



FEB 17 2004

Food and Drug Administration
Washington DC 20204

Sin Hang Lee, MD
Fleminger, Inc.
160 Hawley Lane, Suite 205
Trumbull, CT 06611

RE: Health Claim Petition – Daily consumption of 40 ounces of typical green tea may reduce the risk of certain forms of cancer. Although there is scientific evidence supporting the claim, the evidence is not conclusive.

Dear Dr. Lee:

This letter acknowledges that the Food and Drug Administration (FDA) received your petition for a qualified health claim on February 2, 2004. You submitted this petition pursuant to Section 403(r)(4) or Section 403(r)(5)(D) of the Federal Food, Drug, and Cosmetic Act (FFD&C Act) (21 U.S.C. § 343(r)(4) or § 343(r)(5)(D)) with respect to consumption of green tea and reduced risk of certain forms of cancer. Because your petition is complete, FDA intends to file the petition for comprehensive review and comment within 45 days of its receipt (i.e., by March 18, 2004) in accordance with FDA's Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements.
(<http://www.cfsan.fda.gov/~dms/nuttftoc.html>)

Your petition will be posted on FDA's Division of Dockets Management web page (<http://www.fda.gov/ohrms/dockets/dockets.htm>) and we will be requesting comment on it for 60 days. Interested persons may submit comments until May 17, 2004. Within 270 days of the date we received your petition, we will notify you of our final decision regarding the requested qualified health claim. We have calculated that date to be October 29, 2004.

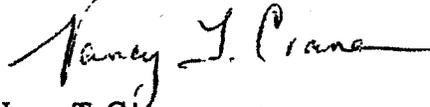
2004Q-0083

ACK

Page 2 - Sin Hang Lee

If you have any questions, please feel free to contact Ms. Nancy Crane with the Nutrition Programs and Labeling Staff at 301-436-1450.

Sincerely yours,

A handwritten signature in cursive script that reads "Nancy T. Crane". The signature is written in black ink and is positioned above the typed name and title.

Nancy T. Crane
Nutrition Programs and Labeling Staff
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition



NOV 12 2004

Food and Drug Administration
College Park, MD 20740

Sin Hang Lee, M.D.
President
Fleminger, Inc.
160 Hawley Lane, Suite 205
Trumbull, CT 06611

RE: Docket No. 2004Q-0083: Qualified Health Claim Petition for Green Tea and
Reduced Risk of Cancer

Dear Dr. Lee:

This letter responds to your October 26, 2004, letter to Kathleen Ellwood, Ph.D. Your letter was written in response to our telephone request on October 25, 2004, for a three month extension of the decision regarding the green tea and cancer qualified health claim petition referenced above. You agreed to the extension of the decision. The request for the extension is to allow more time for review of the petition and does not suggest any particular outcome of our decision on the petition.

You will be notified of the decision by January 28, 2005, when the decision will be made publicly available. The decision letter will be placed in the docket for the petition.

Thank you for your cooperation. If you have any questions, please contact me at 301-436-1450.

Sincerely,

Vincent de Jesus, M.S., R.D.
Nutrition Programs and Labeling Staff
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

2004Q-0083

ANS 1



FEB 9 2005

Sin Hang Lee, M.D.
President
Fleminger, Inc.
160 Hawley Lane, Suite 205
Trumbull, CT 06611

RE: Docket No. 2004Q-0083: Qualified Health Claim Petition for Green Tea and
Reduced Risk of Cancer

Dear Dr. Lee:

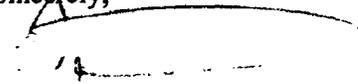
This letter is a confirmation of the new decision date for the green tea and cancer qualified health claim petition referenced above. We have received your letter, dated January 27, 2005, sent to Kathleen Ellwood, Ph.D. agreeing to the requested two-month extension. This extension was requested during our phone conversation on January 27, 2005 in order to provide additional time for review of the petition. This request does not suggest any particular outcome of our decision.

The new decision date is March 25, 2005. In your letter, the two-month extension date is incorrectly written as March 21, 2005. During our follow-up phone conversation on February 1, 2005, you acknowledged the error and accepted the official decision date.

You will be notified of the decision by March 25, 2005, when the decision will be made publicly available. The decision letter will be placed in the docket for the petition.

Thank you for your cooperation. If you have any questions, please contact me at 301-436-1450.

