

VIA EMAIL: Vincent.DeJesus@cfsan.fda.gov; FAX: 301-436-2636

August 1, 2005

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Mr. Vincent de Jesus
Food and Drug Administration (CFSAN)
Director, Division of Nutrition Programs and Labeling
Office of Nutritional Products, Labeling and Dietary Supplements (HFS-830)
5100 Paint Branch Parkway
College Park, Maryland 20740

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RE: Qualified Health Claim Petition-Green Tea and Cardiovascular Disease:
Additional Published Clinical Trial for Incorporation into Petition
Submission

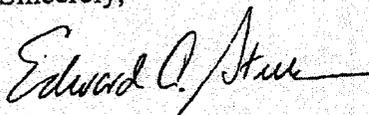
Dear Mr. De Jesus:

As a follow-up to the July 28, 2005 letter from Dr. Barbara Schneeman regarding FDA's acceptance for filing of the Qualified Health Claim Petition on Green Tea and a reduction of risk factors associated with cardiovascular disease, we would like to submit the attached publication of an additional clinical trial conducted by Sung *et al.* (2005): *Ann Clin Biochem.* 2005 Jul; 42(Pt 4):292-7. The effects of green tea ingestion over four weeks on atherosclerotic markers. Sung H, Min WK, Lee W, Chun S, Park H, Lee YW, Jang S, Lee DH. This study also provides supportive evidence for the efficacious effect of green tea consumption in significantly decreasing the levels of oxidized-LDL and sVCAM-1 (soluble vascular adhesion cell molecule-1) in human subjects and thus providing cardiovascular benefits and should be included in the Petition evaluation.

AAC Consulting Group submitted this petition pursuant to Section 403(r)(4) or 403(r)(5)(D) of the Federal Food, Drug and Cosmetic Act on behalf of ITO EN, LTD. 47-10, Honmachi 3-chome, Shibuya-ku, Tokyo 151-8550, Japan with respect to Green Tea. Please note that this is the correct address that should be used in this petition as well. The publication referenced above will be provided by regular mail delivery as well as electronically if you wish. Please keep us apprised of any changes or questions that you may have during the ongoing review.

If you have any questions, please contact Stanley M. Tarka, Jr., Ph.D. at AAC Consulting Group, Inc. He can be reached at 717-243-9216. Alternatively, you can also contact Dr. James W. Barnett, Jr., Ph.D., DABT, at AAC Consulting Group. He can be reached at 512-266-2620. Thank you.

Sincerely,



Edward A. Steele
President

cc: Barbara O. Schneeman, Ph.D., Barbara.Schneeman@cfsan.fda.gov

Enclosure: Sung *et al.* (2005) Publication on Green tea Ingestion and Atherosclerotic Markers

20050-0297

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