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To: <coshita@oehha.ca.gov>  
Date: 4/27/2009 7:29 PM  
Subject: Proposition 65 Implementation  
Attachments: Aspartame%20FDA%20petition[1].doc

Ms. Cynthia Oshita  
Office of Environmental Health Hazard Assessment

re: Proposition 65 Implementation

Please accept the attached citizen's petition to the FDA, which is now in the hands of the FDA, as comment or evidence supporting that Aspartame is a recognized carcinogen... recognized by independent scientific standards (not recognized by industry supported junk science nor federal regulatory agencies.)

I hope the content of my petition helps you in the determination that Aspartame should come under the regulation of Prop 65.

Thank you in advance.

Sign the letter: [www.BodiesinRebellion.com](http://www.BodiesinRebellion.com)

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1 Dockets Management Branch  
2 Food and Drug Administration  
3 Department of Health and Human Services  
4 Room 1061,  
5 5630 Fishers Lane, Rockville, MD 20852.

6 CITIZENS PETITION<sup>1</sup>

7 The undersigned, K Paul Stoller, MD, submits this petition to the Commissioner of  
8 Food and Drugs or Acting Commissioner under 21 CFR 5, 10 to request the  
9 Commissioner of Food and Drugs to withdraw approval for the chemical commonly  
10 known as aspartame as it has been shown to be, and has always been known to be, a  
11 carcinogen.

12 Rationale

13 A long-term aspartame animal feeding study, published in Environmental  
14 Health Perspectives, raised serious questions about the safety of the  
15 artificial sweetener aspartame.<sup>2</sup> Dose-dependent increases in total  
16 malignant tumors, lymphomas/leukemias, and mammary carcinomas were  
17 observed in male and/or female rats. At the higher dosage level, the  
18 increases were statistically significant for lymphomas/leukemias in  
19 both male and female rats, mammary carcinomas in females, and tumor-  
20 bearing males. Nonsignificant increases were observed at the higher  
21 dosage for total tumors in males and females and for mammary  
22 carcinomas in males and at the lower dosage for total tumors in  
23 females, lymphomas/leukemias in males and females, and mammary  
24 carcinomas in females. Those non-significant increases would tend to  
25 elevate the dose-response trend.

The 2007 study follows up on a study from the same laboratory, but is  
more sensitive because the rats were exposed to aspartame in utero; in

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<sup>1</sup> No environmental impact statement is required by anything said in this petition

<sup>2</sup> Soffritti M, et al. EHPonline.org ([www.ehponline.org/members/2007/10271/10271.pdf](http://www.ehponline.org/members/2007/10271/10271.pdf), accessed June 13, 2007).

1 the earlier study the rats were not fed aspartame until they were 8  
2 weeks old. In the new study, groups of animals were exposed from the  
3 12<sup>th</sup> day in utero to aspartame at levels of 0, 20, or 100 mg/kg bw/day  
4 (mg/kg) administered to the pregnant dams and, after weaning, to the  
5 animals through their feed. The previous study used those and several  
6 additional dosages (4; 500; 2,500; 5,000 mg/kg).<sup>3</sup> That study found  
7 statistically significant increased incidences of leukemias/lymphomas  
8 in both male and female rats, malignant schwannomas of peripheral  
9 nerves in males, and transitional cell carcinomas of the renal pelvis  
10 and ureter and their precursors (dysplasias) in females.  
11 Additionally, a few uncommonly occurring brain tumors occurred only in  
12 aspartame-treated animals.

13 The European Food Safety Authority (EFSA) reviewed the study and  
14 concluded, for various reasons, that aspartame was not demonstrated to  
15 be carcinogenic.<sup>4</sup> This only demonstrates the power the industry has to  
16 influence regulatory boards who are often, if not always, compromised  
17 by conflict of interests.

18 To put the doses used in the study in context, consider that the  
19 Acceptable Daily Intake of aspartame in the United States is 50 mg/kg.  
20 The 20 mg/kg dose is equivalent to a 50 pound child's drinking about  
21 2½ cans of soda per day and a 150-pound adult's drinking about 7½ cans  
22 of soda per day (assuming 175 mg per 12-ounce serving of beverage<sup>5</sup>).

