

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION

Citizen Petition for New Labeling  
Requirements for Caffeine in Food

---

Docket No. 2006P-0039

Submitted by the  
FOOD AND DRUG LAW CLASS  
Michigan State University College of Law<sup>1</sup>

January 15, 2006

Neal D. Fortin  
Adjunct Professor  
Michigan State University College of Law  
PO Box 230  
Okemos, MI 48805  
(517) 775-4629

---

<sup>1</sup> The views expressed in this petition are those of the authors and not necessarily those of the Michigan State University College of Law.

2006P-0039

CP1

## **CONTENTS**

### **Citizen Petition for New Labeling Requirements for Caffeine in Food**

I.	ACTIONS REQUESTED .....	1
A.	Introduction .....	1
B.	Disclose the Quantity of Caffeine in Foods .....	3
C.	Study the Need for Advisory Labeling .....	4
D.	FDA has the Authority to Require Caffeine Labeling of Foods .....	4
II.	STATEMENT OF THE REASONS .....	5
A.	Stress and Hypertension .....	5
B.	Bone Density .....	6
C.	Pregnancy .....	7
D.	Withdrawal Symptoms.....	8
E.	Calcium kidney stone risk.....	10
F.	Gastroesophageal reflux disease .....	11
G.	Other Considerations: Diabetes/Hypoglycemia/Obesity .....	12
H.	Conclusions .....	13
III.	ENVIRONMENTAL IMPACT .....	13
IV.	ECONOMIC IMPACT .....	14
V.	CERTIFICATION.....	14

January 15, 2006

0658 6 JAN 19 P2:07

Dockets Management Branch  
Food and Drug Administration  
Department of Health and Human Services  
Room 1-23  
12420 Parklawn Dr.  
Rockville, MD 20857

## **CITIZEN PETITION**

The undersigned submit this petition under Sections 403(a), 201(a), and 701(a) of the Federal Food, Drug and Cosmetic Act (FDCA) or any other statutory provision for which authority has been delegated to the Commissioner of Food and Drugs (under 21 CFR, Part 5.10) to request the Commissioner of Food and Drugs to issue a regulation that would efficaciously inform the general public about the quantitative caffeine content of the foods they consume. In addition, the Petitioners request that the agency initiate action to advise consumers of the potentially addictive nature of caffeine and the possible adverse side effects of caffeine.

### **I. ACTIONS REQUESTED**

**The FDA issue new labeling requirements for caffeinated food products.**

#### **A. Introduction**

On July 31, 1997, the Center for the Science in the Public Interest (CSPI) submitted a citizen petition to the Food and Drug Administration (FDA) requesting that the agency "issue regulations requiring a quantitative disclosure for caffeine-containing products," and "initiate a thorough review of the health effects of caffeine to determine

what additional regulatory and educational actions should be taken to protect consumers from adverse effects of caffeine.”<sup>2</sup>

The Petitioners developed their position independently of the CSPI petition; however, this petition arrives at substantially similar conclusions as the earlier CSPI petition. Accordingly, we support the CSPI petition. Nevertheless, we request FDA consider the unique aspects of this petition and the supporting research that has been reported in the eight years since the CSPI petition.

Caffeine has a variety of well recognized physiological and behavioral effects, such as withdrawal symptoms and gastroesophageal reflux disease (GERD). Other potential adverse effects of caffeine include stress, hypertension, decreased bone density, kidney stones, diabetes, hypoglycemia, and obesity. Evidence also suggests a number of adverse effects on pregnancy, and, since 1980, the FDA has advised pregnant woman to avoid or limit their intake of caffeine.<sup>3</sup> This petition highlights only examples of research on the adverse effects of caffeine, rather than exhaustively cataloging this literature because it sufficiently demonstrates the need for FDA to require quantitative labeling and to conduct an extensive review of the need for advisory statements on the labeling of foods.

