



NOV 12 1999

Mr. Joel E. Rath  
Managing Director  
Herbalogix, Inc.  
987 North Enterprise Street  
Orange, California 92867

Dear Mr. Rath:

This is in response to your letter of October 27, 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 Herbalogix, Inc. is making the following statement, among others, for the product "Objectives Enzyme Time" ":

" . . . regulate the presence of unwanted bacteria. "

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, mitigate, or cure disease, namely, disease caused by pathogenic microorganisms. 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-3 10, 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

975-0163

LET 316

Page 2 - Mr. Joel E. Rath

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-0 163)

HFS-22 (CCO)

HFS-456 (file, r/f)

HFS-450 (r/f, file)

HFD-3 10 (B Williams)

HFD-3 14 (Aronson)

HFS-605

HFV-228 (Benz)

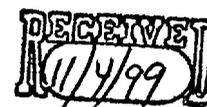
GCF- 1 (Nickerson, Dorsey, Barnett)

f/t:HFS-456:rjm:1 1/1 1/99:docname:67963.adv:disc42

**PROVENANCE™**  
Your path to health and well-being

67963

October 27, 1999



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

VIA U.S. POSTAL, MAIL,

RE: STATEMENTS OF NUTRITIONAL, SUPPORT

Dear Dr. Moore:

Pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994, *Herbalogix, Inc.* 987 North Enterprise Street, Orange, CA 92867, wishes to **notify** the Food and Drug Administration that it has, within the past 30 days, commenced marketing a line of dietary supplements, which bears statements of nutritional support.

The following list notes the structure function claims for each dietary supplement product. These statements are accompanied by the required disclaimer that is prominently displayed in bold-faced type.

These statements of nutritional support are based on a large body of data, which, in our judgment renders these statements, truthful and non-misleading.

Sincerely,

  
Joel E. Rath  
Managing Director

JR:ln

Enclosures

987 N. Enterprise Street  
Orange California 92867-5472  
Phone 714 765 8355  
fax 714 769 1181

# PROVENANCE™

CLAIM	Product Name
Provenance Esteem is a complete three-part weight management and nutritional system, which helps you reduce or manage your weight with these natural, premium quality, nutrient-rich products.*	ESTEEM OVERVIEW PAGE
Brain nutrient Phosphatidylserine for enhancing memory and other cognitive functions, especially as we age. Brain Wave™ Helps support memory and alertness*	Objectives Brain Wave™
Brain Wave™ contains our Exclusive Enhancing Blend of herbs and phytonutrients for boosting brain power and overall enhanced cognitive performance.*	Objectives Brain Wave™
Brain Wave™ is an exceptional combination of nutrients formulated to enhance brain function and improve mental sharpness.*	Objectives Brain Wave™
Ginkgo Biloba improves circulation to the brain and also helps protect the brain by its antioxidant action.* Calm Spirit™ Supports positive well-being*	Objectives Brain Wave™
Calm Spirit™ for a positive well-being*	Objectives Calm Spirit™
Calm Spirit™ for times of stress.*	Objectives Calm Spirit™
Calm Spirit™ provides a highly useful, readily absorbed combination of neuronutrients to help lighten and improve your mood, safely and naturally.*	Objectives Calm Spirit™
Kava Kava, Chamomile, and Passion Flower provide calming and relaxing herbs to complete this synergistic herbal blend.*	Objectives Calm Spirit™
Powerful neuronutrients, L-Glutamine, L-Tyrosine, lecithin, and calcium for mental support.*	Objectives Calm Spirit™
St. John's Wort has long been recognized as a useful and safe herb that promotes a sense of well-being and overall mood support.*	Objectives Calm Spirit™
Chamomile, Hops, and Passion Flower herbs for their soothing and calming properties.* Dream Path™ Promotes sleep and relaxation*	Objectives Dream Path™
Dream Path™ also contains Kava Kava, Chamomile, and other relaxing herbs and essential minerals to support a restful state.*	Objectives Dream Path™
Dream Path™ for enhancing sleep and relaxation*	Objectives Dream Path™
Dream Path™ is a natural formula to promote sleep and relaxation.*	Objectives Dream Path™
Kava Kava root extract to encourage relaxation and promote a sense of well-being.*	Objectives Dream Path™
Valerian, which has been widely used in folk medicine and is known to be one of the most effective herbs for promoting natural deep sleep.*	Objectives Dream Path™
Borage, Evening Primrose Oil and Zinc provide important roles that regulate the normal functioning of the oil glands in the skin.*	Objectives Enzyme Time™
Enzyme Time™ aids the digestive process and enhances overall digestive health and performance.* Enzyme Time™ Assists in the process of digestion*	Objectives Enzyme Time™
Ginger and Licorice Root are traditional digestive herbs that help stimulate and balance digestion.*	Objectives Enzyme Time™
The addition of probiotics such as FOS can enhance the activity and number of good bacteria and regulate the presence of unwanted bacteria.*	Objectives Enzyme Time™
This unique formula is enhanced with traditional digestive herbs and naturally occurring compounds that increase the amount of friendly bacteria in the intestinal tract.*	Objectives Enzyme Time™
Evermore™ contains the most effective antioxidants known in nutritional science. Acting together, this synergistic formula provides powerful antioxidant protection to your cells.*	Objectives Evermore™
Evermore™ provides a dynamic combination of vitamins, minerals, herbs, and enzyme antioxidants to help protect the body from the effects of free radicals.*	Objectives Evermore™