



MAR 18 2004

Food and Drug Administration
College Park, MD 20740

1022 '04 MAR 19 12:08

Sin Hang Lee, M.D.
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.
(Docket No. 2004Q-0083)

Dear Dr. Lee:

This letter is in reference to your petition for a qualified health claim that we received 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)).

We have completed our initial review of this petition. Today (March 18, 2004) we are filing your petition for a qualified health claim about the relationship between green tea consumption and risk of certain cancers for comprehensive review. We will follow the interim procedures for qualified health claims described in the FDA publication entitled, "Consumer Health Information for Better Nutrition Initiative" Task Force Final Report. (<http://www.cfsan.fda.gov/~dms/nutftoc.html>)

Your petition is posted at this web address: <http://www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm> and we are 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.

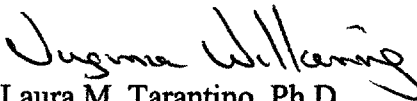
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If you have any questions, please feel free to contact Ms. Nancy Crane with the Nutrition Programs and Labeling Staff at 301-436-1450.

Sincerely yours,


for Laura M. Tarantino, Ph.D.

Acting Director
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition