



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Washington, DC 20204

4857 '00 JAN 28 P2:37

JAN - 5 2000

Ms. Katie Ferren  
Marketing Director  
American Nutraceutical Products, Inc.  
6990 Bandini Boulevard  
Los Angeles, California 90040

Dear Ms. Ferren:

This is in response to your letter of December 10, 1999 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 American Nutraceutical Products, Inc. is making the following claim, among others, for the product **Pure Gels Echinacea & Goldenseal Extract**:

“Especially during Cold and Flu season, both herbs help maintain the body’s natural immune arsenal.”

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, or mitigate disease, namely, the common cold and influenza. 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.

Please contact us if you require 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

975-0163

LET 325

Page 2 - Ms. Katie Ferren

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, Los Angeles District Office, Office of Compliance, HFR-PA240

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-456 (file)

HFS-450 (r/f, file)

HFD-310 (BWilliams)

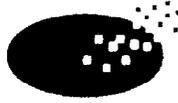
HFD-314 (Aronson)

HFS-605

HFV-228 (Benz)

GCF-1 (Dorsey, Barnett)

f/t:HFS-456:rjm:1/4/00:docname:68636.adv:disc43



american nutraceutical  
products inc

*[Handwritten signature]*

RECEIVED  
11/3/00

December 10, 1999

Dr. Elizabeth Yetley  
Office of Special Nutritionals  
Food and Drug Administration  
200 C Street SW  
Washington D.C. 20204

Dear Dr. Yetley:

We are offering for sale the following product Pure Gels Echinacea & Goldenseal Extract, with the following Structure/Function claim: Temporarily Assists the Body's Natural Defenses. The supporting side panel story is: This synergistic combination supports the body's immune function in times of stress. Especially during Cold and Flu season, both herbs help maintain the body's natural immune arsenal.

The FDA disclaimer will also appear on the label.

Sincerely,

*[Handwritten signature]*

Katie Ferren  
Marketing Director