Caffeine is consumed by millions of Americans every day. “Caffeine is consumed by 80-90% of Americans on a daily basis, making it one of the most commonly used drugs in our society.”<sup>4</sup> Over the years, caffeine has been linked to several health-related issues. The widespread consumption of caffeine coupled with caffeine’s physiological effects compel a conclusion that quantitative labeling of the content of food and drink is a material issue. Therefore, we are requesting that the quantitative caffeine amount

---

<sup>2</sup> Ctr. for Sci. in the Pub. Int. (CSPI), Petition for Amendment of Food-Labeling Regulations to Require Quantitative Labeling of Caffeine Content and Request for Review of Health Effects of Caffeine (July 31, 1997).

<sup>3</sup> U.S. Food and Drug Administration, *Updates*, FDA CONSUMER MAG. (March-April 2001) available at Table of Contents (“FDA has advised women since 1980 to avoid caffeine or consume it only moderately throughout pregnancy.”)

<sup>4</sup> See [www.stress.about.com/cs/substanceabuse/a/aa070202.htm](http://www.stress.about.com/cs/substanceabuse/a/aa070202.htm) (The about website is an information source for hundreds of topics. This information was contained in the section of the website about stress management.)

contained in a food or drink be listed on the label. Food labels should also provide information to consumers about any health risks associated with caffeine consumption. This petition deserves the attention of the Food and Drug Administration for various reasons. Caffeine has been shown to have adverse side effects such as increased stress and hypertension, general skeletal weakness and osteoporosis, and it may cause miscarriages. It has been shown that caffeine is addictive and people who consume vast amounts of caffeine and then stop experience withdrawal symptoms. Caffeinated soft drinks have also been linked to weight gain, which can increase a person's risk of diabetes and other diseases. For the following reasons, it is necessary to label foods containing caffeine with the quantitative amount of caffeine as well as any adverse effects related to the consumption of caffeine. Although information on virtually every subject is available via the Internet with the click of a mouse, it is difficult for the average consumer to sift through the information to get to the truth. The FDA should ensure that Americans are properly informed about caffeine in all caffeinated food and drink.

#### **B. Disclose the Quantity of Caffeine in Foods**

Petitioners request that the Commissioner promulgate a regulation that would require the disclosure of the quantity of caffeine in all food products containing caffeine. Such a label should require disclosure of the metric amount of caffeine contained in the product (e.g., "X mg caffeine") displayed prominently on the information panel. The caffeine disclosure should be adjacent to the ingredient statement because that is where most consumers expect to find content information.

The adverse effects of caffeine reported are of varying degrees of severity, but those effects impact a large percentage of the United States population. The summation of all adverse effects on a large number of the consuming public makes the quantity of caffeine in food necessary information for consumers. Without a quantitative listing of caffeine on food labels, consumers lack the information needed to control their intake of caffeine. For example, pregnant women lack the information they need to follow FDA's advice to avoid or limit their intake of caffeine.

### **C. Study the Need for Advisory Labeling**

Petitioners also requests that the FDA initiate a thorough study to determine what additional educational efforts and regulatory action is necessary. In particular, the Petitioners request that FDA consider a regulation that would provide for a label on all products containing caffeine that is similar to the labeling required in 21 CFR § 340.50 Labeling of Stimulant Drug Products concerning over-the-counter-products. Over-the-counter stimulant drug products are required to have labeling that reads:

The recommended dose of this product contains about as much caffeine as a cup of coffee. Limit the use of caffeine-containing medications, foods, or beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness, and occasionally, rapid heart beat.<sup>5</sup>

Petitioners request that the FDA consider a regulation to require all products containing caffeine to display a prominent label which provides for (1) the potential addiction to caffeine, and (2) the potentially adverse effects on health from the consumption of caffeine. The advisory label associated with the caffeine quantity requirement would perhaps read substantially as follows: "Regular caffeine consumption is known to result in physical addiction. Caffeine may be linked to a number of adverse health risks, including miscarriages, loss of bone density, and physical withdrawal symptoms."

