

Fleminger, Inc.

Office of Sin Hang Lee, M.D.

160 Hawley Lane, Suite 205, Trumbull CT 06611

Tel. 203 385-3836 ⁷ Fax 203 385-3832

June 16, 2005

JUL -5 P2:16

Mr. Sheldon T. Bradshaw
 FDA Chief Counsel
 c/o Mr. Vincent de Jesus
 Food and Drug Administration (HFS-830)
 5100 Paint Branch Parkway
 College Park, MD 20740-3835

Via Fax 301 436-2639 Total pages: 7 inclusive

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 Mr. Bradshaw:

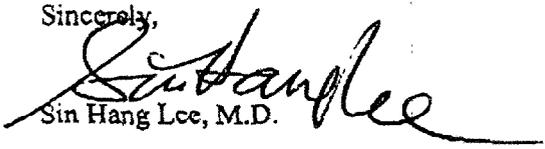
Since cancer is the No. 1 killer of Americans and there are no prescription drugs to prevent this dreadful disease(s), many healthcare providers and consumers have developed a strong interest in using green tea as a conventional food to reduce cancer risk. However, the information available in the lay publications is highly incomplete and often misleading. Therefore, the American public has been anticipating a decision of the FDA, specifically the June 17, 2005 decision of its chief counsel, on my application for a qualified health claim linking possible relationship between green tea consumption and the reduction of the risk of certain cancers. To show the level of this interest in the public sector, I am attaching a copy of Google printout using "Sheldon T. Bradshaw, tea" as the search keywords (Ref.1) and a copy of the Maxworldnews Headline (Ref. 2) for your perusal.

In less than 24 hours from now, my office will be expecting numerous telephone calls from healthcare providers and news media about the decision or indecision of the FDA on my green tea qualified health claim application. In order not to misquote the position of the FDA and its Chief Counsel in case the FDA decides not to announce its final decision tomorrow on this application, I hereby request that the FDA post on its docket management website under Docket No. 2004Q-0083 the following correspondence:

FDA CFSAN fax Memo sent by Vincent de Jesus to Sin Hang Lee, M.D. dated March 24, 2005 (Ref. 3)
 A fax letter from Sin Hang Lee to Sheldon T. Bradshaw, dated April 26, 2005 (Ref. 4)
 An email letter from Sin Hang Lee to Sheldon T. Bradshaw, dated April 26, 2005 (Ref.5)

Thank you for your attention.

Sincerely,


 Sin Hang Lee, M.D.

Attachments: Ref. 1-5.

cc. Senator Chris Dodd; Senator Joe Lieberman; Congresswoman Rosa L. DeLauro; Congressman Christopher Shays (Tom McCabe); Congresswoman Nancy L. Johnson; Congressman John B. Larson; Congressman Rob Simmons.

2004Q-0083

LET 13

Google

Web Images Groups News Froogle Local [more »](#)

Sheldon T. Bradshaw, tea

[Advanced Search](#)
[Preferences](#)

Ref. 1

Web

Results 1 - 10 of about 4,780 for **Sheldon T. Bradshaw, tea**. (0.22 seconds)

Dr. Lee's TeaForHealth™: News and Events

Fleminger submits qualified health claim to FDA regarding green tea and ... Mr. **Sheldon T. Bradshaw**, the FDA's new chief counsel, has announced a new ...
www.teaforhealth.com/PR/042705.htm - 6k - [Cached](#) - [Similar pages](#)

State News Briefs

The letter from Principal Deputy Assistant Attorney General **Sheldon T. Bradshaw** of the Civil Rights Division of the US Department of Justice, states: "it is ...
www.azconservative.org/State%20News%20Briefs.htm - 158k - [Cached](#) - [Similar pages](#)

Bradshaw and Whelan British - porcelain books, ceramic books ...

