



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

APR 25 2000

James P. Clark, Ph.D.
Technology Director
Cognis Corporation
5325 South Ninth Avenue
LaGrange, Illinois 60525

Dear Dr. Clark:

This is in response to your letter to the Food and Drug Administration (FDA), dated April 13, 2000, 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 Cognis Corporation is making the following claims, among others, for the product **Covitol**[®]:

“Scientific evidence suggests this nutrient plays a role in reducing the risk of many of our most common health concerns.”

“Heart helper - helps maintain a healthy heart and blood vessels.”

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 statements that you are making for this product suggests that it is intended to treat, prevent, or mitigate disease, namely coronary heart disease. 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,

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

975-0163

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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, Chicago District Office, Compliance Branch, HFR-MW140

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-800 (file, r/f)

HFS-811 (r/f, file)

HFD-40 (Behrman)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-605

HFV-228 (Betz)

GCF-1 (Barnett, Nickerson, Dorsey)

f/t:rjm:HFS-811:4/24/00:70291.adv:disc46



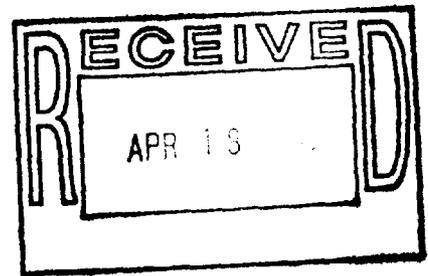
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13 April, 2000

nutrition&health

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



To the Food and Drug Administration:

Pursuant to section 403(r)(6) for the Federal Food, Drug, and Cosmetic Act (FDC Act), 21.U.S.C. § 343 (r)(6), we hereby notify the FDA that Cognis Corporation has included the following statements in labeling for a dietary ingredient that it manufactures and markets for use in dietary supplement products.

The following information is provided:

1. The name and address of the manufacturer and distributor of the dietary ingredient is as follows: Cognis Corporation, 5325 South 9th Avenue, LaGrange, IL 60525-3602.

2. The text of the labeling statements is as follows:

"Scientific evidence suggests this nutrient plays a role in reducing the risk of many of our most common health concerns."

"...one of nature's most powerful free radical quenchers and a potent antioxidant that protects your body's cells from damage."

"Heart helper – helps maintain a healthy heart and blood vessels"

"Immune booster – helps preserve a healthy immune system and reduces excessive levels of free radicals."