



SHANNON MINERALS 26 Washington Street, 3rd Floor Morristown, New Jersey 07960  
(973) 267-6980 p (973) 267-6981 f  
www.shannonminerals.com

Rec'd VL  
JUN 20 2005

June 17, 2005

**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

Dear Ms. Lutwak:

The post-it note formed part of a discussion relating to the two applications, synthetic K-HCA and extract of Garcinia Cambogia.

Historically Shannon Minerals has been using our own HPLC method to test the Appetrim K-HCA for the synthetic product we sell in our EU markets.

When we received the specification sheet and HPLC method from SABINSA for the extract of Garcinia Cambogia we had a discussion as to whether we should include our own method **in addition** to the SABINSA method but we proceeded with just the use of the Sabinsa testing method for the Sabinsa product. Since Shannon Minerals does test all incoming K-HCA shipments, we have attached our HPLC testing method (see attached PDF file). This methodology (in the attached PDF) does apply to both the synthetic and extract of Garcinia Cambogia applications. It should be added after the SABINSA HPLC page on the Extract application and before page 10 on the synthetic application.

I hope this clears up any confusion in this matter. If you need anything further please let me know.

Sincerely,

David Tourville



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June 2, 2005

RE: Replacement pages for the Pre-market Notification of *Extract of Garcinia Cambogia, (-)-Hydroxycitric Acid and Synthetically Produced (-)-Hydroxycitric Acid*

Dear Vicki,

Enclosed are the replacement pages for the smudged copies, 12 sets each already punched for insertion into the applications. Because the numbering of the pages differs from the extract to the synthetic application, we did not attempt to number these pages but hopefully the instructions below will be sufficient for the task at hand.

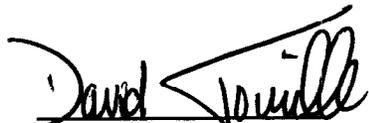
The first set of replacement pages is the 42 page document called, "Diet and Health Benefits of HCA" This goes in the second section of the application behind the light blue tab titled, "History of Use/Safety Evidence" It is the last part of that section (about page 38 on the Extract applications, page 41 on the synthetic applications) and ends just before the Toxicology tab.

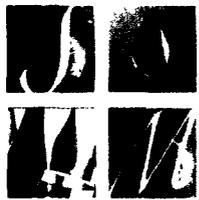
The second set of replacement pages is in Appendix C, the very last set of pages in the each of the applications. These constitute the last 12 pages of each of the applications.

Thank you for your input and help in this matter. If there are any questions or if any further information required, please contact me directly at any of the numbers below.

Tel: (973) 267-6980  
Mobile: (908) 963-3986  
Fax: (973) 267-6981  
Email: [david@brodericktourville.com](mailto:david@brodericktourville.com)

Yours sincerely,

  
David S. Tourville



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MAY 25 2005

FOO/VL

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Victoria L. Lutwak  
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Center for Food Safety and Applied Nutrition  
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Room 4D022  
5100 Paint Branch Parkway  
College Park, MD 20740-3835

May 23, 2005

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

Dear Sir or Madam,

Enclosed, please find our pre-market Notifications 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. for the Coolwater brand (top 3 binders) and our Burren Springs (no preservatives-next 3 binders). The second set of applications are for both brands again with synthetic HCA.

Citrin K BG® has been granted a **Certificate Of Free Sale** within the USA and for export.  
See attached copy in APPENDIX B: *Safety and Toxicology, Certificate of Free Sale*

The notification forwards evidence of safety establishing that the dietary ingredient, when used under the conditions recommended or suggested in the labeling 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).

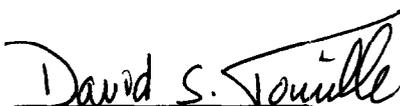
Please note our contact details below for any communication with your office:

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

Tel : (973) 267-6980  
Fax: (973) 267-6981  
Email: [david@brodericktourville.com](mailto:david@brodericktourville.com)

An original and two copies of the notification are submitted.

Yours sincerely,

  
David S. Tourville

C7S 91678