



DEPARTMENT OF HEALTH & HUMAN SERVICES

HFA-305

Food and Drug Administration  
Rockville MD 20857

February 27, 2003

Michael F. Jacobson, Ph.D.  
Executive Director  
Center for Science in the Public Interest  
1875 Connecticut Avenue, N.W.  
Suite 300  
Washington, D.C. 20009-5728

Dear Dr. Jacobson:

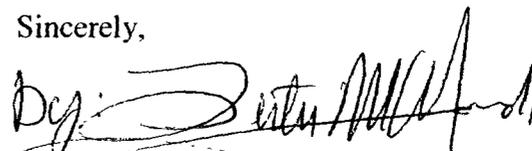
This is in response to your letter of January 14, 2003, urging the Food and Drug Administration (FDA) to immediately initiate rulemaking to require the amount of caffeine per serving to be declared in the labeling of foods containing caffeine.

As FDA noted at the House Committee on Appropriations hearing in 2002, several years ago FDA reviewed your 1997 citizen petition as well as other available data. In particular, FDA reviewed the effects of caffeine on reproduction, bone mineral metabolism, and behavior. FDA also contacted several scientific and advocacy organizations as part of this evaluation. Our analysis has not been completed and FDA has not undertaken any rulemaking in response to your petition.

We understand your concern about caffeine in food products and intend to proceed with our evaluation of your petition and other issues pertaining to caffeine. Specifically, the Center for Food Safety and Applied Nutrition's priorities for FY '03 include a plan to conduct a survey to identify and characterize the sources of caffeine in the food supply.

Thank you for your interest in this issue. If I may be of further assistance, please let me know.

Sincerely,

  
Mark B. McClellan, M.D., Ph.D.  
Commissioner of Food and Drugs

97P-0929

LET 7

# CSPI CENTER FOR SCIENCE IN THE PUBLIC INTEREST

Publisher of *Nutrition Action Healthletter*

January 14, 2003

The Honorable Mark McClellan, M.D.  
Commissioner  
Food and Drug Administration  
Room 14-71  
5600 Fishers Lane  
Rockville, Maryland 20782

Dear Dr. McClellan:

I write to urge you to tell both the Office of Information and Regulatory Affairs (“OIRA”) of the Office of Management and Budget and interested members of the House Committee on Appropriations that the FDA will immediately initiate a rulemaking to require the amount of caffeine per serving to be disclosed on labels of foods and beverages that contain caffeine.

At that committee’s hearing last year on the FDA’s FY 2003 budget, both Representatives Farr and Boyd asked Deputy Commissioner Lester Crawford about the status of CSPI’s 1997 petition on caffeine labeling. In its written response (enclosed) to Representative Farr the FDA merely said “The agency is exploring various options for informing consumers, within its statutory authority, about the presence of caffeine in food products.” In its written response (enclosed) to Representative Boyd the FDA merely said “We will raise the priority of this issue and reevaluate how to respond to the [CSPI] petition.”

Last month OMB’s Office of Information and Regulatory Affairs forwarded to the FDA (and other agencies) various suggestions from the public about possible new regulations. One of those suggestions was caffeine labeling. OIRA asked the FDA to consult with OIRA by February 28, 2003, on what action the FDA will take on caffeine labeling.

Over the past 20 years, the FDA itself has been advising pregnant women to “avoid caffeine-containing foods and drugs, if possible, or consume them only sparingly.”<sup>1</sup> In the last several years, many physicians have routinely advised pregnant women “to avoid caffeine-containing foods and drugs whenever possible. If you can’t give up caffeine during pregnancy,

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<sup>1</sup> U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, *Caffeine and Pregnancy* (FDA) 81-1081. See also Rebecca D. Williams, “Healthy Pregnancy, Healthy Baby,” *FDA Consumer Magazine* (March-April 1999).



keep your intake below 200 milligrams.”<sup>2</sup> That is because several studies have correlated the consumption of several cups of coffee with low birth weight, miscarriages, and other adverse effects on pregnancy. One pregnancy book, for example, tells women that “Consumed in high amounts (500 milligrams or more daily), caffeine increases the amount of time a fetus spends in an active, awake state and may cause a decrease in your baby’s weight and head circumference.”<sup>3</sup>

