



JUN 28 2005  
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James W. Barnett, Jr., Ph.D., DAPT  
AAC Consulting Group  
7361 Calhoun Place,  
Suite 500  
Rockville, Maryland 20855-2765

RE: Qualified Health Claim Petition – Green Tea and Cardiovascular Disease

Dear Dr. Barnett:

This letter acknowledges receipt on June 13, 2005 by the Food and Drug Administration (FDA) of the petition you submitted, on behalf of Ito En, Ltd and Ito En (North America), Inc., pursuant to Sections 403(r)(4) and 403(r)(5)(D) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § § 343(r)(4) and 343(r)(5)(D)) and in accordance with the July 10, 2003 Task Force Final Report on the Consumer Health Information for Better Nutrition Initiative. The petition requests a qualified health claim for the relationship between the consumption of green tea and a reduction in a number of risk factors associated with cardiovascular disease.

The petition is undergoing initial FDA review. In accordance with interim procedures set forth in the aforementioned Task Force Final Report (<http://www.cfsan.fda.gov/~dms/nuttftoc.html>), within 45 days of receipt of your petition, you will be notified of FDA's decision to either file the petition for comprehensive review, or to deny the petition. A denial may be by either FDA action within the initial 45-day period, which ends on July 28, 2005, or by a lack of action by FDA within the initial 45-day period, in which case the petition shall be deemed to be denied unless an extension is mutually agreed upon by FDA and the petitioner.

Please feel free to contact me at 301-436-1450 if you have any questions concerning this petition.

Sincerely yours,

Vincent de Jesus, M.S., R.D.  
Nutrition Programs and Labeling Staff  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

2005Q-0297

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