Bradshaw and Whelan - British, English, Staffordshire, Wedgwood, ... Over 760 beautiful color photographs display Shelley porcelain tea wares. ...
ceramicbooks.com/british.htm - 101k - Jun 14, 2005 - [Cached](#) - [Similar pages](#)

The Tintern Village Web Site

(1) Chairman - Christine **Bradshaw** volunteered to remain in the post for a further ... During tea and coffee Cathy Williams was giving advice to our members. ...
www.tintern.org.uk/vpa2004.htm - 15k - [Cached](#) - [Similar pages](#)

The Tintern Village Web Site

Christine **Bradshaw** mentioned the very varied programme arranged by Judy ... Also, don't forget that date of August 17th when all our members' hard work will ...
www.tintern.org.uk/vpa2002.htm - 14k - [Cached](#) - [Similar pages](#)

White's 1857 Directory of Derbyshire - pages 964-980

1, 3, 4, **Sheldon T. & Son**, 105 Trafalgar st. 2, 3 Slack, Sellers, & Co., 41. Townhead st ... **Bradshaw W.** 92 Broomhall st. **Bradshaw W.** 32 St Thomas st ...
www.n.f.wilson.btinternet.co.uk/964-980.htm - 505k - [Cached](#) - [Similar pages](#)

[PDF] [Page 2](#) [Page 3](#) [Page 4](#)

File Format: PDF/Adobe Acrobat - [View as HTML](#)

school, at city buildings and stores - but don't let paper recycling end there; ... (northbound East Stockton and westbound **Sheldon**) 8:30 am - 3:30 pm ...
www.elkgrovecity.org/community/city-newsletter/03-2005.pdf - [Similar pages](#)

Accelerated Reader Test List Report Test Book Reading Point Number ...

... and Blonde Dyan **Sheldon** 5.1 6.0 28458EN The Tangle Box Terry Brooks 6.9 ... Johnson: The Flag-Burni J. Anthony Miller 9.0 4.0 11541EN Thames Doesn't ...
www.perrytonisd.com/phs/ARList/t.txt - 18k - [Cached](#) - [Similar pages](#)

CTVA Crime - NBC Mystery Movie (Universal) McMillan & Wife (1971) ...

directed by James **Sheldon** director of photography Milton R. Krasner guest stars ... written by Booker T. **Bradshaw** & Richard Danus ...
www.geocities.com/TelevisionCity/Stage/2950/Crime/MysteryMovie_McMillanAndWife.htm - 48k - [Cached](#) - [Similar pages](#)

Bowen Family Systems Theory, family healing meditations

If you're a fan of John **Bradshaw**, you've been exposed to Family Systems Theory,

Ref. 2

ABOUT NNS



NEWS GATHERING & DELIVERY

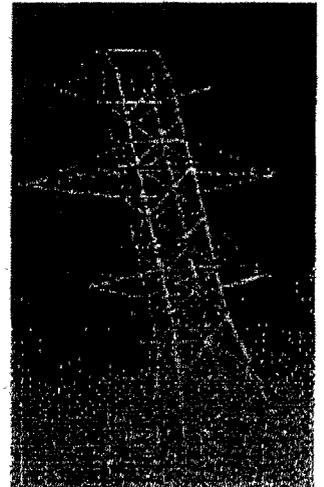
MAXwire®

STATION AREA

CONTACT US

OTHER SERVICES

YOU REPORT, WE DELIVER.



Monday, Apr 4, 2005

**GREEN TEA MAY ACTUALLY BE HARMFUL TO YOUR HEALTH.
The FDA is Currently Considering Whether To Adopt National Cancer Institutes
Standards For Green Tea That is Consumed For Health Benefits.**

Tea on your grocery shelves may not have near the same benefits as tea used for testing in the laboratory. Citing studies, cancer pathologist, Dr. Sin Hang Lee says without standards that are similar to those set for tea used in the laboratory, consumers may not get the health benefit. Worse, they may consume large enough amounts of other substances like fluoride, lead, or pesticide residue to be harmful. *Package includes interview with Dr. Lee and a lesson on the best way to brew green tea to get maximum health benefits.*

Back

Copyright 2002 Network News Source. All rights reserved. This site created and maintained by JustMy.Com Online Services.

Ref. 3
2 pages

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

JUN-16-2005 10:31
03/24/2005 15:53

MILFORD HOSPITAL LAB
2033853832

DR KEE H HAU

203 876 4548 P.05/07

PAGE 02

MAR-24-2005 15:54

FDA

301 436 2636 P.02

Public Health Service
Food and Drug Administration



DEPARTMENT OF HEALTH & HUMAN SERVICES

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.

Office of Sin Hang Lee, M.D.