### **D. FDA has the Authority to Require Caffeine Labeling of Foods**

The Federal Food, Drug, and Cosmetic Act's (FDCA) misbranding definition requires the disclosure of "facts material in the light of representations" made "or material with respect to consequences which may result from the use of the article."<sup>6</sup> The FDA possesses the authority to promulgate regulations for the efficient enforcement of the FDCA.<sup>7</sup> Petitioners urge the FDA find that the amount of caffeine in food is a material fact for consumers.

---

<sup>5</sup> 21 C.F.R. § 340.50.

<sup>6</sup> Federal Food, Drug, and Cosmetic Act (FDCA) § 403(a); 21 U.S.C. § 343(a).

<sup>7</sup> FDCA § 201(n); 21 U.S.C. § 321(n).

## II. STATEMENT OF THE REASONS

### A. Stress and Hypertension

There is significant support for the conclusion that caffeine consumption increases stress levels, blood pressure, and risk of hypertension. A study by researchers at Duke University has linked caffeine consumption to increased levels of stress in the body.<sup>8</sup> James D. Lane, Ph. D. stated “the effects of coffee drinking are long-lasting and exaggerate the stress response both in terms of the body’s physiological response in blood pressure elevations and stress hormonal levels, but it also magnifies a person’s perception of stress.”<sup>9</sup> Additionally, in 1992, an Ohio University study found that “questionnaires administered during baseline periods to assess psychological responses to stress and caffeine revealed a potentiation of anxiety and anger responses to stress.”<sup>10</sup>

While studies to corroborate Lane’s research seem to be scarce, a number of studies have linked caffeine consumption with hypertension.<sup>11</sup> In 2004 the Department of Psychology from National University of Ireland published a study claiming “caffeine produced persistent blood pressure with a vascular hemodynamic profile. The findings suggest that life-long dietary caffeine may contribute significantly to the development of cardiovascular disease.”<sup>12</sup> Additionally, a 2004 article in the American Journal of Cardiology claims “men and women have similar blood pressure responses to caffeine, but the blood pressure may arise from different hemodynamic mechanisms. Women who

---

<sup>8</sup> News Release, Duke University Medical Center, James D. Lane, *Caffeine’s Effects are Long-Lasting and Compound Stress*, <http://www.dukemednews.org/news/article.php?id=5687> (full article appears in the July/August 2002 issue of Psychosomatic Medicine).

<sup>9</sup> *Id.*

<sup>10</sup> C. France & B. Ditto, *Cardiovascular Responses to the Combination of Caffeine and Mental Arithmetic, Cold Pressor, and Static Exercise Stressors*, 29 PSYCHOPHYSIOLOGY 272-82 (1992); see also Terry Hartley et al., *Caffeine and Stress: Implications for Risk, Assessment, and Management of Hypertension*, 93 AM. J. OF CARDIOLOGY 1022-6 (2004).

<sup>11</sup> Iris Goldstein et al., *Blood Pressure Response to the “Second Cup of Coffee”*, 52 Psychosomatic Med. 337-45 (1990); see also Jack James, *A Critical Review of Dietary Caffeine and Blood Pressure: A Relationship That Should be Taken More Seriously*, 66 PSYCHOSOMATIC MED. 63-71 (1997).

