



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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

AUG 8 2005

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

Dear Mr. Tourville:

This is to inform you that the notification, dated May 23, 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 May 25, 2005. Your notification concerned the substance that you identified as "Synthetically produced (-)-hydroxycitric acid" that you intend to market as a new dietary ingredient in a dietary supplement product that you call "Coolwater Trim™".

According to your notification, your new dietary ingredient will be marketed in individual bottles containing 500 ml solution containing 1167 mg tripotassium hydroxycitrate delivering 700 mg (-) HCA. Your notification states that the ingredients will be "Water, Citric Acid, APPETRIM™ synthetic (-) – Hydroxycitrate, Natural Flavour, Aspartame, Sodium Benzoate, Potassium Sorbate as preservatives and Asculfame Potassium" and that the conditions of use will be to "[u]se as a dietary supplement consuming one bottle no more than four times daily. Not recommended for use by young children or by pregnant or lactating women. The 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.

Based on the information in your submission, FDA was unable to determine the identity of your new dietary ingredient, "synthetically produced (-)-hydroxycitric acid". For example, the ingredient is described variously as (-)-HCA, K(-)-HCA, KHCA and tripotassium hydroxycitrate. While your notification contains a description of the synthesis of your proposed new dietary ingredient, that description is inadequate to permit the identification of the substance(s) produced by the synthesis.

Because FDA could not determine the identity of your new dietary ingredient, it is not readily apparent whether the substance that is the subject of your notification is a "dietary ingredient" within the meaning of 21 U.S.C. 321(ff)(1) that may be lawfully used in dietary supplements. The term "dietary supplement" is defined in 21 U.S.C. 321(ff). A dietary supplement means, among other things, a "product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:

- (A) a vitamin;
- (B) a mineral;
- (C) an herb or other botanical;
- (D) an amino acid;
- (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or
- (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E)."

Based on the information in your submission, it is unclear that synthetically produced (-)-hydroxycitric acid is a "dietary ingredient" within the meaning of 21 U.S.C. 321(ff)(1). Therefore, notwithstanding the discussion below of the evidence you rely upon as evidence that your products are reasonably expected to be safe, FDA can not determine, at this time, whether your product contains a dietary ingredient that may lawfully be marketed as a dietary supplement.

Even if synthetically produced (-)-hydroxycitric acid may be a dietary ingredient under the Act, after careful consideration of the information in your submission, FDA has significant concerns about the evidence on which you rely to support your conclusion that a dietary supplement containing "synthetically produced (-)-hydroxycitric acid" will reasonably be expected to be safe.

Your notification provided history of use of the rinds of *Garcinia cambogia* fruits as food. Because the identity of your new dietary ingredient is unclear, it is unclear how it is qualitatively and quantitatively related to the fruit rinds that are consumed as food. In addition, your notification included several publications which discussed the safety of other

salts of hydroxycitric acid. The relationships among the materials discussed in these publications and the material that is the subject of the notification are unclear. It is unclear how the substances discussed in the referenced studies are qualitatively or quantitatively similar to your product or how these studies are relevant to evaluating the safe use of your new dietary ingredient under the recommended conditions of use.

For the reasons discussed above, the information in your submission does not provide an adequate basis to conclude that "synthetically produced (-)-hydroxycitric acid" 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 May 25, 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.
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Division of Dietary Supplement Programs
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