160 Hawley Lane, Suite 205, Trumbull CT 06611

Tel. 203 385-3836 Fax 203 385-3832

Ref. #

April 26, 2005

Mr. Sheldon T. Bradshaw
FDA Chief Counsel
c/o Mr. Vincent de Jesus
Food and Drug Administration (HFS-830)
5100 Paint Branch Parkway
College Park, MD 20740-3835

Via Fax 301 436-2639

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 Mr. Bradshaw:

This letter summarizes our telephone conversation this morning in which the FDA requested my agreement to further extend the review period on the above referenced qualified health claim application for your office to complete its scientific review. You recognized that this is the 4th FDA postponement of its committed deadlines for its decision on this application in six months although it is the first request after you took office as the Chief Counsel at the Agency. Since my disagreement to agree will lead to automatic rejection by the FDA of the application, I have reluctantly agreed to your request for this deadline extension. As a health care professional specializing in cancer pathology, it is to my interest to see that the FDA allow this science-based green tea health claim as part of its public educational programs to implement the DSHEA (1994) passed by the U. S. Congress. If you need any additional data to complete your scientific review process, please contact me as soon as possible.

You indicated that you would make your decision on this application by June 17, 2005. However, I respectfully request that you or your office publish in the FDA docket a firmly set deadline date that the FDA can genuinely honor to restore the credibility of the Agency.

Sincerely,

Sin Hang Lee, M.D.

cc. Dr. Lester Crawford, Acting Commissioner of the FDA
U.S. Senator Chris Dodd, Member of the Senate HELP Committee (DC and CT offices)
U.S. Senator Mike Enzi, Chairman of the Senate HELP Committee (DC office)

Ref. # 5

Lee Sin Hang

From: Lee Sin Hang
Sent: Tuesday, April 26, 2005 7:09 PM
To: 'sheldon.bradshaw@fda.hhs.gov'
Cc: Lee Sin Hang
Subject: Decision on 2004Q-0083



FDA Chief Counsel
Sheldon Brad...

Dear Mr. Bradshaw:

Since I could not find your fax number, I have faxed a copy of the letter attached herewith to you c/o Mr. Vincent de Jesus at the Food Labeling Division. Hopefully, one of these two versions will reach your attention.

I am a hospital-based pathologist. My job is to make cancer diagnoses, advising the surgeons when to cut, when not to cut and how much to cut. Then I would help diagnose the recurrent cancers when treatment fails. Finally, I would analyse the cause of death. In other words, I am practicing hard-science laboratory medicine. Whether the public knows it or not, an enlightened dedicated pathologist is the most knowledgeable medical specialist about the biology of cancer. There is no secret that cancer patients are disappointed with the current chemo treatments. I know why more than 70% of the cancer patients are looking for alternative methods, some downright harmful, to control cancers. The key to success is prevention of occurrence and recurrence of cancer, using the least toxic, or non-toxic but scientifically proven effective substances, namely food or nutrition if possible as the first-line medicine to fight cancer. Green tea is such a conventional food, and its effects are only recognized by the scientific community in the past 10 years. It is the least expensive, and doing no harm. The trend to use green tea to combat cancer, correctly or incorrectly, is set, with or without the leadership of the FDA. However, it would be more effective with a proactive role played by the FDA because much half-truth is being circulated among the confused consumers, intentionally or unintentionally by various people, including some in the healthcare business.

I am an individual citizen and do not have corporate sponsors. I do not have lobbyists calling the FDA. I do not control the green tea distribution in the country, nor own tea plantations. I only want to bring to the attention of the FDA that there is a specification of "typical" green tea which the National Cancer Institute already accepted for cancer research for animal experiments and for phase I clinical trials, based on the tradition of tea drinking habits in the Orient. It has been shown to be effective. I think the consumers should know about it through the FDA because the NCI specification of typical green tea was published in an obscure scientific journal in 1996. I want to set an example to show to the tea industry that it is possible for the big tea companies to offer the NCI-defined and FDA-endorsed typical green tea to the American consumers who may want to use green tea, not only as an occasional beverage, but also for health benefits. I just don't know why the FDA has postponed the decision four times without raising any scientific questions for discussion.

"In science, you don't have to be polite, you only have to be right"-Winston Churchill. I sincerely invite the FDA scientists to post their objections to or concerns about the the contents or claim in my application in the FDA docket. The reviewing of the qualified health claim petitions is designed to be transparent and responsive. If I am incorrect in my application, I would like to know it and learn from the FDA reviewers. I am only a medical scientist.

Thank you for your telephone call. You are the first person to let me know where my application got stuck.

Sincerely,

Sin Hang Lee, MD