



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

JUN 21 2005

W. Patrick Noonan
Warner Center Plaza Suite 840
21800 Oxnard St.
Woodland Hills, California 91367

Dear Mr. Noonan:

This is to inform you that the notification, dated April 7 2005, that you submitted on behalf of your client, Chrysantis, 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 April 8, 2005. Your notification concerns the substance that you call "Zeaxanthin purified concentrate from marigold flowers" derived from *Tagetes erecta* L. that you intend to market as a new dietary ingredient.

According to the notification you intend to market your new dietary ingredient "Zeaxanthin purified concentrate from marigold flowers" "as a new dietary ingredient and a source of Zeaxanthin at a recommended and suggested level of use of 12 mg per day, consumed in a single of divided daily dose. Zeaxanthin Purified Concentrate at a level of use of 12 mg per day will provide consumers 3 mg Zeaxanthin, and additionally 0.32 mg Lutein and 0.14 mg epoxides." You state that the target population for the new dietary ingredient Zeaxanthin Purified Concentrate is adults.

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.

In accordance with 21 CFR 190.6(c), FDA must acknowledge its receipt of a notification for a new dietary ingredient. For 75 days after the filing date, your client must not introduce or deliver for introduction into interstate commerce any dietary supplement that contains the new dietary ingredient that is the subject of this notification.

Please note that acceptance of this notification for filing is a procedural matter, and thus, does not constitute a finding by FDA that the new dietary ingredient or supplement that contains the new dietary ingredient is safe or is not adulterated under 21 U.S.C. 342. FDA is not precluded from taking action in the future against any dietary supplement containing your new dietary ingredient if it is found to be unsafe, adulterated, or misbranded.

Your notification will be kept confidential for 90 days after the filing date of April 8, 2005. After the 90-day date, the notification will be placed on public display at FDA's Division of Docket Management Branch in docket number 95S-0316. Prior to that date, you may wish to identify in writing specifically what information that 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.
Director
Division of Dietary Supplement Programs
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and Dietary Supplements
Center for Food Safety
and Applied Nutrition