<sup>12</sup> Jack James & Elizabeth Gregg, *Hemodynamic Effects of Dietary Caffeine, Sleep, Restriction, and Laboratory Stress*, 41 PSYCHOPHYSIOLOGY 914-23 (2004).

consume a dietary dose of caffeine showed an increase in cardiac output, whereas men showed increased vascular resistance.”<sup>13</sup>

## **B. Bone Density**

Caffeine consumption has been linked to general skeletal weakness and osteoporosis. Caffeine has been shown to have a statistically relevant “negative association with most of the skeletal sites.”<sup>14</sup> Although one study has concluded that “coffee does not stimulate bone loss in the animal model,”<sup>15</sup> other research has shown that caffeine has similar detrimental effects on animals. Young, male Wistar rats, for example, demonstrated lower weight and total calcium in the femur with increased caffeine intake. Further, these negative effects of caffeine could not be counterbalanced with exercise.<sup>16</sup>

Caffeine’s effect on bones is particularly threatening for postmenopausal women. One analysis of 489 women aged 65-77 years old found that caffeine intake had a direct relationship to bone loss at the spine.<sup>17</sup> Specifically, women who consumed a high quantity of caffeine (more than 300 mg daily) had significantly higher rates of bone loss at the spine, in comparison to women who consumed more moderate amounts of caffeine.<sup>18</sup> The Framingham Study specifically concluded that “[c]affeine increases urinary calcium output and has been implicated as a risk factor for osteoporosis.”<sup>19</sup> This

---

<sup>13</sup> Terry Hartley et al., *Cardiovascular Effects of Caffeine in Men and Women*, 93 AM J CARDIOLOGY 1022-6 (2004).

<sup>14</sup> J.Z. Ilich et al., *To drink or not to drink: how are alcohol, caffeine and past smoking related to bone mineral density in elderly women?*, 21 J. AM. C. NUTRITION 536, 536 (2002).

<sup>15</sup> W Sakamoto et al., *Effect of Coffee Consumption on Bone Metabolism*, 28 J. BONE & MIN. RES. 332-36 (2001).

<sup>16</sup> T.H. Huang, et al., *Effects of Caffeine and Exercise on the Development of Bone: A Densitometric and Histomorphometric Study in Young Wistar Rats*, 30 BONE 293, 293 (2002).

<sup>17</sup> Prema B. Rapuri et al., *Caffeine Intake Increases the Rate of Bone Loss in elderly Women and Interacts with Vitamin D Receptor Genotypes*, 74 AM. J. CLINICAL NUTRITION 694 (2001).

<sup>18</sup> *Id.*

<sup>19</sup> D.P. Kiel et al., *Caffeine and the Risk of Hip Fracture: the Framingham Study*, 132 AM. J. EPIDEMIOLOGY 675 (1990).



conclusion was reached after tracking 3,170 individuals over a 12-year period.<sup>20</sup> This study further found a direct relationship between the amount of caffeine consumed and the risk of hip fracture. While the relative risk of fracture was not significantly impacted by moderate caffeine consumption (that is, 1.5 – 2.0 cups of coffee per day), this relative risk was increased when consumption exceeded 2.0 cups of coffee (or 4.0 cups of tea) per day.<sup>21</sup>

There is, however, research to the contrary. One study in particular tracked 138 women over the course of two years; this study concluded that caffeine was not a risk factor for bone loss in healthy, postmenopausal women.<sup>22</sup> Although this study was controlled so that caffeine was the sole significant variable, the results of the study may be undermined by the fact that its sample size was significantly smaller than the Framingham Study and by the fact that the length of the study was notably shorter.<sup>23</sup>

### C. Pregnancy

Caffeine may negatively affect pregnancy and, in particular, caffeine may cause miscarriages.<sup>24</sup> Caffeine can be detrimental to an expecting mother or a woman trying to become pregnant. Too much caffeine consumption during a woman's pregnancy can create substantial problems for the woman and the fetus. Some studies have shown an association of high doses of caffeine with an increased rate of miscarriages, premature deliveries or low birth rates.<sup>25</sup> Further studies show that caffeine leads to an increased

---

<sup>20</sup> *Id.*

<sup>21</sup> *Id.*

<sup>22</sup> Tom Lloyd et al., *Bone Status Among Postmenopausal Women with Different Caffeine Intakes: A Longitudinal Investigation*, 19 J. AM. C. NUTRITION 256, 256 (2000).