In the fall of 2001 the British government issued similar advice to pregnant women after a review by independent experts, who concluded that “caffeine intakes above 300 mg/day may be associated with low birth weight and, in some cases, miscarriage.”<sup>4</sup>

Almost six years ago the American Medical Association called on the FDA to require that the amount of caffeine in foods be declared on the label (see enclosed resolution). Yet the FDA has taken no action on CSPI’s July 1997 petition asking the FDA to require disclosure of the caffeine content of food and beverages.<sup>5</sup>

Thus, pregnant women (and others<sup>6</sup>) still cannot know how much caffeine is in a serving of a particular food or beverage, such as coffee, tea (except Lipton’s tea, boxes of which disclose the caffeine content per serving of black tea, green tea, decaffeinated tea, and herbal tea), colas and other soft drinks, caffeinated water, coffee-flavored dairy products (ice cream, frozen yogurt, yogurt), chocolate milk, and chocolate candies.

In conclusion, on behalf of our 800,000 members I urge you to immediately initiate a

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<sup>2</sup> Robert V. Johnson, M.D., ed. *Mayo Clinic Complete Book of Pregnancy & Baby’s First Year* (1994) at 101 (enclosed). See also Tracie Hotchner, *Pregnancy & Childbirth* (1997) at 76; Arlene Eisenberg, Heidi E. Murkoff, and Sandee E. Hathaway, *What to Expect When You’re Expecting* (1996) at 60 (enclosed).

<sup>3</sup> Johnson at 101.

<sup>4</sup> Food Standards Agency of United Kingdom October 10, 2001 press release (enclosed).

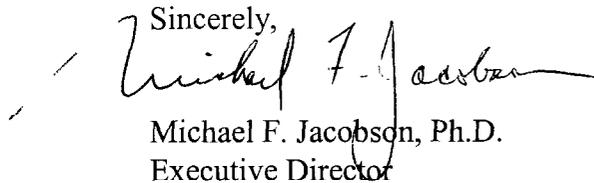
<sup>5</sup> CSPI filed this 1997 petition after the FDA officially denied in October 1996 the petition CSPI had filed in 1979.

<sup>6</sup> Caffeine can also adversely affect both non-pregnant women because of its effect on bone-mineral metabolism and children because of its possible impact on anxiety and restlessness. See enclosed letter of February 13, 2001, from the American Psychological Association to the FDA supporting CSPI’s petition.

- Page 3 -

rulemaking to require the disclosure on labels of the amount of caffeine in a food or beverage.

Sincerely,

A handwritten signature in black ink that reads "Michael F. Jacobson". The signature is written in a cursive style with a long horizontal flourish at the end.

Michael F. Jacobson, Ph.D.  
Executive Director

enclosures: excerpts from March 1, 2002 House of Representatives hearing on FDA's FY 2003 budget request

excerpts from Robert V. Johnson, M.D., ed. *Mayo Complete Book of Pregnancy & Baby's First Year* (1994); Tracie Hotchner, *Pregnancy & Childbirth* (1997); and Arlene Eisenberg *et al.*, *What to Expect When You're Expecting* (1996)

press release of Food Standards Agency of United Kingdom (October 10, 2001)

1997 resolution on caffeine of the American Medical Association

February 13, 2001 letter on caffeine from American Psychological Association to the FDA

cc: The Honorable Lester M. Crawford, D.V.M., Ph.D.  
Deputy Commissioner

part 6, FY 2003 Meeting

respects, to change the mentality of consumers around the country, and others who don't realize probably that we are all paying for it literally, the cost of it in taxes and health care costs and low productivity and so forth. I think we need to address that issue straight on and firmly and aggressively.

Mr. Chairman, I will have other questions, if I may, later.  
Mr. LATHAM. Very good.  
Mr. Farr.

CAFFEINE

Mr. FARR. Thank you very much, Mr. Chairman, and thank you for all being here today. My question kind of relates to a very personal issue. My daughter recently told me that she was expecting a baby, our first grandchild, in October next year, and I was drinking coffee and she asked me how many cups of coffee, and I was embarrassed to tell her many, many a day, as supposedly most Members of Congress do, and she was telling me that her physician had recommended against her having a high intake of caffeine.

So we started it talking about caffeine, and then I found out about 5 years the American Medical Association called on the FDA to require the amount of caffeine in foods and beverages to be declared on food labels, as you do, as it does for NoDoz, and then in July of 1997 the Center for Science and Public Interest petitioned the FDA to require the disclosure of caffeine content in food beverages.

