



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

4163 '98 DEC 11 16:49

NOV 25 1998

Nitin Patel
Vedihealth, Inc.
P.O. Box 1535
Soquel, CA 95073

Dear Mr. Patel:

This is in response to your letter of November 20, 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 Vedihealth, Inc. is making the following claim for the product **Allergy Balance**:

“helps support the body’s natural balance in times of hypoallergenic sensitivities”

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, including the name of the product, suggests that it is intended to treat, prevent, or mitigate a disease, namely, allergies. 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.

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

978-0163

LET 245

Page 2 - Mr. Nitin Patel

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-456 (file)

HFS-450 (r/f, file)

HFD-310 (BWilliams)

HFD-314 (Aronson)

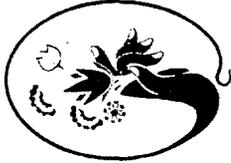
HFS-600 (Reynolds)

HFS-605 (Bowers)

GCF-1 (Dorsey)

f/t:HFS-456:rjm:11/24/98:docname:62448.adv:disc33

VEDAHEALTH.



Authentic Ayurveda

VediHealth, Inc.

Post Office Box 1535

Soquel, CA 95073

Phone (408)465-9084

Fax (408)465-9085

<http://www.vedahealth.com>



TO:
Office of Special Nutritionals
HFS-450
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 Cst.SW
Washington DC 20204

Statement of Nutritional Support-Allergy Balance

Pursuant to 21 CFR part 101.93, Vedihealth Inc files the following statement of Nutritional support for the Dietary Supplement marketed as ALLERGY BALANCE:

1. Name and address of distributor: Vedihealth Inc.
720 D, Capitola Ave.,
Capitola, CA 95010
2. Text of Nutritional support statement being made:
"helps support the body's natural balance in times of hypoallergenic sensitivities"
3. Name of the dietary ingredients: 1.Pimpali (Piper longum) 2.Clove (Eugenia aromatica)
3.Turmeric (Curcuma longa) 4.Haritaki (Terminalia chebula) 5.Ginkgo Biloba.
4. Brand Name: ALLERGY BALANCE
5. Substantiation Information on file at the company office. The corporate officer who can certify same is Dr.Nitin Patel, CEO.

Yours truly,



Nitin Patel
Vedihealth Inc.

