



OCT 24 2000

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Terry Rey
Vice President of Operations
Nature's Herbs
600 East Quality Drive
American Fork, Utah 84003

Dear Mr. Rey:

This is in response to your letter of September 15, 2000 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 Nature's Herbs is making the following claim, among others, for the product "**Gingko-Ginseng Complex:**"

"...help offset age-related memory decline;"

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 suggest that it is intended to treat, prevent, or mitigate a disease, namely a decline or loss in memory associated with age. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim 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,

John B. Foret
Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling,
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

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Copies:

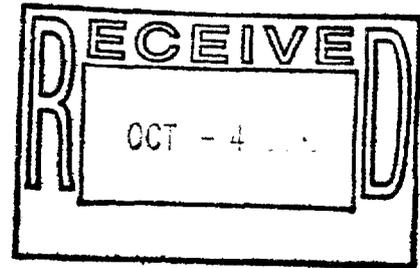
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, Denver District Office, Office of Compliance, HFR-SW240

cc:

HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-800 (r/f, file)
HFS-811 (file)
HFS-22 (CCO)
HFD-310
HFD-314 (Aronson)
HFV-228 (Benz)
GCF-1 (Nickerson, Dorsey)
f/t:HFS-811:afp:10/17/00:docname:72828:disc1

September 15, 2000

Margaret Binzer, Consumer Safety Officer
Regulatory Branch – Division of Programs & Enforcement Policy
Office of Special Nutritionals
Center for Food Safety & Applied Nutrition
HFS 456
200 C Street S.W.
Washington DC 20204



Dear Ms. Binzer:

This letter serves as a 30-day notification, pursuant to 403R6 of the Food, Drug & Cosmetic Act, for our product Gingko-Ginseng Complex.

The statements we are making for this product are:

Nutritionally helps the body adapt to physical and mental stress.

Gingko has been shown to increase the blood circulation to the brain and to help offset age-related memory decline.

Ginseng has been shown to be an adaptogen to support the body during times of stress and to support mental and physical energy.

Sincerely,

Terry Rey
Vice President of Operations