I think I have learned we have caffeine in coffee but it is in teas, colas, soft drinks, caffeinated water, ice cream, frozen yogurt, chocolate milk and chocolate candies. Caffeine is a big issue in America. My question, I guess, is when is the FDA going to take action on the Center for Science and Public Interest petition and begin rulemaking on this important issue?

Dr. CRAWFORD. I am going to ask the recipient of that petition, Mr. Joe Levitt, to come forward, but as he is lumbering towards the table, let me say that caffeine is a big issue, and it is in places that we don't expect it to be. There are contradictory studies on what population may be at some risk for it. As you know, it is a chemical that is rapidly dissipated from the body, but it is not without its risk and Joe is going to address what we are dealing with.

Mr. LEVITT. Thank you. As the committee has pointed out, we have a lot of issues we try to deal with. What we have tried to do in our Center for Food Safety and Applied Nutrition is to have an annual priority setting process for which we start with an external request for comment and where our stakeholders feel we should apply our efforts, and we then develop that into what I call the Yellow Book because that is the cover of it. It is also available on the Web page.

And we go through and prioritize what can we try to accomplish this year, what can we try to make a lot of progress on, what is still kind of there in the wings that we will get to if time permits. It is a hard process to go through because we have so many competing demands. At the end of the year, we report out what we have accomplished. We have been very successful in accomplishing most of what we set out to do in that year. Regretfully we can't do

everything. We have our so-called petition has not really risen yet to ities. We have talked about food really have that right now as soon at and certainly not this year.

Mr. FARR. It is not even on your Dr. CRAWFORD. But what we can is give you a recitation of what we think it is and give you some list, and having raised the question list, and also puts it on my list. So [The information follows:]

CAFF

Following receipt of two Citizen petitions submitted by the petitioners as well as other agency has reviewed the effects of caffeine on growth, fertility, and miscarriage), bone-m of this evaluation FDA contacted scientific interest in the effect of caffeine including Obstetricians and Gynecologists, American Osteoporosis Foundation, and the various FDA tentatively concluded that, at this time, it is not possible to establish a quantitative level of caffeine and effects of caffeine withdrawal is exploring various options for informing about the presence of caffeine in food products efforts to explore the amounts of caffeine use the agency's Food Advisory Committee Pending the outcome of these activities with caffeine.

EPHE

Mr. FARR. Mr. Chairman, we can respond like that. I am glad some petitions are important. Let me ask you cause I think I have the capital of the district. Santa Cruz, California is the sort of drawn into this ephedrine finding myself confused. There have been efforts together to try to convene a scientific panel you withdrew portions of the 97 petitioning this and there is still part of the petition is are you going to withdraw the rule in order to allow the agency to science available as well as the final rule.

Dr. CRAWFORD. We are evaluating the FDA food advisory committee was on some adverse reactions that we have had of ephedra-containing substances, that FDA take some regulatory action on that 1997 proposal.

Since I have been on board we have looked again at the ephedra products of the ephedra products are separate products which are obviously



shipment. The shipments that you state were not examined by an FDA investigator. This may give the impression that it is more likely a function of the nature of the products of McEwen Laboratories in Canada, they have been tested in 2000 for EPD allergens because FDA has found them to be allergen delivery systems to the U.S.

#### DIETARY SUPPLEMENTS

FDA awarded a \$1 million two-year contract to the Institute of Medicine of the National Academies to study the safety of dietary supplements and to apply this study to dietary supplements. What is the status of this project? If you plan to give an extension of time for its completion? You were awarded into a contract entitled Framework for Evaluating Dietary Supplements, with the Food and Nutrition Board of the National Academies of Health, with the Food and Nutrition Board of the National Academies of Health, to provide an appropriate protocol for the safety of dietary supplements. The contract covers the period through September 29, 2002. The contract is currently in progress. Meetings have been held.

Will you either FY 2002 or FY 2003 put additional funds into the program more than seven dietary supplements can be studied? If so, how many?

The \$1 million two-year contract to the Food and Nutrition Board of the National Academies to develop a framework for evaluating dietary supplements and to apply this framework to at least seven dietary supplements does not plan on putting additional funds into this program. Currently, FDA feels this project is funded at a level of \$1 million.

