends against dietary Vitamin C and Zinc deficiency during the cold season and throughout the year, as Zinc and Vitamin C are important elements of the body's natural immune system. These items are combined in a base of Echinacea extract, which historically is the world's most popular seasonal herb, to provide a truly superior product.

**SUGGESTED USES:** Take one tablet daily to provide the complete Recommended Daily Allowance of both Vitamin C and Zinc. If additional amounts of Zinc are desired, up to two tablets can be taken for a short period, not to exceed seven days.

**WARNINGS:** Echinacea should not be used by anyone with autoimmune diseases. Do not use if you are allergic to the daisy (asteraceae) family or if you are pregnant or nursing.

\*These statements have not been evaluated by the FDA. This product is not intended to treat, diagnose or prevent any disease. Please consult a physician before beginning any nutritional supplement program.

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