



MAY 31 2005

Food and Drug Administration
5100 Paint Branch Parkway
College Park, Maryland 20740Susan D. Brienza
Patton Boggs, LLP
Suite 1900
1660 Lincoln St.
Denver, CO 80264

Dear Ms. Brienza:

This is to inform you that the notification, dated March 7 2005, that 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)) was filed by the Food and Drug Administration (FDA) on March 9, 2005. Your notification was filed on behalf of your client, Soft Gel Technologies, Inc., and concerns the substance "Wheat germ-derived ceramides", prepared from *Triticum aestivum* L. that they intend to market as a new dietary ingredient.

According to the notification, Soft Gel Technologies, Inc. intends to market their new dietary ingredient "Wheat germ-derived ceramides" in the form of a gel cap. You indicate that "[t]he ingested amount of Ceramides in the proposed supplement is 30 mg per serving and 60 mg per day." According to your notification, the label will contain the following warning:

"WARNING: This product contains ceramides which are derived from wheat germ oil. Do not take this product if you are allergic to wheat in any form." Your notification also states that the label will contain the following statement, "Caution: [N]ot to be taken by pregnant or lactating women. Not recommended for longer than 30 continuous days."

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 submission, and the agency has concerns about the evidence on which you rely to support your conclusion that a dietary supplement containing "Wheat germ-derived ceramides" will reasonably be expected to be safe.

FDA was unable to clearly establish the identity of your new dietary ingredient, "Wheat germ-derived ceramides". Pages 7-9 of your notification contain a description of the manufacturing process for your ingredient. Your notification also contains an appendix containing a description of the manufacturing process, said to have been provided by the manufacturer. These descriptions differ both as to the starting materials (wheat flour vs. wheat germ oil) and the manufacturing processes. Moreover, your notification refers to Cennamides™, Ceramide Oil, and Ceramides without describing how these substances are qualitatively and quantitatively related to one another, to "Wheat germ-derived ceramides" or to the substances described in the safety material appended to your notification. Because the identity of your new dietary ingredient and the materials described in the safety material were not clear, it is not clear how these studies are relevant to evaluating the safe use of your new dietary ingredient under the recommended condition of use in your dietary supplement product.

For the reasons discussed above, the information in your submission does not provide an adequate basis to conclude that the dietary supplement product containing "Wheat germ-derived ceramides", when used under the conditions recommended or suggested in the labeling of your product, will reasonably be expected to be safe. Therefore, your product may be adulterated under 21 U.S.C. 342(f)(1)(B) as a dietary supplement that contains a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury. Introduction of such a product into interstate commerce is prohibited under 21 U.S.C. 331(a) and (v).

Your notification will be kept confidential for 90 days after the filing date of March 9, 2005. After the 90-day date, the notification will be placed on public display at FDA's Division of Docket 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 Linda Pellicore, Ph.D. at (301) 436-2375.

Sincerely yours,



Susan J. Walker, M.D.
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