

Jane Henney, M.D.,  
Commissioner, U.S. Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

Re: Docket No. 97P-0498/CPI

Dear Dr. Henney,

The FDA has failed to act on the petitions submitted by CSPI and several scientists in summer 1997 calling for quantitative caffeine labeling on foods and for a broader scientific review of potential problems related to caffeine. We believe that this is an important matter that has a significant impact on the public's health.

Recent reports, including scientific studies, highlight the need for FDA to act on this matter.

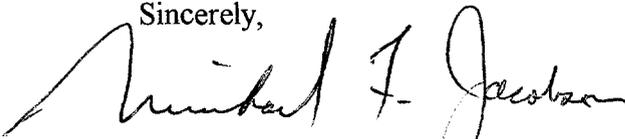
- \* Several studies clearly indicate that the amounts of caffeine in a soft drink have distinct pharmacological and behavioral effects. Evans and Griffiths found that the caffeine equivalent of 2-3 cans of soft drink per day (100 mg/day) is sufficient for producing physical dependence, characterized by withdrawal symptoms of tiredness and headache if consumption is stopped. That study also shows that a dose of 25 mg of caffeine is sufficient to suppress caffeine withdrawal headache.<sup>1</sup> A study by Smith, Sturgess, and Gallagher shows that 40 mg of caffeine (roughly the amount in one can of soda) produces mood and performance effects.<sup>2</sup> A study by Smit and Rogers shows cognitive and performance effects of low doses of caffeine, including cognitive effects at doses as low as 12.5 mg.<sup>3</sup>
- \* A study by Griffiths and Vernotica found that most regular cola-soft-drink consumers cannot detect caffeine's flavor when the substance is consumed in soft drinks.<sup>4</sup> That suggests that companies add caffeine primarily for its physiological effects, not necessarily for flavor and raises once again the question as to the appropriateness of permitting the addition of the pharmacologically active substance to food.
- \* A case-control study by researchers at Brown University found an association between caffeine intake greater than 400 milligrams per day and urinary incontinence.<sup>5</sup> Compared to low-caffeine consumers, women who consumed more than 400 mg/day had a 2.4 times greater chance of having incontinence. The researchers advise women to avoid more than 400 mg/day and said that women who are suffering symptoms of incontinence may want to limit caffeine even further. Quantitative labeling would enable women to monitor their caffeine intake.



- \* A randomized, double-blind, crossover study by Shepard and colleagues at the University of Oklahoma found that the amount of caffeine in about two cups of coffee increased blood pressure in 31 white male medical students who were regular consumers of caffeine.<sup>6</sup> The effect was seen in students with normal blood pressure, but was especially pronounced in students with moderately elevated blood pressure, particularly when they were under stress (exam days): 9/5 mm Hg in the low-risk group and 10/6 mm Hg in the high-risk group.
- \* Two reports presented at the 22nd Congress of the European Society of Cardiology provide additional evidence that caffeine can increase blood pressure.<sup>7</sup> In a study of 18 middle-aged healthy volunteers, researchers at St. Vincent's Hospital in Sydney, Australia, found that 250 mg of caffeine led to a loss of aortic elasticity and raised blood pressure.
- \* The Netherlands adopted regulations requiring caffeine labeling of certain foods. The European Union has stayed the implementation of those regulations, but only in order to develop an EU-wide regulation on caffeine labeling. It would be appropriate for the U.S. to follow the EU's lead in this area.
- \* The Australia New Zealand Food Authority recently published a non-comprehensive review of caffeine's safety.<sup>8</sup> The report concluded that (a) the amounts of caffeine in one or two cans of caffeinated soft drink can affect performance and mood, increase anxiety in children, and reduce the ability to sleep, though "the threshold dose for possible behavioural effects in children remains unclear..."; (b) typical doses of caffeine "may lead to withdrawal effects and some physical dependence in adults...Further research will be required ... in children"; (c) there is little evidence for adverse cardiovascular effects.

We urge you to ensure that the Center for Food Safety and Applied Nutrition puts caffeine on its "A" priority list for action in the coming fiscal year. We would welcome the opportunity to meet with you about the need for FDA action.

Sincerely,



Michael F. Jacobson, Ph.D.  
Center for Science in the Public Interest

cc: Ms. Virginia Wilkening