



FEB 17 2004

Food and Drug Administration  
Washington DC 20204

Sin Hang Lee, MD  
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.

Dear Dr. Lee:

This letter acknowledges that the Food and Drug Administration (FDA) received your petition for a qualified health claim 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)) with respect to consumption of green tea and reduced risk of certain forms of cancer. Because your petition is complete, FDA intends to file the petition for comprehensive review and comment within 45 days of its receipt (i.e., by March 18, 2004) in accordance with FDA's Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements.  
(<http://www.cfsan.fda.gov/~dms/nutftoc.html> )

Your petition will be posted on FDA's Division of Dockets Management web page (<http://www.fda.gov/ohrms/dockets/dockets.htm>) and we will be 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.

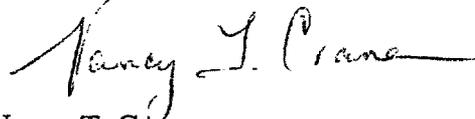
2004Q-0083

ACK

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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,

A handwritten signature in cursive script that reads "Nancy T. Crane". The signature is written in black ink and is positioned above the typed name.

Nancy T. Crane  
Nutrition Programs and Labeling Staff  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition