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MAY 16 2001

Dr. Cindy Schweitzer
Senior Scientist
Cognis Corporation
5325 South Ninth Avenue
LaGrange, Illinois 60525

Dear Dr. Schweitzer:

This is in response to your letter of April 26, 2001 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 Cognis Corporation is making the following claim, among others, for the dietary ingredient **Betatene®**:

“Carotenoids are antioxidants that quench free radicals...that can...contribute to...disease.”

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, cure, or mitigate diseases. 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.

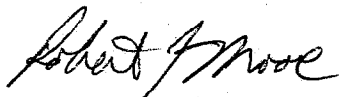
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Please contact us if we may be of further assistance.

Sincerely,



for

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, Office of Compliance, HFR-MW140

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cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-800 (r/f, file)

HFS-810 (Foret)

HFS-811 (file)

HFD-40 (Behrman)

HFD-310

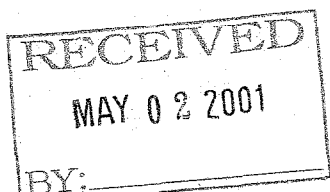
HFD-314 (Aronson)

HFS-607 (Bayne-Lisby)

HFV-228 (Benz)

GCF-1 (Nickerson)

f/t:HFS-811:rjm:5/14/01:docname:75825.adv:disc57



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April 26, 2001

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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 a new brochure that is 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:

"Carotenoids are antioxidants that quench free radicals, hazardous molecules that can damage cells and contribute to aging and disease."

"For example, scientific research suggests that beta-carotene may enhance immune function, lutein may help maintain eye health and lycopene may help maintain a healthy prostate."

"For example, a study of almost 2000 men found that high blood levels of total (mixed) carotenoids were more likely to maintain healthy hearts, compared with men who had low levels of carotenoids."

"Scientific research suggests that algae-sourced natural beta-carotene may help maintain healthy skin after exposure to UV light."

"Beta-carotene also maintains the activity of immune cells, to help keep us healthy."

"Laboratory and animal experiments suggest that alpha-carotene may play a role in maintaining healthy cells and tissues, and a study of men reported that diets high in alpha-carotene were associated with enhanced lung health."

"Preliminary research suggests beta-cryptoxanthin assists in healthy cell communication and may be associated with maintaining healthy tissues such as lung and prostate."

3. The dietary ingredients that are the subject of the statements are natural mixed carotenoids, including beta-carotene, alpha-carotene, cryptoxanthin, lutein and zeaxanthin. The brand name for this ingredient is Betatene®.
4. We do not manufacture or distribute retail dietary supplement products, only bulk dietary ingredients used by others in the manufacture of their dietary supplements. The information provided above relates to the labeling that will be used by Cognis Corporation and for which Cognis Corporation is responsible.

Pursuant to FDA regulations concerning "notification procedures for certain types of statements on dietary supplements," 21C.F.R. § 101.93, I certify that, to the best of my knowledge and in my opinion, the information contained in this notice is complete and accurate, and that Cognis Corporation has substantiation that the statements are truthful and not misleading.

We trust this provides the information that is needed. If you should have any questions, please just let us know.

Sincerely,



Cindy Schweitzer, Ph.D.
Senior Scientist
Cognis Nutrition and Health