



**Memorandum**

JUN 30 2004

Date: \_\_\_\_\_ 2326 104 100-4 0130  
From: Division of Dietary Supplement Programs, Office of  
Nutritional Products, Labeling and Dietary Supplements, HFS-810  
Subject: 75-Day Premarket Notification of New Dietary Ingredients  
To: Dockets Management Branch, HFA-305

Subject of the Notification: Phyto-derived Ceramides  
Firm: Soft Gel Technologies Incorporated  
Date Received by FDA: April 4, 2004  
90-Day Date: July 4, 2004

In accordance with the requirements of section 413(a) of the Federal Food, Drug, and Cosmetic Act, the attached 75-day premarket notification and related correspondence for the aforementioned substance should be placed on public display in docket number 95S-0316 as soon possible since it is past the 90-day date. Thank you for your assistance.

*Laura L. Jackson, I.D.S.*

95S-0316

RPT240

Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, Maryland 20740

Ms. Susan D. Brienza  
Patton Boggs, LLP  
Attorneys at Law  
1660 Lincoln Street, Suite 1900  
Denver, Colorado 80264

JUN 18 2004

Dear Ms. Brienza:

This is to inform you that the notification, dated April 2, 2004, you submitted pursuant to 21 U.S.C. 350b(a)(2)(section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (the Act)) on behalf of your client, Soft Gel Technologies, Inc. (SGTI) was filed by the Food and Drug Administration (FDA) on April 5, 2004. Your notification concerns the substances called, "phyto-derived Ceramides", extracted from wheat germ and other wheat sources, *Triticum aestivum* L., or rice seeds, *Oryza sativa* L., that you intend to market as new dietary ingredients.

You state that your client intends to market those "phyto-derived Ceramides" extracted from wheat germ under the trade name Cennamides™. You also state that both rice and wheat "phyto-derived Ceramides" will initially be marketed in soft gel capsule form. Each soft gel will contain 30 mg of "phyto-derived Ceramides" and the recommended dose of "phyto-derived Ceramides" will be 60 mg per day. The notification states that "most probably, SGTI will place the following caution on the label of the dietary supplement containing ceramides": "Not to be taken by pregnant or lactating women".

Under 21 U.S.C. 350b(a), the manufacturer or distributor of a dietary supplement containing a new dietary ingredient that has not been present in the food supply as an article used for food in a form in which the food has not been chemically altered must submit to FDA, at least 75 days before the dietary ingredient is introduced or delivered for introduction into interstate commerce, information that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such new dietary ingredient will reasonably be expected to be safe. FDA reviews this information to determine whether it provides an adequate basis for such a conclusion. Under section 350b(a)(2), there must be a history of use or other evidence of safety establishing that the new dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe. If this requirement is not met, the dietary supplement is considered to be adulterated under 21 U.S.C. 342(f)(1)(B) because there is inadequate information to provide reasonable assurance that the new dietary ingredient does not present a significant or unreasonable risk of illness or injury.

FDA has carefully considered the information in your notification and has significant concerns about the evidence on which you rely to support your conclusion that the ingredients, "phyto-derived Ceramides", will be reasonably expected to be safe for the suggested or intended uses.

Although your notification included a general description of a manufacturing process for Cennamide CERP5, your notification does not contain any information about the actual preparation, composition, product specification, methods of analysis, and purity of your "phyto-derived Ceramides" extracted from either wheat or rice sources. There is inadequate information presented in the notification to characterize and identify your specific "new dietary ingredient". A description of the method of manufacture or process of obtaining your product, "phyto-derived Ceramides", may have helped FDA clarify the identity of your product.

It is unclear to FDA whether the test substances used in the referenced studies are the same as the "phyto-derived Ceramides", in your notification. It is not evident that the test substances used in the referenced studies are qualitatively or quantitatively similar to your "phyto-derived Ceramides", or how these studies are relevant to evaluating the safe use of your new dietary ingredient under the recommended conditions of use.

Your notification will be kept confidential for 90 days after the filing date of April 5, 2004. After the 90-day date, the notification will be placed on public display at FDA's Division of Dockets Management in docket number 95S-0316. Prior to that date, you may wish to identify in writing specifically what information you believe is proprietary, trade secret or otherwise confidential for FDA's consideration.

If you have any questions concerning this matter, please contact Victoria Lutwak at (301) 436-2375.

Sincerely yours,



Susan J. Walker, M.D.  
Director  
Division of Dietary Supplement Programs  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition