



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

FEB - 8 2001

3614 '01 MAR 16 A7:16

Mr. Michael Hernandez
Vice President of Regulatory Affairs
Vitamina
2809 Lenwood Road
Suite 8-1
Barstow, California 92311

Dear Mr. Hernandez:

This is in response to your letter of January 17, 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 submissions state that Vitamina is making the following claim, among others, for the product **MigraCare Plus**™:

“...may inhibit the secretion of serotonin, which may cause the constriction of blood vessels throughout the head”

“...known to dilate...blood vessels”

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, in conjunction with the name of the product (i.e., MigraCare), suggest that it is intended to treat, prevent, or mitigate a disease, namely migraine headaches. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims 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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Please contact us if we may be of 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

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, San Francisco District Office, Office of Compliance, HFR-PA140

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-800 (r/f, file)

HFS-810 (file)

HFS-811

HFD-40 (Behrman)

HFD-310

HFD-314 (Aronson)

HFS-607

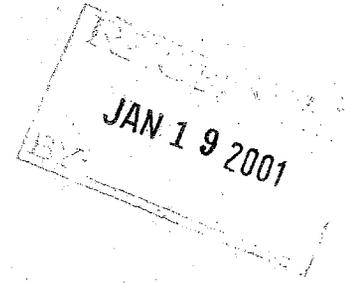
HFV-228 (Benz)

GCF-1 (Nickerson)

f/t:HFS-811:rjm:1/30/01:docname:74102.adv:disc53



74102



January 17, 2001

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 "C" Street SW
Washington, DC 20204

Section 403(r)(6) Notification

Dear Sir or Madam:

In accordance with the requirement of section 403(r)(6) of the Federal Food, Drug and Cosmetic Act, **VitaMania** notifies the FDA that it is going to begin to use the following phrase and statement:

MigraCare Plus™ combines three nutrients, feverfew, magnesium and riboflavin, which support normal cerebrovascular tone. This unique dietary supplement, when taken on a daily basis, increases the likelihood that you'll receive the specific nutrition to help maintain optimal cerebrovascular health and function.

MigraCare Plus™ provides the following nutrients in one unique complex:

- Feverfew may inhibit the secretion of serotonin, which may cause the constriction of blood vessels throughout the head. Feverfew also inhibits the secretion of histamines.
- Magnesium (citrate and oxide) are known to dilate and support healthy blood vessels.
- Riboflavin is important for energy production in the cell. Deficient energy reserves may interfere with cerebral blood vessel tone.

Only **MigraCare Plus™** has **PARTHENOPUR™**, an Standardized Feverfew Extract. **PARTHENOPUR™** is a unique feverfew extract that has been specially developed to address specific nutritional needs. **PARTHENOPUR™** has been standardized to deliver an effective dietary amount of feverfew extract in each dose.

on the following product:

MigraCare Plus™

Very truly yours,

VitaMania™

Michael Hernandez,
Vice President of Regulatory Affairs