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24 <sup>3</sup> Soffritti M, et al. *Env Health Persp.* 2006;114:379-85

25 <sup>4</sup> Opinion of the Scientific Panel on Food Additives, Flavouring, Processing Aids and Materials in Contact with Food. *The EFSA Journal.* 2006;356:1-44.

<sup>5</sup> A Coca-Cola website indicates that a diet soda contains 175 mg of aspartame. (<http://www.beverageinstitute.org/ingredients/pdf/Aspartame.pdf>, accessed June 18, 2007) Other web sites indicate slightly different amounts.

1 The higher dose is equivalent to about 12½ and 37½ cans of soda per  
2 day.<sup>6</sup> The lower dose is something that about 5 percent of American  
3 teenagers actually consume.<sup>7</sup> Obviously, few people drink the larger  
4 amounts of aspartame-sweetened soda, but one must presume that lower  
5 levels of consumption would lead to increased, but proportionately  
6 lower, cancer risks. Of course, increasing exposure to aspartame is  
7 the fact that Americans are also consuming aspartame in powdered soft  
8 drinks, chewing gum, confections, gelatins, dessert mixes, puddings  
9 and fillings, frozen desserts, yogurt, tabletop sweeteners, and some  
10 pharmaceuticals such as vitamins and sugar-free cough drops.

11 In comparison to most animal toxicology studies, the 2007 Soffritti  
12 study has three significant strengths. First, it used more than the  
13 usual number of animals per sex/dosage group (95 controls and 70 in  
14 each group exposed to aspartame, as compared to the usual 50), thereby  
15 increasing the sensitivity of the study. Second, the animals were  
16 monitored until they died a natural death (as long as three years), as  
17 opposed to most studies, which are terminated after two years (104  
18 weeks). Rats at two years of age are very roughly comparable to  
19 people at "retirement age," about 65, whereas three-year-old rats are  
20 more equivalent to people 80 to 90 years of age. Thus, the longer  
21 experiment sheds light on the effects of aspartame on "elderly"  
22 animals. Third, as noted above, the animals were exposed to aspartame  
23 during part of their fetal life. In utero exposure reflects human  
24 experience and likely increases the sensitivity of the study.

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25 <sup>6</sup> The quantities of soft drinks would be significantly lower if dosages were calculated on the basis of body surface, as some agencies do, instead of body weight.

<sup>7</sup> Jacobson M. Liquid Candy—Supplement (Center for Science in the Public Interest, 2005).

1 Perhaps the FDA discounted the reliability of the first aspartame  
2 study on several grounds, particularly because the sponsor did not  
3 provide all the desired data.<sup>8</sup> Another reason was that transgenic mouse  
4 assays done by the National Toxicology Program did not identify  
5 problems. However, compared to such short-term or medium-term assays  
6 and modes-of-action conjectures, chronic animal feeding studies are  
7 accepted widely as valid predictors of likely carcinogenic risks for  
8 humans: importantly, all acknowledged human carcinogens when tested  
9 adequately in animals are also carcinogenic, and many known human  
10 carcinogens were first discovered in animals. The FDA has also made  
11 note that a large epidemiology study did not associate aspartame use  
12 with cancer. However, that study involved people who did not consume  
13 aspartame until they were over 50 years old, and measurement of  
14 aspartame consumption was imprecise, and epidemiology is a science  
15 that is often manipulated to demonstrate something not possible to  
16 demonstrate with epidemiology. The 2007 Sofritti animal study is much  
17 stronger in those respects. The FDA must invoke the "Delaney  
18 amendment" based on this study alone and revoke its approval. Yet  
19 this is not a new issue to the FDA as the Bressler report revealed.<sup>9</sup>

20 The Bressler Report showed GD Searle's original research that they  
21 presented to the FDA to obtain approval of aspartame was fraudulent.  
22 They would excise brain tumors from the rats, put the rats back in the  
23 study and then when they died resurrected them on back on paper. They  
24

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25 <sup>8</sup> FDA-CFSAN. FDA statement on European aspartame study. April 20, 2007.  
(<http://www.cfsan.fda.gov/~lrd/fpaspar2.html>, accessed June 19, 2007)

<sup>9</sup> [http://dorway.com/dorwblog/?page\\_id=56](http://dorway.com/dorwblog/?page_id=56)

1 got caught filtering out neoplasms they didn't want the FDA to know  
2 about. Over and over again they got caught. On January 10, 1977 in a  
3 33 page letter, FDA Chief Counsel Richard Merrill recommended to U.S.  
4 Attorney Sam Skinner that a grand jury investigate Searle for  
5 "apparent violations of the Federal Food, Drug, and Cosmetic Act, 21  
6 USC 331 (e), and the False Reports to the Government Act, 18 U.S.C.  
7 1001, for "their willful and knowing failure to make reports to the  
8 Food and Drug Administration required by the Act, 21 U.S.C 355 (i) and  
9 making false statements in reports of animal studies conducted to  
10 establish the safety of aspartame."