#### CAFFEINE

Mr. Boyd: Almost five years ago the American Medical Association called on the FDA to require that the amount of caffeine in foods and beverages be declared on food labels as it is on labels of No Doz. In July 1997, the Center for Science in the Public Interest petitioned the FDA to require disclosure of the caffeine content of foods and beverages. But five years have passed, and the FDA has taken no action on that petition, and so pregnant women still don't know how much caffeine is in a serving of a particular food or beverage, such as coffee, tea, colas and other soft drinks, caffeinated water, ice cream, frozen yogurt, yogurt, chocolate milk, and chocolate candies. When is the FDA going to take action on the CSPI petition and begin a rulemaking on this important public health matter?

Response: Following receipt of the Citizen petition in question in 1997, FDA reviewed the literature submitted by the petitioners as well as other available data. In particular, the Agency has reviewed the effects of caffeine on reproduction (including birth defects, fetal growth, fertility and miscarriage), bone-mineral metabolism, and behavior. As part of this evaluation, FDA has contacted scientific and advocacy organizations that had an interest in the effects of caffeine including the March of Dimes, American College of Obstetricians and Gynecologists, American Academy of Pediatrics, National Osteoporosis Foundation, and the National Institutes of Health. We will raise the priority of this issue and reevaluate how to respond to the petition.

#### MEDICAL DEVICE APPLICATION REVIEW

Mr. Boyd: Last year, this subcommittee included language in the report accompanying the FY 2002 Appropriations bill directing FDA to provide updates on medical device application review performance in January and July 2002. Has the Agency submitted those reports to this subcommittee?

Response: The first of the Medical Device Application Performance Review reports due to the Subcommittee in January, is undergoing administrative review. We expect the report to be forwarded to the Subcommittee within the next several weeks.

Mr. Boyd: The most recent reports from the Agency indicate that mean approval time for breakthrough technologies is up to 411 days, more than double the statutory limit of 180 days. Not since the passage of FDAMA has CDRH been so far behind in the approval of new technologies. I asked this question last year and I'll ask it again this year: What resources does CDRH need to meet all requirements for safety and effectiveness and approve all categories of medical devices within the statutory timeframes?

Response: At this time, FDA is unable to provide the Committee with a thorough and comprehensive review of resource estimates needed to meet the statutory deadlines for all categories of medical device applications. Device technology advances and global impact will continue to impact review performance. In addition, submissions are becoming increasingly more complex, which also contributes to review performance. Any additional resources in future budget requests would be used to give our reviewers the capability to do high quality, interactive, and timely reviews required by FDAMA, and allow us to keep the public well informed about medical product safety associated with these devices.

*MAYO CLINIC  
COMPLETE  
BOOK OF  
PREGNANCY &  
BABY'S FIRST  
YEAR*

Robert V. Johnson, M.D.  
Editor-in-Chief

William Morrow and Company, Inc.  
New York

## Caffeine

Caffeine is a drug that has been part of the human diet for thousands of years. It occurs naturally in coffee, tea, chocolate and cocoa. Caffeine is frequently added to soft drinks and over-the-counter drugs, including headache and cold tablets, stay-awake medications and allergy remedies. An abundance of research indicates that moderate consumption of caffeine (200 milligrams daily) has no negative effects during pregnancy. Consumed in high amounts (500 milligrams or more daily), caffeine increases the amount of time a fetus spends in an active, awake state and may cause a decrease in your baby's birth weight and head circumference.

Coffee is the most common source of caffeine. Drinking more than two or three cups of coffee a day is not recommended. Other foods that contain caffeine include tea, carbonated beverages and chocolate. To reduce the amount of caffeine in hot beverages you drink, consider changing how you brew them. The shorter the brewing time, the lower the caffeine concentration. You can also lower your caffeine consumption considerably by switching from perked to instant coffee.

If you love a soothing hot cup of tea, brewing a tea bag for just one minute, instead of five, can reduce caffeine content by as much as half. Because little is known about herbs and their effects on pregnancy, avoid herbal teas. Don't take anything that contains comfrey; this herb can cause serious liver disease.

The best advice is to avoid caffeine-containing foods and drugs whenever possible. If you can't give up caffeine during pregnancy, keep your intake below 200 milligrams daily.