<sup>23</sup> *Id.*

<sup>24</sup> Press Release, Center for Science in the Public Interest, *Label Caffeine Content of Foods, Scientists Tell FDA: Health Activists Say Caffeine Causes More Than a 'Buzz': Miscarriages, Withdrawal Symptoms, Poor Nutrition* (July 31, 1997) <http://www.cspinet.org/new/caffeine.htm> (last visited Nov. 17, 2005).

<sup>25</sup> University of Michigan University Health Service, *Caffeine*, [www.uhs.umich.edu/health/caffeine.html](http://www.uhs.umich.edu/health/caffeine.html).

risk of infertility.<sup>26</sup> Additionally, caffeine consumption in high amounts can affect the fetal birth breathing and heart rate.<sup>27</sup> Doctors say that consuming caffeine should be cut out of the diet completely or at the very least consumed in moderation during a pregnancy.<sup>28</sup> The amount of caffeine intake is patient specific. Therefore, further action is needed informing pregnant women about products and their caffeine content.

#### **D. Withdrawal Symptoms**

Suddenly ceasing consumption of caffeine may result in withdrawal symptoms including headaches and fatigue.<sup>29</sup> Individuals who consume large amounts of caffeine daily are at risk of side effects when they cease drinking caffeinated beverages. These withdrawal symptoms or side effects from cessation of drinking caffeinated beverages include headaches, depression, irritability, fatigue or drowsiness, insomnia, anxiety, difficulty concentrating, nervousness, nausea (even vomiting), and muscular tension (stiffness) and pain. "These symptoms usually appear about 12-24 hours after someone has stopped consuming caffeine and usually last about one week."<sup>30</sup> "The peak intensity for withdrawal symptoms is between one and two days."<sup>31</sup> In order to combat these withdrawal symptoms from sudden cessation of caffeine intake, it is recommended that individuals gradually decrease their caffeine consumption rather than quitting cold turkey. "In general, the more caffeine consumed, the more severe withdrawal symptoms are likely to be."<sup>32</sup>

---

<sup>26</sup> *Supra* note 24.

<sup>27</sup> *Supra* note 25.

<sup>28</sup> *Supra* note 24.

<sup>29</sup> *Id.*

<sup>30</sup> *Supra* note 25.

<sup>31</sup> News release, Johns Hopkins University Department of Neuroscience, Caffeine Withdrawal Recognized as a Disorder (Sept. 2004) [https://hopkinsnet.jhu.edu/servlet/page?\\_pageid=1721&\\_dad=portal30p&\\_schema=PORTAL30P](https://hopkinsnet.jhu.edu/servlet/page?_pageid=1721&_dad=portal30p&_schema=PORTAL30P) (full study published by Roland Griffiths & Laura Juliano in the October 2004 issue of the journal *Psychopharmacology*).

<sup>32</sup> *Id.*

Another aspect of caffeine withdrawal symptoms is that when individuals start to feel the onset of these symptoms they will revert back to caffeine consumption in order to avoid these feelings. In other words, "avoidance of caffeine withdrawal symptoms motivates regular use of caffeine."<sup>33</sup> Also playing a hand in withdrawal symptoms is an individual's tolerance to caffeine. "Tolerance to a drug (in this case caffeine) refers to an acquired change in responsiveness of a subject repeatedly exposed to the drug and can be considered in two ways. First, tolerance might indicate that the dose necessary to achieve the desired euphoric or reinforcing effects will increase with time, thus influencing people to gradually consume more of the drug. Second, tolerance to the adverse effects of high doses of the drug may occur, leading people to consume higher doses of the drug over time."<sup>34</sup> Overall, individuals who consume more and more caffeinated beverages over time due to their increasing tolerance to the effects of caffeine will have a harder time ceasing consumption because it will take them longer to gradually decrease their consumption and avoid withdrawal symptoms.

