



**DR. LEE'S
TeaForHealth™**

03-31-05 P03:24 IN

March 28, 2005

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

Re: Dr. Lester Crawford: why FDA blocks consumer health information

*note: Copies of this letter have also been sent to
The Senators members on the HELP Committee
Dr. Lester Crawford, Acting Commissioner, FDA*

Dear Dr. Crawford:

At the U.S. Senate HELP Committee hearing (March 17, 2005), Dr. Crawford stated: "...we need to continue to do more to empower our citizens with better health information about the foods they eat, the medicines they use, and the other health products they consume." As a medical doctor specializing in cancer pathology, I am encouraged by this objective to educate the American consumers to manage their health. However, my enthusiasm has been dampened by the brick wall I seem to have hit at the FDA as I wait for it to decide whether or not to grant my application for a qualified health claim relating the drinking of certain quality green teas to the reduction of the risk of certain cancers. The original date for a final FDA decision on this health claim application was set for October 29, 2004. However, there have been three last-minute postponements of the decision, none of which cite any scientific reason for the delay. I wrote to Dr. Crawford on January 31, 2005 for assistance, but have received no response from him or his office. The last FDA notice of postponement was received via fax at 4 p.m. on March 24, 2005, informing me "that the decision on your petition for a qualified health claim regarding green tea and reduced risk of cancer (Docket No. 2004Q-0083) will not be announced tomorrow March 25, 2005", the last FDA-committed date for its decision. Since it appears that I have no other effective way to communicate with the Acting Commissioner, I believe that I have no alternative but to bring this issue to your attention at his confirmation hearing so that our future FDA may relay science-based relevant health information to the consumers more expeditiously.

I would like to take this opportunity to elaborate my position in this matter for your advice and guidance. Cancer has become the No. 1 killer of Americans below the age 85. Many consumers are confused when they hear the seemingly conflicting news reports on the benefits of using tea as a conventional food for cancer prevention. For example, tea is frequently reported to be effective in cancer prevention in laboratory mice. Green tea is reported to reduce cancer rates among people living around the tea plantations. Tea may cause skeletal fluorosis with bone pains if excessive quantities are consumed. In fact, some tea extracts have caused liver damage in women and may even promote cancer cell growth, the

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opposite effect of cancer prevention, when the dosage used is too high. The recent case of a patient suffering from tea skeletal fluorosis in St. Louis which has been widely reported in the news illustrates the potential health hazards of drinking certain tea in large quantities without addressing the quality issues of the tea being consumed. The FDA has set a fluoride limit for bottled water and bottled beverages, but has not set any standard for teas. Certain FDA-evaluated information is helpful to empower the consumers with the tools they need to make informed choices in selecting their teas to achieve better health.

One way to empower consumers on the issue of selecting tea for health protection is to inform them that there is a "typical green tea" specification which was adopted in 1996 by the National Cancer Institute (NCI), Division of Cancer Prevention and Control, for cancer research. This "typical green tea" has been proven to be effective in controlling cancer growth in experimental animals and in reducing certain cancer risk among human heavy tea drinkers living around traditional tea plantations. If a "typical green tea" is provided to the consumers, they will not suffer from tea fluorosis because the fluoride level in a typical green tea is too low to exceed the limit of fluoride allowed for bottled water set by the FDA. In other words, if the consumers drink "typical green tea" as defined by the NCI in increasing quantities, there is absolutely no danger or risk of tea fluorosis. Epidemiological data have shown that one must drink at least 1,200 ml of typical green tea a day to get its full chemopreventive anticancer benefits. If the tea drink contains too much fluoride or not enough natural antioxidants, it would defeat the purpose of drinking tea for health protection.

