



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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

Mr. David S. Tourville
Managing Director
Shannon Minerals Inc
26 Washington St., 3rd Floor
Morristown, New Jersey 07960

DEC - 6 2005

Dear Mr. Tourville:

This is to inform you that the notification, dated September 22, 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 September 22, 2005. Your notification concerned the substance that you identified as "Extract of *Garcinia Cambogia*," which you intend to market as a new dietary ingredient (Citrin K BG[®]) in a dietary supplement called "Coolwater Trim."

According to your notification, your new dietary ingredient will be marketed in individual bottles with each bottle containing 1400 mg of Citrin K BG[®], an "Extract of *Garcinia Cambogia*" delivering 700 mg of (-)-HCA. Your notification states that Citrin K BG[®] is an extract from *Garcinia cambogia* (Gaertn.) Desrouss. and that the other ingredients of "Coolwater Trim" will be "Water, Citric Acid, Natural Flavour, Aspartame, Sodium Benzoate & Potassium Sorbate as preservatives and Acesulfame Potassium." Regarding conditions of use, the notification states that the product is for use as a dietary supplement consuming not more than one bottle three times daily. The notification also states that the product is not recommended for use by young children or by pregnant or lactating women and that the product label will provide the phenylketonurics cautionary statement (21 CFR § 172.804(d)(2)).

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.

Your new dietary ingredient notification for "Extract of Garcinia Cambogia" that you intend to market as a new dietary ingredient (Citrin K BG[®]) in a dietary supplement presents FDA with an issue that requires further examination. You have proposed a dietary supplement product in liquid form with a serving size comparable to that of an ordinary beverage. It is not clear that such a product meets the requirements for a dietary supplement in 21 U.S.C. 321(ff)(2) and 350(c).

FDA cannot determine, at this time, whether your product may be lawfully marketed as a dietary supplement under the conditions of use you intend to recommend in its labeling. FDA intends to complete its evaluation shortly and send a response to your notification explaining the agency's decision about whether your product is a dietary supplement within the meaning of 21 U.S.C. 321(ff).

This letter is to alert you within the 75-day notification period that FDA has concerns about whether your product can lawfully be marketed as a dietary supplement. Please note that failure to respond to a notification within the 75-day timeframe does not constitute a finding by the agency that the ingredient or a product that contains the ingredient is safe or is not adulterated under 21 U.S.C. 342 (21 CFR. 190.6(f)).

Your notification will be kept confidential for 90 days after the filing date of September 22, 2005. After the 90-day date, the notification will be placed on public display at FDA's Docket Management Branch 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 S. Pellicore, Ph.D. 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