### Caffeine content of common foods

	Milligrams of caffeine	
	Average	Range
Coffee, 5 ounces		
Brewed, percolator	115	60-180
Brewed, drip method	80	40-170
Instant	65	30-120
Tea, 5 ounces		
Brewed, imported	60	25-110
Brewed, U.S. brands	40	20-90
Instant	30	25-50
Iced (12 ounces)	70	67-76
Soft drinks, 12 ounces	36	30-50
Cocoa, 5 ounces	4	2-20
Chocolate milk, 8 ounces	5	2-7
Semisweet chocolate, 1 ounce	20	5-35
Milk chocolate, 1 ounce	6	1-15
Chocolate syrup, 1 ounce	4	4-5

## A Final Word

Start now to improve your diet, so that you can feel good and give your baby a healthful head start. Good nutrition can be easy if you take the time to plan. It won't mean giving up your favorite snack foods or treats.

Don't forget to share your healthful eating habits with your partner. Remember that after your baby is born, the foods you both eat will help to guide your child's eating habits. Now is a good time to make the small changes that can offer a significant improvement in the diet of your whole family.

TRACIE HOTCHNER

PREGNANCY  
&  
CHILDBIRTH

REVISED AND UPDATED

The Only Book You'll Ever Need

Foreword by Karen Blanchard, M.D., OB/GYN

Interior illustrations by Christine Leahy

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the Americas,

AVON BOOKS  NEW YORK

carcinogens, which are substances that can cause cancer. These carcinogens form when fat drips onto the coals. However, there are steps you can take to prevent carcinogens from forming when you use the grill: see the chart on page 75.

The safest methods of cooking your food are stewing (sautéing) on top of the stove, poaching, or microwaving. If you're used to cooking a lot on the grill, you can get ideas for other ways to prepare your food by looking through cookbooks for easy, tasty alternatives to barbecuing. For a change, you might try roasting or baking your food in the oven with lots of herbs and spices to give it flavor.

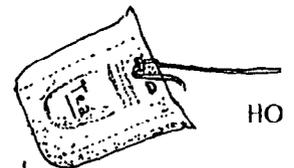
### Caffeine

! Especially when you are trying to conceive and in the first 3 months of pregnancy, eliminate (or at least drastically reduce) your caffeine consumption. In animal studies caffeine caused reproductive problems such as miscarriage, stillbirth, and fetal death. It is believed that caffeine may have disrupted cell division at a stage when constant splitting of the cells was necessary for development of the fetus. High caffeine consumption is considered more than 3 cups of coffee (or the equivalent amount of caffeine) a day.

And even if you take in a lot of caffeine during the months right before you actually get pregnant, it raises your risk of a miscarriage once you have conceived. The most conservative attitude about caffeine is to assume there is *no* amount that is really safe during pregnancy.

#### WAYS TO CUT DOWN ON CAFFEINE

- Use decaffeinated coffee and tea (but be aware that it still has a little caffeine).
- Do not take any of the pain medications containing aspirin (see the directory on page 172).
- Don't let tea steep very long and do not ever boil it, both of which increase the amount of caffeine.
- Be aware which colas and other sodas have high amounts of caffeine. Switch to another kind.
- After the first trimester, continue trying to keep your coffee intake to a minimum. Even if you drink only 4 cups of coffee a day (or the equivalent in caffeine), it may have an effect on the developing fetus.



HO

*Coffee* (5 oz.)  
automatic drip  
percolated  
instant  
decaffeinated

*Tea* (5 oz.)  
steeped 5 minutes  
steeped 2 minutes  
canned iced tea (12 c  
decaffeinated

*Chocolate*  
baking chocolate (1 c  
cocoa beverage  
milk chocolate (1 oz.)

*Soft drinks* (12 oz.)  
Mountain Dew, Mello  
Coca-Cola, Tab, Shast  
Sunkist orange  
(Sunkist diet orange)  
Pepsi, Dr. Pepper, RC  
Diet-Rite  
7-Up, Sprite, Fresca, g  
root beer

*Nonprescription medi*  
Dexatrim, Dietac  
No-Doz, Vivarin, Caff  
Excedrin  
Anacin, Midol  
Dristan, Coryban-D  
plain aspirin (any brar

# WHAT TO EXPECT WHEN YOU'RE EXPECTING

**T**he pregnancy guide that reassuringly answers the concerns of mothers-and fathers-to-be, from the planning stage through postpartum.

