



NOV 20 1998 3378 '98 NOV 25 P2:23

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 October 2, 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 product St. John's Wort (Flowers):

- "Beat the blues...feel brighter, naturally"
- "Herbal help for the blues"
- "Feel good about life again"
- "Not feeling you [sic] best"
- "Feel good about yourself naturally"
- "It's only half a life when you feel "down" all the time...irritable...anxious...constantly tired...overwhelmed...or suffering from poor sleep"
- "There may be a way back to a brighter life"
- "So you can enjoy life to the fullest again"

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 this product suggests that it is intended to treat, prevent, or mitigate a disease, namely, depression. 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.

978-0163

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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 (r/f, file)  
HFD-310 (BWilliams)  
HFD-314 (Aronson)  
HFS-600 (Reynolds)  
HFS-605 (Bowers)  
GCF-1 (Dorsey)  
r/d:HFS-456:RMoore:11/20/98  
Init:GCF-1:DDorsey:11/20/98  
f/t:HFS-456:rjm:11/20/98:docname:62370.adv:disc33

# GENERAL VITAMIN CORP

PO Box 1500 Chapel Hill NC 27516

919-929-5785 fax 919-929-2458

62370

October 2, 1998



**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 statement is being made is as follows:

ST. JOHN'S WORT (Flowers) .3% hypericin 600 mg

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

- Beat the blues... feel brighter, naturally.
- Herbal help for the blues
- Feel good about life again
- Not feeling your best?
- Feel good about yourself naturally.
- It's only half a life when you feel "down" all the time... irritable...anxious...constantly tired  
...overwhelmed...or suffering from poor sleep
- Stress is a major concern affecting some 17 million Americans every year
- there may be a way back to a brighter life
- users report feeling more energetic and cheerful
- so you can enjoy life to the fullest again
- help yourself feel your best, naturally
- a natural mood enhancer
- facilitator of sound sleep and calmness

Sincerely,  
GENERAL VITAMIN CORP.

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

Robin Criffield  
Marketing Manager