The potential adverse effects of regular and sustained caffeine consumption, withdrawal symptoms in particular, can have very serious impacts on the lives of Americans. While the majority of the ramifications of withdrawal symptoms are non-life threatening, some do possess the possibility of leading to severe problems affecting an individual's life span. Therefore, the FDA should consider a requirement for labeling on products containing caffeine informing the consumer about the potential health risks from consuming the product. In addition, certain individuals may be unusually sensitive to caffeine such that "even a small amount of caffeine makes them uncomfortable."<sup>35</sup>

---

<sup>33</sup> *Id.*

<sup>34</sup> Astrid Nehlig, *Does caffeine lead to psychological dependence?* 29 CHEMTECH 30-35 (July 1999) available at: <http://pubs.acs.org/hotartcl/chemtech/99/jul/negli.html> (last visited Nov. 17, 2005).

<sup>35</sup> *Supra* note 25.

### E. Calcium kidney stone risk

While it is a generally accepted proposition that the intake of inadequate fluids is a major contributing factor in the formation of calcium kidney stones,<sup>36</sup> the tenet that “[s]oft drinks provide a pleasant and refreshing way to consume part of a person’s daily fluid requirement, thereby encouraging adequate fluid intake,”<sup>37</sup> is highly inappropriate, especially if you are prone to kidney stones. Specifically, if you are one of the many individuals partaking in the repetitive consumption of vast quantities of caffeinated products and are prone to kidney stones, this process may create an elevated content of calcium within one’s urine which will significantly increase a person’s risk for developing more kidney stones.<sup>38</sup>

In relation to kidney stone occurrences, while increased beverage consumption is desirable for those individuals prone to stone forming, it appears that consumption of specific kinds of beverages are precursors to kidney stone risk.<sup>39</sup> Specifically, non-caffeinated beverages may be a better choice when seeking to reduce such risk.<sup>40</sup> In support of this point, several scientific studies have deduced that the beverage type used in this hydration process may have a substantive effect on stone formation.<sup>41</sup> In particular, these studies observed that caffeine increased urinary calcium, magnesium and sodium in a set of stone forming individuals selected for study.<sup>42</sup>

---

<sup>36</sup> Linda K. Massey & Roger A. L. Sutton, *Acute Caffeine Effects on Urine Composition and Calcium Kidney Stone Risk in Calcium Stone Formers*, 172 J. UROLOGY 555, 557 (2004).

<sup>37</sup> Coca-Cola Company, *Products and Packaging Myths & Rumors: Soft Drinks Cause Kidney Failure*, [http://www2.coca-cola.com/contactus/myths\\_rumors/packaging\\_kidney.html](http://www2.coca-cola.com/contactus/myths_rumors/packaging_kidney.html) (last visited on October 29, 2005).

<sup>38</sup> *Watch Your Caffeine Intake if You are Prone to Kidney Stones*, MED. NEWS TODAY (September 5, 2005), available at <http://www.medicalnewstoday.com/printerfriendlynews.php?newsid=12937>.

<sup>39</sup> See Gary C. Curhan, et al., *Beverage Use and Risk for Kidney Stones in Women*, 128 ANNALS OF INTERNAL MED. 7:534-540 (1998); and Gary C. Curhan, et al., *A Prospective Study of Dietary Calcium and Other Nutrients and the Risk of Symptomatic Kidney Stones*, 328 NEW ENG. J. MED. 833-838 (1993).

<sup>40</sup> See *supra* note 36 at 557.

<sup>41</sup> See *id.*; *supra* note 39.

<sup>42</sup> See *supra* note 36 at 557.

