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The Office of Sin Hang Lee, M.D., F.R.C.P. (C)

February 25, 2005

Lester M. Crawford, D.V.M., Ph.D.
Acting Commissioner
U. S. Food and Drug Administration
5600 Fishers Lane
Rockville MD 20857-0001

Via Federal Express #8485 4086 1096

Subject: Request for FDA Guidance Concerning Perceived Health Hazards of Tea Consumption

Dear Dr. Crawford:

In support of your FDA program on "Empowering Consumers for Better Health" (the policy report you signed September 2004), enclosed is information about fluoride levels in green tea, which we will make public on March 7, 2005. We welcome any comment prior to our release, and encourage your leadership in addressing this timely consumer safety issue related to tea consumption by supporting efforts toward setting standards for tea.

To support our pending, qualified health claim petition to the FDA, we have submitted evidence to show that daily consumption of 1,200 ml of typical green tea may reduce the risk of certain forms of cancer (Docket No. 2004Q-0083). However, if the tea contains harmful substances, such as excess fluoride, pesticide residues or lead contaminants, the purpose of drinking tea for health will be defeated. The recent reported case of tea fluorosis (*Am J Med* 2005;118:78-82) illustrates the potential health hazards of consuming tea in large quantities without paying attention to the other qualities of the tea.

Since *Thea sinensis* is on the FDA generally recognized as safe (GRAS) substances list, most American consumers and health care providers are not aware of the potential hazards of drinking tea. They do not know that dry tea leaves may vary in fluoride content as much as 10 to 15 times from one brand to the other. In general, the level of fluoride is inversely related to the contents of (-)-epigallocatechin gallate (EGCG), or less specifically of tea catechins, in tea leaves harvested from the same tea plantation.^{1,2}

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Consumers may also not understand that some teas do contain pesticide residues or lead contaminants. We, the health care professionals, have the responsibility to empower citizens with the tools they need to make informed choices about their health as exemplified by the FDA.

Enclosed herewith are copies of three analytical reports to show that high EGCG (7% or higher) green tea leaves brewed in non-fluorinated water meets the FDA-set fluoride limit of 1.4 to 2.4 ppm for bottled beverages (for example, 0.25 ppm in a sample of typical green tea).³ In addition, the FDA may consider setting the maximum allowable residues of lead in the tea leaves, say, not to exceed 5 ppm as a future goal for the tea industry to meet (our sample is reported to be 0.96 ppm).⁴ Comprehensive pesticide assays of tea leaves should show non-detectable pesticide levels by Organochlorine, Organophosphate/Organonitrogen and Carbamate screens.⁵

We are planning to release this information to alert the public of the potential health hazards of tea consumption in the absence of standards. I hereby respectfully request that the FDA take a leadership role through education and by setting a standard for tea. In addition, we are open to your guidance so that we may coordinate our efforts in the best interest of public education, and as such consumer empowerment.

Thank you for your anticipated prompt attention and response to this suggestion.

Sincerely,


Sin Hang Lee, M.D.

References (enclosed)

1. Lu Y, Guo WF, Yang XQ. Fluoride content in tea and its relationship with tea quality. *J Agric Food Chem.* 2004 Jul 14;52(14):4472-6.
2. Fung KF, Zhang ZQ, Wong JW, Wong MH. Aluminium and fluoride concentrations of three tea varieties growing at Lantau Island, Hong Kong. *Environ Geochem Health.* 2003 Jun;25(2):219-32.
3. Tea analytical report for fluoride - Stillwell & Gladding Testing Laboratories, Highland Park, NJ 08904
4. Tea analytical report for lead - Environmental Micro Analysis, Inc. Woodland, CA 95776
5. Tea analytical report for pesticide residues - Environmental Micro Analysis, Inc. Woodland, CA 95776

cc. Dr. Kathy Ellwood and Mr. Vincent de Jesus, Division of Nutrition Programs and Labeling

U.S. Senator Joe Lieberman, Hartford, Connecticut