*Clear, comprehensive  
month-by-month  
format*

By Arlene Eisenberg,  
Heidi E. Murkoff, and  
Sandee E. Hathaway,  
B.S.N.

*With a foreword by  
Dr. Richard Aubry,  
Director of Obstetrics,  
State University of  
New York Health  
Sciences Center  
at Syracuse*



a single use in the third trimester can trigger contractions and an abnormal fetal heartbeat.

Tell your practitioner about any cocaine use since you've conceived. As with every aspect of your medical history, the more your doctor knows, the better care you and your baby will receive. If you have any difficulty giving cocaine up entirely, seek professional help immediately.

Pregnant women who use drugs of any kind—other than those that have been prescribed by a physician who knows they are pregnant—are also putting their babies in jeopardy. Every known illicit drug (including heroin, methadone, crack, "ice," LSD, and PCP), and every prescription drug of abuse (including narcotics, tranquilizers, sedatives, and diet pills) can cause serious harm to a developing fetus and/or to the pregnancy with continued use. Check with your practitioner or another knowledgeable doctor about any drugs you've used during pregnancy, or call one of the hotlines listed in the Appendix to see what effect they could have had. Then, if you are still using drugs, get professional support (from a certified addiction counselor, an addictionologist, or a treatment center) to help you quit now.

## CAFFEINE

*"I find it difficult to start the day without my two cups of coffee. Is it true that caffeine isn't safe during pregnancy?"*

**P**ossibly. Caffeine (found in coffee, tea, colas and other soft drinks) does cross the placenta and enter the fetal circulation. Although animal studies have shown numerous harmful effects from caffeine on developing fetuses, until recently, human studies showed no such effects. The most cur-

rent research, however, suggests that the equivalent of one and a half to two cups of coffee a day can double the risk of miscarriage. Until more is known, it certainly makes sense to play it safe and to try to start your day without those two cups of coffee.

Here are some additional reasons to give up caffeinated coffee (and tea and colas) during pregnancy. First of all, caffeine has a diuretic effect, drawing fluid and calcium—both vital to maternal and fetal health—from the body. If you're having a problem with frequent urination anyway, caffeine intake will compound it. Second, coffee and tea, especially when taken with cream and sugar, are filling and satisfying without being nutritious and can spoil your appetite for the nutritious food you need. Colas are not only filling but may contain questionable chemicals in addition to unneeded sugar. Third, caffeine can exacerbate your normal pregnancy mood swings and also interfere with adequate rest. Fourth, caffeine may interfere with the absorption of the iron both you and your baby need. Fifth, research suggests excessive caffeine use could result in temporary abnormal heartbeat, rapid respiration, and tremors in the newborn and the development of diabetes<sup>3</sup> later in life. Finally, the fact that many women lose their taste for coffee early in pregnancy suggests that mother nature herself considers the substance to be unsuitable for pregnant women.

**How Do You Break the Caffeine Habit?**  
The first step, finding your motivation, is easy in pregnancy: giving your

3. In countries where caffeine consumption is highest, the incidence of diabetes is highest too; it is suspected that caffeine builds up in the fetal pancreas and eventually damages the cells that produce insulin.

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Wednesday, 10th October 2001  
2001/0153

### **ADVICE FOR PREGNANT WOMEN ON CAFFEINE CONSUMPTION**

Pregnant women should limit their intake of caffeine to less than the equivalent of four average cups of coffee a day according to new advice published by the FSA today.

The advice, which for the first time puts a figure on previous Department of Health guidance for pregnant women to moderate caffeine consumption, follows a review by independent experts, the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (CoT).

The CoT looked at the effects of caffeine on reproduction and concluded that caffeine intakes above 300 mg/day may be associated with low birth weight and, in some cases, miscarriage.

Deputy Chair of the Agency, Suzi Leather, said:

"In practice this doesn't mean cutting out coffee completely but is about taking a sensible precaution and not having more than the equivalent of four cups of coffee a day.

"Of course it's easy to forget that it's not just coffee that contains caffeine, but tea, soft drinks and chocolate too. Because of this we have tried to set out our advice in a way that is practical and easy to understand."

