

**INTRODUCTION
AND PURPOSE**

June 9, 2005

PETITIONER

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Co-Petitioner

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Subject: Petition for a qualified health claim for green tea

Petition submitted to:

Food and Drug Administration
Office of Nutritional Products, Labeling and Dietary Supplements
HFS-800
5100 Paint Branch Parkway
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INTRODUCTION AND PURPOSE

The undersigned, ITO EN (North America) INC., submits this qualified health claim petition pursuant to section 403(r)(4) and 403(r)(5)(D) of the Federal Food, Drug, and Cosmetic Act, and in accordance with the guidelines of the Task Force on the Consumer Health Information for Better Nutrition, with respect to consumption of green tea in leaf and ready-to-drink (RTD) beverage products and its relationship to reducing the risk of cardiovascular disease. Attached hereto, and constituting a part of this petition, is the information required by 21 CFR §101.70(f).

On December 18, 2002, FDA launched the "Consumer Health Information for Better Nutrition" initiative and stated that it would develop a process to allow qualified health claims (QHC) on both conventional foods and dietary supplements. A Task Force was established to

develop recommendations for implementing the QHC process. In July 2003, FDA issued recommendations provided by the Task Force on Consumer Health Information for Better Nutrition for implementation of this new program beginning September 2003. The intent of this initiative is to help consumers make informed choices about their diet and nutrition in order to improve the overall health of the American public. The stated goals of the FDA initiative are to: 1) allow for more understandable and science-based information in labeling of foods and nutritional supplements; 2) better inform the consumer on how dietary choices affect their health and 3) encourage companies to compete based on the health and nutritional consequences of their ingredients, in addition to non-health related features like taste and convenience.

The petitioner, ITO EN (North America) Inc., believes that the FDA's qualified health claim program is a positive step, which can greatly benefit the health of consumers in making informed decisions regarding their diet. The petitioner is requesting that FDA authorize a qualified health claim for reduction of risk of cardiovascular disease from ingestion of green tea in both leaf form and in ready-to-drink beverages brewed with green tea as the primary ingredient. Suggested wording for the claim is below in Section D.

The petitioner uses the term "green tea" as the common name for the substance that is the subject of this petition. As noted by Graham, (1992)⁽¹⁾ and Yang and Landau (2000)⁽²⁾, green tea is manufactured by drying fresh tea leaves from the plant *Camellia sinensis*. Its composition on a percentage dry weight basis is made up of polyphenols (36%), methylxanthines (3.5%), amino acids (4%), organic acids 1.5%, carotenoids (<0.1%), carbohydrates (25%), protein (15%), lignin (6.5%), lipids (2%), chlorophyll (0.5%), ash (5%) and volatiles (<0.1%). Green tea also contains B-vitamins and ascorbic acid, which are destroyed in the process of making black tea. Green tea has about 600 mg vitamin C and 80 mg vitamin E per 100 grams of freshly dried leaves. Inorganic substances that are relatively high in green tea leaves are potassium, aluminum, manganese, and fluorine. The fluorine content of tea is 100 to 300 parts-per-million, which is higher than the level found in most other plants. Each serving of green tea can provide 0.5 to 0.8 mg of fluorine, approximately one-fifth of the daily fluorine requirement for humans (Liao *et al.*, (2001)⁽³⁾). Most of these green tea constituents are soluble in hot water and are the major components in green tea beverage. The polyphenol compounds found in green tea are more commonly known as flavanols or catechins. It is this class of compounds that has been the focus of extensive research due to their biological and physiological effects. Green tea typically

contains 16-30% tea catechins of which (-)-epigallocatechin-3-gallate (EGCG) is the most abundant ranging from 7-13%, depending on the growing conditions and the environment of the tea plantations. Other catechins include (-)-epigallocatechin (EGC), (-)-epicatechin-3-gallate, (ECG), and (-)-epicatechin (EC). A typical tea beverage, prepared in a proportion of 1 gram leaf to 100 mL water in a 3-minute brew, usually contains 250-350 mg tea solids, comprised of 30-42% catechins and 3-6% caffeine. A typical RTD green tea beverage is composed of a mixture of catechins (total 127 mg) with the following composition in a 240 ml (8 ounce) serving: EGCG, 21 mg, Gallocatechin gallate (GCG), 24 mg, ECG, 4 mg, Catechin gallate (CG), 2 mg, EGC, 19 mg, Gallocatechin (GC), 44 mg, EC, 5 mg, and Catechin (C), 8 mg. (ITO EN, 2004). The major chemical entities of the substance are the catechins identified here. For clarity, the term green tea is used to provide a description of the complex mixture of catechins, which have been shown to be the active components that are the subject of this petition.

The petitioner has developed the technology to manufacture consistently high quality unfermented green tea as well as RTD green tea beverages. The petitioner provides several commercial products in both the leaf form as well as several varieties of RTD green tea beverages. These products are all manufactured from the dry green tea leaf of the plant *Camellia sinensis*. No powders or concentrates are used.

This petition has been prepared according to the requirements for health claim petitions in 21 CFR §101.70 and the guidance documents for qualified health claims provided by the Task Force on Consumer Health Information for Better Nutrition in July 2003 (<http://www.fda.gov/oc/mcclellan/chbn.html>). As part of this petition, the petitioner is presenting a comprehensive evaluation of the scientific basis for its claim, including biological hypotheses by which green tea is thought to reduce the risk of cardiovascular disease. The petition presents the rationale for preferentially using green tea either in a leaf or RTD beverage form as part of a balanced diet. The petition also includes scientific reports, human clinical, and epidemiological studies on the relationship between intake of green tea and reduction in risk of both cardiovascular disease (CVD) and a number of risk factors associated with CVD. We believe that the petition presents far more than just credible evidence that the scientific data support the proposed claim. As this petition also shows, there is an abundance of scientific evidence, general acceptance by the scientific community and increasingly, recognition by various expert bodies and private institutions, that an increased dietary intake of green tea with its unique catechin

components and their attendant antioxidant properties will contribute to a meaningful decrease in several key risk factors associated with the onset of cardiovascular disease. Specific data is presented in this petition demonstrate that consumption of green tea can consistently and significantly reduce both total and LDL-cholesterol over sustained periods of time in controlled double-blind studies. The scientific evaluation presented herein and the proposed claim have been reviewed and approved by consensus of an expert panel qualified to evaluate the scientific evidence. The signatures of the expert panel agreeing to the summary consensus statement, as well as attached curriculum vitae, are included as part of this petition in Section J of this binder.