DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

JUN - 7 2000

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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 May 22, 2000. In your letter, you asked us to clarify the basis upon which we had concluded that certain claims identified in our letter dated April 25, 2000 were not claims subject to 21 U.S.C. 343(r)(6).

In our letter, we stated that the claims "Scientific evidence suggests this nutrient plays a role in reducing the risk of many of our most common health concerns" and "Heart helper - helps maintain a healthy heart and blood vessels" suggested that your product was 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 because the statements suggested that it was intended to treat, prevent, or mitigate disease, namely coronary heart disease.

In the January 6, 2000 Federal Register (65 FR 1000), FDA issued final regulations defining the types of statements that can be made concerning the effect of a dietary supplement on the structure or function of the body. In the preamble to the final rule, FDA stated that it would not always be possible to draw a line between structure/function and disease claims with great specificity, but, that the context in which a claim is presented would be important in distinguishing between structure function claims and disease claims (see discussion at 65 FR 1011). With respect to the claims for your product that were cited in our April 25, 2000 letter, the context of all of the claims presented for the product is an implied disease claim that suggests that the product is intended to treat, prevent, or mitigate coronary heart disease (i.e., "reducing the risk of many of our most common health concerns" in conjunction with a claim regarding the maintenance of a healthy heart and blood vessels). Absent context that links statements about maintaining a healthy heart or blood vessels to information about reducing the risk or preventing disease, such claims would appear to be structure/function claims under 21 U.S.C. 343(r)(6).

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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

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
HFD-314 (Aronson)
HFS-605
HFV-228 (Betz)
GCF-1 (Nickerson, Dorsey)
f/t:rjm:HFS-811:6/1/00:70849.adv:disc47

70849

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nutrition&health

22 May, 2000

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MAY 23

Mr. John B. Foret, Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling, and
Dietary Supplements
Food and Drug Administration
200 C Street, SW
Washington, DC 20204

Dear Mr. Foret:

This is in response to your April 25, 2000 letter responding to our notification of statements in labeling pursuant to 21 U.S.C. 343(r)(6) of the Federal Food, Drug and Cosmetic Act. In your letter, you listed two claims pertaining to our Covitol® natural-source vitamin E product which you concluded do not meet the requirements of 21 U.S.C. 343(r)(6) in that they suggest that this product is intended to treat, prevent or mitigate disease, namely coronary heart disease.

One of the above-mentioned claims is, "Heart Helper – helps maintain a healthy heart and blood vessels." We respectfully request clarification as to why this claim does not meet the requirements of 21 U.S.C. 343(r)(6), and as to how it can be modified to be consistent with FDA regulations.

Sincerely,

James P. Clark

James P. Clark, Ph.D.
Technology Director