DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

0434 6 JAN 12 P2:34

Date: DEC 21 2005

From: Consumer Safety Officer, Division of Dietary Supplement Programs , Office of Nutritional Products, Labeling and Dietary Supplements, HFS-810

Subject: 75-Day Premarket Notification of New Dietary Ingredients

To: Dockets Management Branch, HFA-305

Subject of the Notification: Extract of Garcinia Cambogia (Burren Spring Trim)

Firm: Shannon Minerals Inc

Date Received by FDA: 09/22/2005

90-Day Date: 12/21/2005

In accordance with the requirements of section 413(a) of the Federal Food, Drug, and Cosmetic Act, the attached 75-day premarket notification and related correspondence for the aforementioned substance should be placed on public display in docket number 95S-0316 as soon possible since it is past the 90-day date. Thank you for your assistance.

Victoria Lutwak

1995S-0316

RPT 305

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 "Burren Spring 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 "Burren Spring Trim" will be "Water, Citric Acid, and Natural Flavour " 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 C.F.R. 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

Burren Springs TRIM™
75 DAY PRE-MARKET NOTIFICATION

RECEIVED
SEP 22 2005
FDA

Sent Via Fed Ex Confirmed Delivery
Victoria L. Lutwak
Division of Dietary Supplement Programs (HFS-822)
Office of Nutritional Products, Labeling and Dietary Supplements
Center for Food Safety and Applied Nutrition
Food and Drug Administration
Harvey W. Wiley Federal building
Room 4D022
5100 Paint Branch Parkway
College Park, MD 20740-3835

Monday, 19 September 2005

RE: Pre-market Notification of ***Extract of Garcinia Cambogia, (-)-Hydroxycitric Acid***

Dear Sir or Madam,

Enclosed, please find our pre-market Notification for our new Dietary Ingredient, *Extract of Garcinia Cambogia,* (-) - Hydroxycitric Acid, specifically Citrin K BG® by Sabinsa Corporation, pursuant to 21 C.F.R. § 190.6.

The notification forwards evidence of safety establishing that the dietary ingredient, when used under the conditions recommended in the labelling of the dietary supplement, will reasonably be expected to be safe by providing the Food and Drug Administration with information, including citations to, and copies of, published articles, which are the basis on which the manufacturer has concluded that the dietary supplement containing the dietary ingredient will reasonably be expected to be safe. See generally 21 U.S.C. § 350b(a)(2).

2005-6262
Aims

We would also like to point out that for commercial reasons we do not intend re-submitting an application for a synthetic version of (-)-HCA.

We have attached an executive summary regarding our parent company and the reasons for the application; we trust that this will provide you with some background information on our market strategy.

Please note our contact details below for any communication with your office:

Mr. David Tourville
Shannon Minerals Inc.
26 Washington Street
3rd Floor, Morristown
NJ 07960

Tel: +1 973-2676-980
Fax: +1 973-2676-981
Email: david@brodericktourville.com

An original and two copies of the notification are submitted.

Yours sincerely,

David S. Tourville

Executive Summary

Shannon Minerals Ltd. was established in 1960 by the O Mara family and since its inception has been a family owned and managed business. Up until 1996 the first generation of the family guided the business and since 1996 the company has been under the direction of Brendan O Mara, a former senior executive with GE Capital, a subsidiary of General Electric.

Shannon Minerals Ltd. specialises in the manufacture of functional products, both branded and own label products and we currently sell to the World's leading food retailers in 24 countries on 2 continents.

Shannon Minerals Ltd. operates from a modern purpose built facility. The facility has achieved higher accreditation from EFSIS for the past four years. Shannon Minerals Ltd. has received numerous awards for innovation and export achievements; we also continue to enjoy the support of the Irish Government and its development agencies.

The purpose of this 'New Dietary Ingredient Notification for extract of Garcinia Cambogia (-)-HCA' is to allow us sell our functional product in the United States of America as a dietary supplement.

In this 'New Dietary Ingredient Notification for extract of Garcinia Cambogia (-)-HCA' we describe the identity of our new dietary ingredient, its long history of use and scientific articles relating to its safety, identity and testing. We establish the relevancy of any safety studies to our product and demonstrate a long history of use in food without adverse effect.

We describe in detail the daily-recommended usage, how this recommended level is 25% less than the daily safe level

We also set out our ability to produce and market products in a safe and traceable manner, regulated to the highest food safety standards.

Shannon Minerals Ltd. has built a solid reputation for innovation and market leading product development over the last 10 years, focusing on scientific development of new and exciting products. Safety and solid scientific research coupled with investment in modern technology form the basis of our market leading strategy.

We strongly believe, on the basis of all the scientific evidence and history of use, that (-)-HCA is a safe ingredient and that products made with this ingredient can reasonably be expected to be safe.

CONFIDENTIAL

PREMARKET NOTIFICATION

EXTRACT OF GARCINIA CAMBOGIA *(-)-HCA, Citrin K*

SUBMITTED BY

BRENDAN O MARA
SHANNON MINERALS LTD.
UPPER CLARE STREET
LIMERICK
IRELAND

September 2005

Burren Springs TRIM™
75 DAY PRE-MARKET NOTIFICATION

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