

01-29-05P09:55 RCVD

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

2005-697

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

Fleminger, Inc.

160 Hawley Lane, Suite 205, Trumbull CT 06611
Tel. 203 385-3836 Fax 203 385-3832

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:

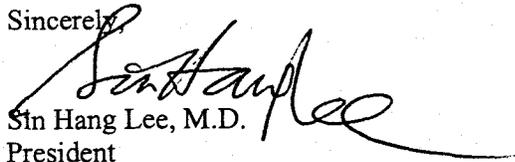
This letter is to confirm our telephone conversation of today that the petitioner for the above referenced application has reluctantly agreed to the FDA's request for a second postponement of its final decision on the green tea health claim until March 15, 2005, from January 28, 2005. Please send an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


Sin Hang Lee, M.D.
President

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

A.