



OCT 29 1998 7 37 6 '98 NOV -4 P1:45
Food and Drug Administration
Washington DC 20204

Robin Criffield
• Marketing Manager
General Vitamin Corporation
P.O. Box 1500
Chapel Hill, North Carolina 27516

Dear Sir/Madam:

This is in response to your letter of September 23, 1998 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 making the following claims, among others, for the products:

VARICARE

“to help promote increased blood flow and circulation in the legs”
“to promote strong blood vessels”

NUTRA SKIN

“help overcome...acne...and dandruff”

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 statements that you are making for these products, including the name of the product VARICARE in the context of the claims made for it, suggest that they are intended to prevent, treat, cure, or mitigate disease, namely varicose vein conditions, acne and disorders causing dandruff. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B) and that they are 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

LET 229

Page 2 -Robin Criffield

Please contact us if we may be of further assistance.

Sincerely,

Lynn A. Larsen, Ph.D.
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, Atlanta District Office, Office of Compliance, HFR-SE140

cc:

HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO)
HFS-456 (File)
HFS-450 (file, r/f, OSN#61924)
HFD-310 (BWilliams)
HFD-314 (Aronson)
HFS-600 (Reynolds)
HFS-605 (Bowers)
GCF-1 (Nickerson, Dorsey)
Init:GCF-1:DDorsey:10/27/98
f/t:HFS-456:rjm:10/28/98:docname:61924.adv:disc32

GENERAL VITAMIN CORP

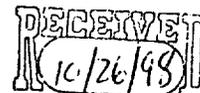
PO Box 1500 Chapel Hill NC 27516

919-929-5785 fax 919-929-2458

September 24, 1998

61924

CERTIFIED MAIL
Return Receipt Requested



Office of Special Nutritionals
HFS-450
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 statements are being made is as follows:

VARICARE

Vit C	100 mg
Citrus Bioflavonoids	50 mg
Rutin	50 mg
Magnesium Oxide	50 mg
Vit E	30 IU
Witch Hazel	30 mg
Horse Chestnut	50 mg
Stone Root	25 mg
Yellow Dock Root	25 mg
Ginkgo Biloba	25 mg

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

- to help promote increased blood flow and circulation in the legs
- to promote strong blood vessels

Sincerely,
GENERAL VITAMIN CORP.

Robin R. Criffield

Robin Criffield
Marketing Manager

Also see docket 975-0163

61924

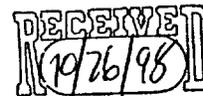
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NUTRA SKIN

Vit A	5,000 IU
Vit D	400 IU
Vit E	60 IU
Vit B1	6 mg
Vit C	60 mg
Vit B2	4 mg
Vit B6	4 mg
Folic Acid	200 mcg
Niacinamide	40 mg
Aloe Vera Powder	10 mg
Zinc Sulfate	20 mg
RNA Substances	2 mg
DNA Substances	2 mg
Chamomile Root Powder	10 mg

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

- help promote healthy skin
- help overcome dryness, acne, fragile nails and dandruff

Sincerely,
GENERAL VITAMIN CORP.

A handwritten signature in black ink that reads "Robin R. Criffield".

Robin Criffield
Marketing Manager

Also see docket 975-0163

61924