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April 26, 2001

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

nutrition&health

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."

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"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."

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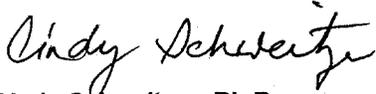
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3. The dietary ingredients that are the subject of the statements are natural mixed carotenoids, including beta-carotene, alpha-carotene, cryptoxanthin, lutein and zeaxanthin. The brand name for this ingredient is Betatene®.
4. We do not manufacture 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