



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

DEC 27 2001

Alex Santoso, Ph.D.
President
Nutrica, Inc.
16 Baypark Circle
South San Francisco, California 94080

Dear Dr. Santoso:

This is in response to your letter of October 29, 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 Nutrica, Inc. is making the following claim, among others, for the product Venaron SV:

“Helps protect against swelling by promoting vein circulation.”

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 suggests that it is intended to treat, prevent, cure, or mitigate diseases, namely disorders of venous circulation. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim 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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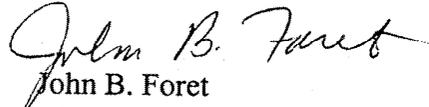
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Please contact us if we may be of further assistance.

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:

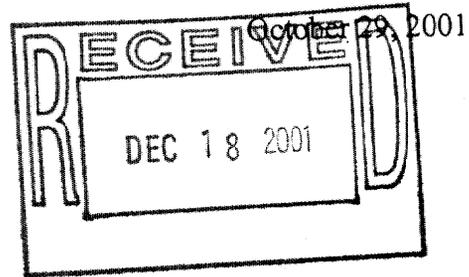
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

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

NUTRICA

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



Dear Sir or Madam:

This letter is a 30-day notification pursuant to section 6 of the Dietary Supplement Health and Education Act of 1994, by Nutrica, Inc.

Name and address of distributor:

Nutrica, Inc.
16 Baypark Circle
South San Francisco, CA 94080

Name of dietary supplement:

Venaron SV (Ingredient: Valeriana hardwickii and polygonum hydropiperis extracts)

Text of statements being made:

- Helps promote leg vein circulation
- Helps protect against swelling by promoting vein circulation
- Support the nutritional needs for optimal leg vein health.
- Improve leg appearance
- Helps maintain beautiful legs
- Support optimal circulation for healthy legs

The undersigned certifies that the information presented and contained in this correspondence is complete and accurate.

Sincerely yours,

Alex Santoso, Ph.D.
President