A typical person will generally consume caffeinated beverages on several occasions throughout the course of a day, such as an early morning coffee, a mid afternoon soda, etc.<sup>43</sup> However, this increased fluid consumption may not be as beneficial if these additional beverages contain caffeine, since increased calcium excretion is likely to follow consumption.<sup>44</sup> Generally, caffeine effects a person's urinary composition by increasing human urinary calcium excretion by decreasing re-absorption. Specifically, it has been found that caffeine has the ability to block receptors responsible for this re-absorption contained within the distal tubule, known as adenosine A1 receptors.<sup>45</sup> This failure by the body to reabsorb the increased levels of calcium and sodium in the body due to caffeine, create a greater likelihood of one developing kidney stones.

Clearly there are negative associations that exist between urinary kidney stones and the consumption of caffeine. While the intake of caffeine in the course of these studies may be at an elevated level of single intake in furtherance of research, the results of these tests lead to a definitive assertion that urine tests after taking calcium show elevated levels of calcium within the that urine.<sup>46</sup> Consequently, the more calcium and sodium you have in your urine, the higher risk there is in a person to develop kidney stones.<sup>47</sup> As such, there is a need for a greater and more express regulation for products containing caffeine as to the discomfort and urinary problems that the consumption of such may induce.

#### **F. Gastroesophageal reflux disease**

Gastroesophageal reflux disease (GERD) is a chronic condition that currently affects more than 21 million Americans,<sup>48</sup> and an estimated lifetime prevalence of 25 to

---

<sup>43</sup> *See id.*

<sup>44</sup> *Id.*

<sup>45</sup> *Id.*

<sup>46</sup> *See id.*; *see also* MED. NEWS TODAY, *supra* note 38.

<sup>47</sup> *See* MED. NEWS TODAY, *supra* note 38.

<sup>48</sup> Chronic Heartburn, <http://www.aboutgerd.org/week112303.html> (last visited Dec. 7, 2005).

35 percent in the U.S. population.<sup>49</sup> Drinks with caffeine can be associated with GERD.<sup>50</sup> In fact, caffeine is one of the most common xanthines to adversely affect GERD.<sup>51</sup>

#### **G. Other Considerations: Diabetes/Hypoglycemia/Obesity**

Caffeine may create difficulties for people with diabetes to regulate their glucose and insulin levels.<sup>52</sup> In a Duke University study, caffeine was shown to raise both the glucose and insulin levels of type 2 diabetes subjects more than the control group not given the caffeine.<sup>53</sup> Caffeine may even be a cause of adult diabetes development.<sup>54</sup> The resulting fluctuations in insulin and glucose levels within a person's body can be caused by consumption of caffeine.

Finally, "several studies have provided experimental evidence that soft drinks are directly related to weight gain. That weight gain, in turn, is a prime risk factor for type-2 diabetes, which, for the first time, is becoming a problem for teens as well as adults."<sup>55</sup> This weight gain is related to withdrawal symptoms because studies seem to conclude that individuals would rather avoid withdrawal symptoms and consume more caffeinated beverages. More consumption leads to the aforementioned weight gain and the health risks involved, such as heart attacks, strokes, and cancer on top of diabetes. Again, as individuals' tolerance to caffeine's effects increase over time, they will consume more

---

<sup>49</sup> Mark Scott & Aimee R. Gelhot, *Gastroesophageal Reflux Disease: Diagnosis and Management*, AM. FAM. PHYSICIAN (Mar. 1999).

<sup>50</sup> Gastroesophageal Reflux Disease – GERD, <http://heartburn.about.com/cs/articles/a/gerd.htm> (last visited Dec. 7, 2005); Heartburn, Hiatal, and Gastroesophageal Reflux Disease (GERD), <http://digestive.niddk.nih.gov/ddiseases/pubs/gerd/#3> (last visited Dec. 7, 2005); National Sleep Foundation, <http://www.sleepfoundation.org/sleepdictionary/index.php?id=13> (last visited Dec. 7, 2005).

<sup>51</sup> ROY C. ORLANDO, GASTROESOPHAGEAL REFLUX DISEASE (2000).

<sup>52</sup> *Caffeine 'Makes Diabetes Worse'*, BBC NEWS, July 31, 2004, <http://news.bbc.co.uk/2/hi/health/3936333.stm>.

