

MAY 31 2001

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Ms. Megan Joslin
Product Development Coordinator
General Vitamin Corporation
P.O. Box 1500
Chapel Hill, North Carolina 27516

Dear Ms. Joslin:

This is in response to your letter of May 18, 2001 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 General Vitamin Corporation is marketing the product **CholesteForm**, which contains the ingredient Red Yeast Extract. This letter is to advise you of the current legal status of products that contain red yeast rice containing lovastatin.

FDA announced its administrative decision on May 20, 1998 that a product named "Cholestin¹", manufactured by Pharmanex, Inc., which was promoted as a dietary supplement intended to affect cholesterol levels, is not a dietary supplement, but is instead an unapproved drug under the Act. This decision meant that Cholestin could not be legally sold in the United States.

A February 16, 1999 United States District Court for the District of Utah decision that "held unlawful and set aside" the FDA's May 20, 1998 decision was reversed by a United States Court of Appeals for the 10th Circuit decision on July 21, 2000. This reversal reinstates FDA's administrative decision that Cholestin is a drug, not a dietary supplement. The reversal also remanded the case back to the District Court for consideration of record-based issues not previously reached by the lower court in its original decision. On March 30, 2001, the United States District Court for the District of Utah issued a Memorandum Decision and Order on the remaining record-based issues. The District Court affirmed the FDA's administrative decision that Cholestin is a drug,

¹Cholestin consists of the yeast *Monascus purpureus* when fermented on premium rice powder. The fermentation of the rice with this yeast, under certain conditions, produces a product that contains lovastatin, the active ingredient in the prescription cholesterol-lowering drug Mevacor.

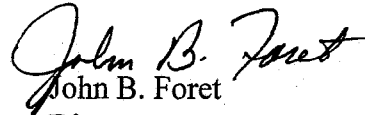
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not a dietary supplement. Taken together, the courts' decisions in the Pharmanex litigation mean that red yeast rice or similar products containing lovastatin are unapproved new drugs in violation of the Act. Marketing of a product that is in violation of the Act may result in enforcement action being initiated by FDA without further notice. Among other remedies, the Act provides for the seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

If we can be of further assistance, please contact us.

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

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, Atlanta District Office, Office of Compliance, HFR-SE140

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cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-800 (r/f, file)

HFS-810

HFS-811 (file)

HFD-310

HFD-314 (Aronson)

HFS-607 (Bayne-Lisby)

HFV-228 (Benz)

GCF-1 (Nickerson, Parker, Fain)

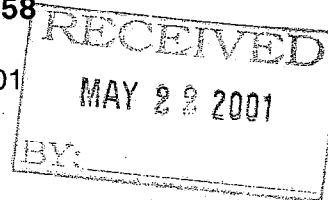
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GENERAL VITAMIN CORP

PO Box 1500 Chapel Hill NC 27516

919-929-5785 fax 919-929-2458

May 18, 2001



CERTIFIED MAIL
Return Receipt Requested

Office of Nutritional Products, Labeling and Dietary Supplements
HFS-800
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, SW
Washington, D.C. 20204

To Whom it May Concern,

This letter is submitted pursuant to Section 406 (r)(6) of the Federal Food, Drug, and Cosmetic Act for the purpose of notifying the agency of statements being made in connection with the marketing of dietary supplements being distributed by this company.

The product name and the dietary ingredients for which the statement is being made is as follows:

CholesteForm

Vitamin E (as d-alpha tocopherol succinate)	20 IU
Niacin	50mg
Folic Acid	800mcg
Tocotrienol Complex (Elaeis guineensis Fruit)	100mg
Red Yeast Extract	100mg
Borage Oil (Borago officinalis seed) (standardized 22% [11mg] gamma-linolenic acid [GLA])	50mg
Novasoy (soy extract standardized to 40% [20mg] isoflavones)	50mg
Green Tea Extract (camellia sinensis leaf) (standardized 50% [25mg] polyphenols)	50mg

Other ingredients: Microcrystalline cellulose, stearic acid, silica and pharmaceutical glaze

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HeartForm

Vitamin E (as d-alpha tocopheryl succinate)	100 IU
Folic Acid	100mcg
Vitamin B6 (as pyridoxine HCl)	5mg
Vitamin B12 (as cyanocobalamin)	15mcg
Magnesium (as amino acid chelate)	200mg
Selenium (as selenomethionine)	50mcg
Potassium (as amino acid complex)	99mg
Chinese Garlic Clove (<i>Allium sativum</i>)	100mg (standardized 1% [1mg]total allicin potential)
English Hawthorne Berry (<i>Crataegus</i> <i>Laevigata</i>) (standardized 3.2%[1.6mg]vitexin)	50mg
Taurine (pharmaceutical-grade free form Amino acid)	50mg
Cayenne (<i>Capsicum frutescens</i> fruit)	50mg (standardized min. 50,000 Scoville Thermal Units [STU])

Other ingredients: Di-calcium phosphate, microcrystalline cellulose, stearic acid, silica and pharmaceutical glaze

The text of the statements that are being made in regards to the above stated products are listed below:

CholesteForm

-CholesteForm

- nutritionally support healthy cholesterol levels that are already in the normal range
- Balancing act for maximum health
- help you maintain cholesterol levels already within normal range
- nutritional support
- to maximize well being throughout the bloodstream

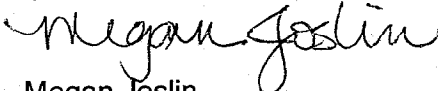
HeartForm

-HeartForm

- nutritionally support a healthy heart
- support for healthy heart function
- support the optimal functioning
- help maintain strong and regular heartbeat
- support general cardiac health
- support healthy heart function

Sincerely,

GENERAL VITAMIN CORP.



Megan Joslin

Product Development Coordinator