Sincerely,


Vincent de Jesus, M.S., R.D.
Nutrition Programs and Labeling Staff
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

2004Q-0083

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FDA

CFSAN

FOOD & DRUG ADMINISTRATION

CENTER FOR FOOD SAFETY & APPLIED NUTRITION

**OFFICE OF NUTRITIONAL PRODUCTS, LABELING,
& DIETARY SUPPLEMENTS**

**DIVISION OF NUTRITION PROGRAMS
& LABELING (HFS-830)**

**5100 Paint Branch Parkway
College Park, MD 20740**

**TEL. NUMBER (Office): 301/ 436-2373
TEL. NUMBER (Division): 301/ 436-1450
FAX NUMBER: 301/ 436-2639**

DATE: March 24, 2005
TO: Sin Hang Lee, M.D., President, Fleminger, Inc.
FAX #: 203/ 385-3832
FROM: Vincent de Jesus

Comments: Memorandum for Docket No. 2004Q-0083: Qualified Health Claim Petition for Green Tea and the Reduced Risk of Cancer



MAR-24-2005 15:54

FDA

301 436 2636 P.02

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: March 24, 2005
From: FDA/CFSAN, Office of Nutritional Products, Labeling and Dietary Supplements
Division of Nutrition Programs and Labeling
Subject: Qualified Health Claim Petition

This communication is to inform you that the decision on your petition for a qualified health claim regarding green tea and reduced risk of cancer (Docket No. 2004Q-0083) will not be announced tomorrow March 25, 2005. Notification of the agency's determination will instead be issued on April 29, 2005. As always, you may contact the division or the office if you have any questions.

Fleminger, Inc.

160 Hawley Lane, Suite 205, Trumbull CT 06611

Tel. 203 385-3836 Fax 203 385-3832

The Office of Sin Hang Lee, M.D., F.R.C.P. (C)

January 31, 2005

Lester M. Crawford, D.V.M., Ph.D.
Acting Commissioner
U. S. Food and Drug Administration
5600 Fishers Lane
Rockville MD 20857-0001

Via Federal Express overnight delivery

**Subject: FDA's Proactive Role in Public Education on Drinking Tea to Prevent Cancer-
docket no. 2004Q-0083**

Dear Dr. Crawford:

This letter requests your attention to direct the agency staff to review and modify, if necessary, this said green tea health claim (docket no. 2004Q-0083) without further delay. At the request of Dr. K. Ellwood, we have again agreed to a second extension date when is March 15, 2005 for the FDA to make its final decision, as stipulated in my letter dated January 27, 2005 to the Administration (Exhibit A). The reason given for the need of another extension was "case overload" at the agency. However, this reason contradicts a public statement of Sebastian Cianci, spokesman for the FDA's Center for Food Safety and Nutrition, who was quoted as saying "...that companies have been slow to submit qualified claim petitions. The agency has accepted only 15 petitions for review, including four for reduction of cancer risk: soy protein, lycopene (found in tomato products), calcium and green tea." (J National Cancer Institute 2004;96:1198-1199)

The American consumers need guidance from the FDA on this subject now. They are confused by the half-truth reports in the lay news on the health benefits of drinking tea, especially for cancer prevention. Here are a few recent news headlines the consumers have heard or read:

Cancer is now the No. 1 killer in the U.S. (Exhibit B).

Green tea is effective against cancer (Exhibit C).

Drinking too much tea causes fluoride poisoning-case report from St. Louis (Exhibit D).

Ingestion of green tea extracts may cause liver damage (Exhibit E).

The tea merchants and the healthcare providers are generally unfamiliar with the biochemistry and pharmacology of teas. Consumption of "typical" green tea as defined by the National Cancer Institute has never been known to cause fluoride intoxication which is endemic in Tibet among

Continued page 2-Dr.Lee to Dr. Crawford FDA, 01/31/2005

people drinking brick tea, a low-quality black tea (Exhibit F). The FDA should set a standard for tea if it is to be consumed for health care reasons in large quantities.

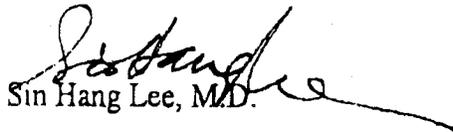
I am a private citizen without corporate sponsors. My specialty is hospital-based cancer pathology and clinical microbiology. The attached copy of an entry on Sin Hang Lee extracted from **Marquis' Who'sWho in the World** (Exhibit G) summarizes my professional education and experience. I filed the petition on January 26, 2004 under docket no. 2004Q-0083 for a qualified health claim which can be used by the tea industry as food labeling for consumer education. I recognize that evaluating and granting food labeling is a role played by the FDA in implementing the Dietary Supplements Health and Education Act of 1994 (DSHEA).

It is much appreciated if the review committee on this project would contact me immediately for additional materials or data, if needed, to complete their scientific review.

I will also make myself available to meet with the reviewing staff to answer any scientific questions relating to this health claim petition if necessary.

Thank you for your attention to this matter.

Sincerely,


Sin Hang Lee, M.D.

Encl.: Exhibits A-G.

cc: Senator Joe Lieberman
One Constitution Plaza
7th Floor
Hartford, CT 06103