Caffeine occurs naturally in a range of foods such as coffee, tea and chocolate. It is also added to some soft drinks and so called 'energy' drinks. 300 mg of caffeine is roughly equivalent to:

- 4 average cups or 3 average size mugs of instant coffee
- 3 average cups of brewed coffee
- 6 average cups of tea
- 8 cans of regular cola drinks
- 4 cans of so-called "energy" drinks

400 grams (8 standard 50 g bars) of normal chocolate

The individual intakes are:

- Average cup of instant coffee - 75 mg
- Average mug of coffee - 100 mg
- Average cup of brewed coffee - 100 mg
- Average cup of tea - 50 mg
- Regular cola drink - up to 40 mg
- Regular energy drink - up to 80 mg
- Normal bar of chocolate - up to 50 mg

These sources should be added together to calculate total intake of caffeine. For example, 1 bar of chocolate, 3 cups of tea, a can of cola and a cup of instant coffee would add up to 300 mg/day.

There are other, less common sources of caffeine, including certain cold and flu remedies. Pregnant women should always seek advice from their Doctor or other health professionals on the appropriate diet during pregnancy.

#### **Notes to Editors:**

1. [Click here to view a copy of the COT Report](#)



[END]

Room 245,  
Aviation House,  
125 Kingsway,  
London WC2B 6NH

Telephone: 020 7276 8888  
Out of hours duty pager: 07669 074642  
Fax: 020 7276 8833  
Email: [press.mailbox@foodstandards.gsi.gov.uk](mailto:press.mailbox@foodstandards.gsi.gov.uk)

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AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 523  
(A-97)

Introduced by: Florida Delegation  
Subject: Caffeine Drinks  
Referred to: Reference Committee E  
(Ira D. Godwin, MD, Chair)

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1 Whereas, Caffeine is a substance that has considerable effects on patients with ulcer disease as  
2 well as cardiac problems; and  
3  
4 Whereas, Many physicians have advised their patients for medical reasons to avoid caffeine; and  
5  
6 Whereas, Caffeine is now being added extensively to non-cola soft drinks as well as to some fruit  
7 juices and even bottled water; and  
8  
9 Whereas, These products are being aggressively advertised with the word caffeine appearing only  
10 in extremely small letters under ingredients; and  
11  
12 Whereas, Many consumers will not realize caffeine is in these products; and  
13  
14 Whereas, AMA Policy H-150.988 pertaining to Caffeine Labeling provides that "The AMA  
15 (1) supports a continued review of the safety of dietary caffeine intake, and (2) supports continued  
16 efforts to disseminate information to the public and physicians on the caffeine content of food and  
17 beverages"; therefore be it  
18  
19 RESOLVED, That the American Medical Association work with the Food and Drug Administra-  
20 tion to ensure that when caffeine is added to a product the label reflects this in prominent letters  
21 and the amount of caffeine in the product be written on the label.

Fiscal Note: No significant fiscal impact



AMERICAN  
PSYCHOLOGICAL  
ASSOCIATION

February 13, 2001

Dr. Bernard Schwetz  
Acting Principle Deputy Commissioner  
U.S. Food and Drug Administration  
5600 Fishers Lane  
Room 1471  
Rockville, MD 20857

Dear Dr. Schwetz:

Caffeine is the only drug that is widely added to the food supply and a large proportion of the population consumes it. For over 20 years the Center for Science in the Public Interest (CSPI) has been engaged in efforts to increase public awareness about potential adverse health consequences associated with caffeine consumption. As part of that effort, CSPI has petitioned the Food and Drug Administration to require that caffeine content be disclosed on food and beverage labels and requested that FDA conduct additional studies on the health effects of caffeine (Docket #97PO329).

The American Psychological Association supports this petition, particularly given the well-documented psychopharmacological and behavioral effects of caffeine including anxiety, sleeplessness, and addiction. Whether health-conscious adults want to monitor their own caffeine intake or that of minors in their charge they have a legitimate right to know how much caffeine they are consuming. As the CSPI petition asserts, the FDA has the authority to require quantitative caffeine-content labeling of foods and beverages. Additionally, consistent with its mission to promote public health, the FDA should conduct a thorough review of the effects of caffeine on health and behavior to determine if further regulatory or educational actions should be taken to inform consumers about adverse effects associated with caffeine consumption.

Sincerely,

L. Michael Honaker, PhD  
Chief Operating Officer and Deputy CEO

cc. Mr. Joseph Levitt, FDA Center for Food Safety and Applied Nutrition

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