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Letter Updating the Green Tea and Risk of Breast Cancer and Prostate Cancer Health Claim April 17, 2012

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Sin Hang Lee, MD
Fleminger, Inc.
180 Hawley Lane, Suite 205
Trumbull, CT 06611

RE: Health Claim Petition: Green Tea and Reduced Risk of Cancer Health Claim (Docket No. FDA-2004-Q-0427)

Dear Dr. Lee:

Pursuant to the February 23, 2012 Memorandum Decision of the United States District Court for the District of Connecticut, see *Fleminger, Inc. v. U.S. Dep't of Health & Human Servs., et al.*, No. 10-CV-855 (VLB) (D. Conn.) (slip op., Feb. 23, 2012), the Food and Drug Administration (FDA or the agency) has drafted revised qualified health claims as to an association between green tea and a reduced risk of breast or prostate cancer. FDA intends to consider exercising enforcement discretion for either of the following qualified health claims, which include appropriate qualifying language:

Green tea may reduce the risk of breast or prostate cancer although the FDA has concluded that there is very little scientific evidence for this claim.

Green tea may reduce the risk of breast or prostate cancer. FDA has concluded that there is very little scientific evidence for this claim.

Please refer to the agency's February 24, 2011 amended response to your January 27, 2004 health claim petition for FDA's analysis of the scientific evidence and consideration of disclaimers or other qualifying language.

The qualified health claims set forth above are the only claims for which FDA intends to consider exercising enforcement discretion as to the relationship between green tea and a reduced risk of breast or prostate cancer.

We note that FDA issued a Warning Letter to you dated February 22, 2010, that identified several violations of the Federal Food, Drug, and Cosmetic Act in connection with your marketing of green tea products. Among other things, your web site made health claims other than those for which FDA stated, in the 2005 Response Letter, that it intended to consider exercising enforcement discretion.

If you market green tea products using health claims other than the qualified health claims set forth above, FDA may take enforcement action, including an injunction against a manufacturer or distributor of green tea products bearing such illegal health claims, or a seizure of such products, without further notice. You should take prompt action to bring your firm into compliance with the law.

Please note that scientific information is subject to change, as are consumer consumption patterns. FDA intends to evaluate new information that becomes available to determine whether it necessitates a change in the agency's consideration of enforcement discretion. For example, scientific evidence may become available that will support significant scientific agreement, that will support a qualified health claim for the claims that have been denied, that will no longer support the use of the above qualified health claims, or that raises safety concerns about the substance that is the subject of the claim.

Sincerely,

Barbara O. Schneeman, Ph.D.
Director
Office of Nutrition, Labeling, and Dietary Supplements
Center for Food Safety and Applied Nutrition