<sup>53</sup> *Id.*

<sup>54</sup> Raymond Francis, *Caffeine Causing Diabetes?*, BEYOND HEALTH, <http://www.beyondhealth.com/caffeine-diabetes.htm> (last visited Dec. 7, 2005).

<sup>55</sup> CTR. FOR SCI. IN THE PUB. INT., LIQUID CANDY: HOW SOFT DRINKS ARE HARMING AMERICA'S HEALTH (2005), <http://www.cspinet.org/liquidcandy>.

caffeinated beverages to either achieve the feeling they get from caffeine consumption, or to avoid the feeling they get from not enough caffeine consumption.

#### **H. Conclusions**

Caffeine alone is not a life-threatening substance. However, it is linked to numerous diseases and health problems, some more serious than others. Caffeine consumption is very prevalent in the United States, and the health affects linked to caffeine affect large percentages of people.

Multiple studies have shown that caffeine consumption is linked to hypertension which can lead to very serious health effects. There are some studies which show that caffeine consumption may also be linked to osteoporosis, a problem affecting many women. Additionally, studies show that caffeine may have adverse affects on women's fertility as well as the unborn fetus during pregnancy. Caffeine is also linked to calcium kidney stones by increasing the likelihood of an occurrence; and exacerbating the problems associated with gastroesophageal reflux disease. Research also shows that caffeine in the form of soft drinks is directly linked to obesity, hypoglycemia and diabetes. Less serious, but still unfortunate effects are those that follow caffeine consumption. These are the withdrawal symptoms that occur when one stops consuming caffeine.

The Petitioners feels that given recent findings, such as those just mentioned, various segments of society have a vital interest in knowing how much caffeine is in a given product and should be more adequately warned of its addictive qualities and potentially adverse effects on health. Pregnant women, individuals with unusual sensitivity to caffeine, and those averse to addictive substances have a right to be adequately warned of these dangers before they purchase a caffeine-containing product.

### **III. ENVIRONMENTAL IMPACT**

The action requested is subject to a categorical exclusion under 21 C.F.R. §§ 25.30 and 25.32 and, therefore, does not require the preparation of an environmental assessment.

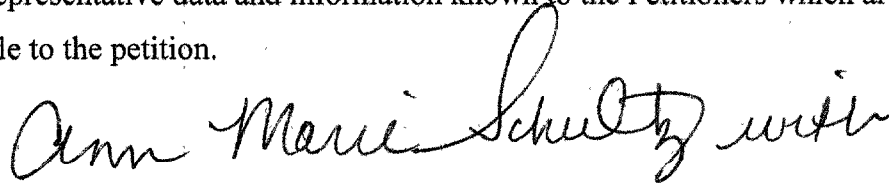
#### IV. ECONOMIC IMPACT

No statement of the economic impact of the requested action is presented because none has been requested by the Commissioner; therefore, no statement of the economic impact is required at this time.<sup>56</sup>

Nonetheless, any costs incurred by a quantitative labeling requirement would be offset, in whole or in part, by the savings from the possible health benefits. The cost of revising labels would be modest if firms are allowed time to replace existing labeling stock. In addition, the economic impact would only apply to the small fraction of food manufacturers that have caffeine content in their foods.

#### V. CERTIFICATION

The undersigned certify that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and it includes representative data and information known to the Petitioners which are unfavorable to the petition.



Julie Burke

Kara Clemens

Robert Golding

Michael Gorman

Heidi M. Hendrick

Rachel Hurley

Layla Kuhl

Elijah Milne

Joshua Nucian

Brian Quint

Ann Marie Schultz

David Seibert

Mailing Address: Ann Marie Schultz, 2094 Lac DuMont, Apt. A1, Haslett, MI 48840

Telephone: (517) 575-0394

---

<sup>56</sup> 21 C.F.R. § 10.30(b).