

Fleminger, Inc.

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April 26, 2005

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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 summaries 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)

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