

Fleminger, Inc. 160 Hawley Lane, Suite 205, Trumbull CT 06611
Tel. 203 385-3836, Fax 203 385-3832

May 21, 2004

1209 '04 JUN -1 P1 51

Mr. Vincent DeJesus
Division of Nutrition Programs and Labeling
Center for Food Safety and Applied Nutrition
Food and Drug Administration (HFS-830)
5100 Paint Branch Parkway
College Park, MD 20740-3835

Re: Docket No. 2004Q-0083: Request for streamlining the language of Model Health Claim as:
"Daily consumption of 40 ounces of typical green tea containing 710 µg/ml natural (-)-epigallocatechin gallate (EGCG) may reduce the risk of certain forms of cancer. There is scientific evidence supporting this health claim although the evidence is not conclusive."

Dear Mr. DeJesus:

This letter requests streamlining the language of the model health claim in the above-referenced petition as a food labeling without changing the contents and intents of the claim of the petition.

In order to facilitate the scientific review process, the model health claim in the original petition submitted to the FDA on January 26, 2004 was written in two separate paragraphs, one being a footnote to define "typical" green tea which was stated in the first sentence of the claim, citing an NCI publication as the supportive reference. However, when the language is to be used in food labeling, as it is intended to be, it would be easier for the consumers to read the claim if the two separate paragraphs are to be streamlined and consolidated into one sentence, and the claim to be followed by a standardized FDA category B qualifying sentence in the following format:

"Daily consumption of 40 ounces of typical green tea containing 710 µg/ml natural (-)-epigallocatechin gallate (EGCG) may reduce the risk of certain forms of cancer. There is scientific evidence supporting this health claim although the evidence is not conclusive."

This petition for a qualified health claim about the relationship between green tea consumption and risk of certain cancers is now under comprehensive review by the FDA according to the "Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements". As stated in the letter of March 18, 2004 from Dr. Laura M. Tarantino to the petitioner, we understand that the 60-day period for public comments ended on May 17, 2004, and the FDA will be making its final decision regarding the claim by October 29, 2004.

We believe that the request submitted in this letter does not disturb the current accomplishments in the reviewing process concerning this petition. The standardized category B qualifying sentence is consistent with the supporting scientific evidence presented to the FDA.

Thank you for considering this revised language of the model health claim in your review of this petition without delaying the final decision as a result of this request.

Sincerely,


Sin Hang Lee, MD
President

2004Q-0083

SUP 2