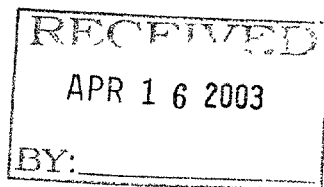




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**Cognis Corporation**  
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LaGrange, IL 60525-3602  
USA

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8 April 2003

Office of Nutritional Products, Labeling and Dietary Supplements (HFS-810)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Pkwy  
College Park, MD 20740

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 9<sup>th</sup> Avenue, La Grange, IL 60525-3602.

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

"Clinical and laboratory research indicates that TONALIN®CLA helps reduce body fat while maintaining or increasing lean body mass."

"Studies have shown that CLA decreases the activity of lipoprotein lipase (LPL)."

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**“CLA also stimulates lipolysis, or the breakdown of stored triglyceride, in the adipocytes.”**

**“CLA has also been shown to increase adipocyte apoptosis.”**

**“By increasing the rate of apoptosis, CLA is able to decrease the number of existing fat cells.”**

**“By increasing the activity of CPT in the skeletal muscles, CLA is able to increase the transport of fat into the mitochondria. This process leads to an increase in the rate of energy production from fat, called  $\beta$ -oxidation.”**

- 3. The dietary ingredient that is the subject of the statements is conjugated linoleic acid. The brand name for this ingredient is TONALIN<sup>®</sup> CLA.**
- 4. We do not manufacture or distribute retail dietary supplement products but only bulk dietary ingredients used by others in their manufacture of their dietary supplements. The information provided about 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,” 21 C.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,**

A handwritten signature in black ink, appearing to read "Heather Nelson Cortes". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

**Heather Nelson Cortes, Ph.D.  
Research Scientist  
Cognis Nutrition and Health**