

# Fleminger, Inc.

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January 27, 2005

Kathleen Ellwood, Ph.D.  
Director  
Division of Nutrition Programs and Labeling  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration (HFS-830)  
5100 Paint Branch Parkway  
College Park, MD 20740-3835

Via Fax 301 436-2636 and Federal Express overnight delivery

Re: Docket No. 2004Q-0083: Daily consumption of 40 ounces of typical green tea containing 710µg/mL natural (-)-epigallocatechin gallate (EGCG) may reduce the risk of certain forms of cancer.

Dear Dr. Ellwood:

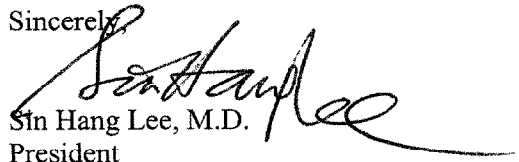
This letter is to confirm our telephone conversation of today that the petitioner for the above referenced application has reluctantly agreed to the FDA's request for a second postponement of its final decision on the green tea health claim until March 15, 2005, from January 28, 2005. Please send an official letter to the undersigned to confirm this newly scheduled date for the FDA's final decision.

You stated that this need for further time extension is not due to any scientific objection raised by the FDA to the contents of the petition or to the health claim proposed at this time; but rather is necessitated by an overwhelming case load and a shortage of agency staff. I am sympathetic.

As I reiterated in our telephone conversation, the FDA has not published all the correspondence records under docket no. 2004Q-0083, including a single comment entered as EC1, 04/02/2004, under the website summary (see attached printout dated 1/27/2005 from the Qualified Health Claim website). To this day, the undersigned does not know if any objections have been raised against the approval of this petition. As a result, this petitioner has not been given the chance to answer any scientific questions raised about this petition. In contrast, other petitioners for qualified health claims are able to see the negative comments on the FDA dockets and given opportunities to rebuttal or to submit additional scientific data to support their applications. You said you would look into the reason for the paucity of entries on this website.

Thank you for your cooperation.

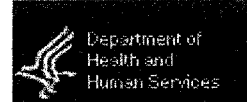
Sincerely,

  
Stan Hang Lee, M.D.  
President

Encl.: FDA 2004Q-0083: Qualified Health Claim summary page printed 1/27/2005-one page.

2004Q-0083

LET 7



[FDA Home Page](#) | [Dockets Home Page](#) | [Dockets Contacts and Location](#) | [Operating Status](#) | [Item Code Definitions](#)

[Up](#)

**2004Q-0083: Qualified Health Claim (QHC): Green Tea and Reduced Risk of Cancer**

Item Code	No.	Received Date	Submitter	Signature	FR Date	FR Page	Electronic form
LET	1	03/19/2004	HFS-200 to Fleming, Inc.	Laura M Tarantino PhD			<a href="#">pdf</a>
EC	1	04/02/2004	W Stephens	W Stephens			
SUP	1	03/18/2004	Fleming, Inc.	Sin Hang Lee MD			<a href="#">pdf</a> Copyrighted materials
ACK	1	03/18/2004	HFS-830 to Emord & Associates, PC	Nancy T Crane			<a href="#">pdf</a>
QHC	1	03/16/2004	Fleming, Inc.	Sin Hang Lee MD			<a href="#">Cover Letter</a> <a href="#">Petition Part 1</a> <a href="#">Petition Part 2</a> <a href="#">Petition Part 3</a> <a href="#">Petition Part 4</a> <a href="#">Petition Part 5</a> Copyrighted materials

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Page created April 12, 2004 jb

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