As a medical scientist, I was able to review and summarize the totality of the world's scientific literature on the subject of green tea and its relationship with cancer. I submitted the evidence to the FDA on January 27, 2004 in an application for a qualified health claim relating the drinking of typical green tea to the reduction of the risk of certain forms of cancer. This qualified health claim may be used by the tea industry as a guideline when promoting the health benefits of drinking green tea. The entire petition has been published for more than a year for public comments under the FDA Docket No. 2004Q-0083. The FDA, following its Interim Procedures set forth in the July 10, 2003 Task Force Final Report of the Consumer Health Information for Better Nutrition Initiative, had set October 29, 2004 as the original deadline for announcing its final decision on the petition. The FDA scientific review process is structured to be transparent and responsive. All public comments and correspondence between a petitioner and the FDA reviewer on the application are supposed to be published on the dockets. To this date, there has been no objection to, or even any questions raised concerning, the contents of the application or the proposed health claim under Docket No. 2004Q-0083. However, the FDA has since extended the deadline for announcing its decision to January 28, 2005, March 15, 2005, March 25, 2005, and now to April 29, 2005, citing no reason for any of these extensions.

At his March 17, 2005 Senate Committee hearing, in answering a question about the FDA delay to decide on the Plan B pill application, Dr. Crawford told the Senators that missing such deadlines was unusual. Thus, for the FDA to miss its own deadlines three times in a row on the green tea health claim decision without a reason from October 2004 to March 2005 must be highly unusual.

Six documents are attached herewith for your reference. Please draw your attention to the language of the FDA letters (2), (3) and (4). In each of these letters, the FDA had set and was committed to a specific new date for its final decision on this health claim petition. However, none of the administration-committed deadlines was kept. Frankly, I am astonished to have discovered that the FDA appears to believe that it has the option of not honoring what it promises and commits to on the government Dockets. I would like to request your assistance and that of the HELP Senate Committee members to ask the Acting Commissioner to set a true deadline on which the American consumers and I could really count on hearing the FDA's final decision on the green tea health claim petition under Docket No. 2004Q-0083.

As a member of the Tea Association of the U.S.A., I have written to Senator Joe Lieberman and Senator Chris Dodd from my state of Connecticut asking them to cast their Senate votes to confirm Dr. Lester Crawford, who has been a strong supporter of the American tea industry, as the next Food and Drug Commissioner of the United States.

I have been continuously and actively practicing full-time medicine for 49 years since my graduation from medical school in 1956. Forty-two (42) years of my professional career have been spent in this country with the last 34 years in New Haven County. I began to practice cancer pathology before oncology was a specialty in modern medicine. Based on my experience, I fully support the wisdom of the Dietary Supplements Health and Education Act of 1994 (DSHEA) passed by the U.S. Congress and the "Empowering Consumers for Better Health" policy initiative signed by the Acting Commissioner of the FDA in September 2004. I am happy to answer any questions that may be raised by the Committee on HELP with respect to this letter, and I will be happy to offer my services to support the activities of the Committee and the FDA whenever such need arises.

Thank you for your attention.

Sincerely,


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

References attached

- (1) JNCI 2004;96:1198-1199. FDA reviews expanded claims on health benefits of certain foods. Solae, Inc., H. J. Heinz Company, Sin Hang Lee, MD and Marine Bio USA are four petitioners for cancer-related health claims submitted to the FDA. Sebastian Cianci, spokesman for the FDA's Center for Food Safety and Nutrition, said that companies have been slow to submit qualified claim petitions (in other words, there was no case overload at the CFSAN.)
- (2) FDA letter dated February 17, 2004. According to the FDA Interim Procedures, the final decision date for this qualified health claim was set for October 29, 2004.
- (3) FDA letter dated November 12, 2004. FDA extended deadline of its decision to January 28, 2005.
- (4) FDA letter dated February 9, 2005. FDA extended deadline of its decision to March 25, 2005.
- (5) FDA fax letter dated March 24, 2005, time 15:54, notified petitioner the postponement of its announcement of decision from March 25 to April 29, 2005.
- (6) Petitioner's letter to Dr. Crawford on January 31, 2005 requesting his attention to the importance of consumer education on the quality of teas and tea fluoride poisoning.