

From : Sin Hang Lee, M.D., Fleminger, Inc.
Petitioner for the Green Tea Qualified Health Claim-2004Q-0083
Return Fax: 203 385-3832; Tel. 203 385-3836

To: Food and Drug Administration, Center for Food Safety and Applied Nutrition, Harley
W. Wiley Auditorium, 5100 Paint Branch Pkwy., College Park, MD 20740.

RE: Public Meeting on November 17, 2005 Docket No. 2005N-0413

Via FAX: 301-827-6870

Date: November 17, 2005 (corrected copy)

Re: Confusing language of the FDA food qualified health claims is the result of failure of the
FDA to follow its own rules in the review processes-double standard is applied in various
petitions.

Dear participants:

I am the petitioner for the green tea qualified health claim approved by the FDA under docket
No. 2004Q-0083. This health claim contains the most confusing language to the consumers.
The FDA violated its own rules in the review process at least in the following counts, which led
to the confusing and misleading language.

- (1) The FDA violated its own rule by inserting the words "highly unlikely" in an approved claim, a vocabulary not included in any of the qualified health claim categories.
- (2) The FDA violated its own rule by arbitrarily, selectively, unilaterally handpicking two poorly designed studies which were published after the submission date, namely the official closing date, of the original petition as the negative weighing evidence to counter the positive evidence supportive of green tea as an effective functional food against breast cancer and prostate cancer (per rulings of Dr. Barbara Schneeman and Mr. Michael M. Landa).
- (3) The FDA applied the standard of requiring "significant scientific evidence" (per Dr. Kathy Ellwood in an interview with the Los Angeles Times reporters), a standard set for unqualified health claim to evaluate the green tea petition, a petition for a qualified health claim. This standard has never been invoked in reviewing all other qualified health claim petitions.

I hereby request that this letter be placed as part of the record of today's meeting.

Thank you for your cooperation.

Sincerely yours,

Sin Hang Lee, M.D.

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