

cognis

Cognis Corporation 5325 South Ninth Avenue LaGrange, IL 60525 USA

Phone 708/579-6150 Fax 708/579-6152 www.cognis-us.com

nutrition&health

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7 June, 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

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:

"Vitamin E is critically important to protect the brain and neural tissues from oxidative damage."

"In some situations, vitamin E supplementation, alone or in combination with other antioxidants, can help maintain the quality of life and the ability to function independently."

- 3. The dietary ingredient that is the subject of the statements is vitamin E. The brand name for this ingredient is COVITOL®.
- 4. We do not manufacture or distribute retail dietary supplement products but only bulk dietary ingredients used by others in their manufacture of

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