



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 "Extract of *Garcinia Cambogia*" that you extract from *Garcinia cambogia* (Gaertn.) Desrouss. that you intend to market as a new dietary ingredient in a dietary supplement product which you call "Coolwater Trim™".

According to your notification, your new dietary ingredient will be marketed in individual bottles containing 500 ml solution containing 1400 mg of "Extract of *Garcinia Cambogia*". Your notification states that the ingredients will be "Water, Citric Acid, Citrin K natural Potassium 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 not more than one bottle three 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.

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 "Extract of *Garcinia Cambogia*" will reasonably be expected to be safe.

Your notification fails to adequately identify your new dietary ingredient, "Extract of *Garcinia Cambogia*". The identity of 48% of the ingredient is presumably potassium (-)-hydroxycitrate which you refer to as (-)-hydroxycitric acid. Insufficient manufacturing, characterization and specifications information is provided to confirm the identity and 52% of the composition of the ingredient. Since approximately 50% of its composition is unstated, the identity of your new dietary ingredient is unclear.

Your notification provided history of use of the rinds of *Garcinia cambogia* fruits as food. Because the identity of "Extract of *Garcinia Cambogia*" 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 new dietary ingredient 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 "Extract of *Garcinia Cambogia*" 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.

Page -3- Mr. David S. Tourville

If you have any questions concerning this matter, please contact Linda S. Pellicore, Ph.D. at (301) 436-2375.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'S. Walker', with a long horizontal flourish extending to the right.

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