

Fleminger, Inc.

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2/2/04

January 27, 2004

Ms. Jillonne Kevala
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: 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 Ms. Kevala:

Per advice of Dr. Christine Taylor in her letter dated August 15, 2003, a copy of which is enclosed herewith for your reference, the undersigned submits this petition to your attention.

The petitioner requests that the Food and Drug Administration (FDA) authorize or allow the proposed category B qualified health claim: "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", to be used as dietary supplement labeling. The petitioner has corrected the deficiencies in the previous submission which were pointed out by Dr. Taylor and submits this new petition for FDA consideration. Specifically, the petitioner has corrected the following deficiencies.

1. A section "C" Analytical Data is provided to show that quality green tea leaves contain at least seven (7) percent of (-)-epigallocatechin gallate (EGCG) in dry weight.
2. In section "D" of the petition, a brief capsulized statement of the relevant conclusions of the summary is provided, as (1), and a statement of how this substance helps the consumer to attain a total dietary pattern or goal associated with the health benefit that is provided, as (2).
3. To fulfill the requirements of 21 C.F.R. 101.70(f)(E), this submission has included copies of the computer printouts representing the PubMed literature search results obtained on June 12, 2003 at the website www.ncbi.nih.gov, using the search key words of "Green tea and cancer risk" and "Green tea and cancer epidemiology" to find the totality of the world literature titles listed. In addition, actual copies of the publications which the petitioner relied upon for the support of the health claim have been included. No adverse reactions to green tea were found on the literature search, as indicated on the PubMed search printout listed on page 149 a.
4. The petitioner has declared in the petition that the proposed health claim is categorically excluded from an EA or EIS under 21 C.F.R. 25.32(p).
5. A 21 C.F.R.101.70(c) and 21 C.F.R.101.70(d) declaration has been added to the petition.

Thank you for your assistance.

Sincerely,


Sin Hang Lee, MD
President, Fleminger, Inc.

Encl.

2004 Q-0083

QHC 1