11 The FDA called special attention to studies investigating the effect  
12 of NutraSweet on monkeys and hamsters.

13 Unfortunately Sam Skinner hired on to the defense team instead of  
14 doing the job he was mandated to do, so U.S. Prosecutor William Conlon  
15 took up Skinner's position only to leave government service for the  
16 same defense team and by then the statute of limitations had expired  
17 (conveniently).

18 Just the same, the FDA had no intention of approving aspartame -in  
19 fact, the fraud was so great that Dr. John Olney told Searle to do  
20 studies in his lab so he could see that the studies were done honestly  
21 and with supervision. Dr. Olney thought the FDA would never approve  
22 it because the studies showed that aspartame damaged the brain.

23 However, what he didn't know is Searle failed to submit these findings  
24 to the FDA.

25 On January 30, 1980 the FDA Public Board of Inquiry revoked the  
petition for approval saying they had "not been presented with proof

1 of reasonable certainty that aspartame is safe for use as a food  
2 additive."

3 There were 3 Congressional hearings from 1985 to 1987, but a Senator  
4 linked with Monsanto made sure the bill to put a moratorium on  
5 aspartame and have NIH do independent studies on the problems being  
6 reported to the FDA, never got out of committee.

7 Aspartame could never be proven safe so the manufacturers funded  
8 professional organizations like the American Diabetes Assn,  
9 American Dietetic Assn, etc. to "push the propaganda". The scientists  
10 doing studies and finding out aspartame was a poison received threats.  
11 A United Press International Investigation discusses how Dr. Wurtman  
12 was threatened and if he did studies on aspartame and seizures he  
13 would lose his funding. In 1987, UPI filed a report on this coercion.<sup>10</sup>

14 Over the years many independent studies have been done. It's of  
15 interest that the manufacturer of aspartame will always say there are  
16 200 studies that show safety. If these studies were done before  
17 approval then these are the studies that the FDA complained about and  
18 tried to have Searle indicted over it. If these studies were done  
19 after approval they were fudged studies, such as the aspartame seizure  
20 studies by Monsanto, who bought Searle in 1985.<sup>11</sup>

21 Why did they bother to do frausulant studies? First of all, seizures  
22 are listed 5 times on the FDA report of 92 symptoms from male sexual  
23 dysfunction to Death.<sup>12</sup> If you look over these seizure studies above  
24 you'll see investigators were so worried somebody would have a seizure

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25 <sup>10</sup> [http://www.mpwhi.com/upi\\_1987\\_aspartame\\_report.pdf](http://www.mpwhi.com/upi_1987_aspartame_report.pdf)

<sup>11</sup> <http://www.holisticmed.com/aspartame/abuse/seizures.html>

<sup>12</sup> [http://www.mpwhi.com/92\\_aspartame\\_symptoms.pdf](http://www.mpwhi.com/92_aspartame_symptoms.pdf)

1 that in the Rowan study they actually gave 16 people anti-seizure  
2 medication. They used one capsule of aspartame for a one day study,  
3 sort of tantamount to smelling the bottle. Then they got it peer  
4 reviewed by exercising the power only a member of Big Pharma can do.  
5 So when consumers complain of seizures they say "we did studies and  
6 aspartame doesn't cause seizures".

7 Today there are full-time front groups like Calorie Control Council,  
8 which do most of the dirty work making sure manufacturers can keep  
9 pushing this poison.<sup>13</sup>

10 When 60 Minutes did a story about aspartame and brain tumors, again  
11 the manufacturer was saying they had all these studies showing safety.  
12 So Dr. Ralph Walton, who was on the show, decided to do some research,  
13 having to do with scientific peer reviewed research and funding.<sup>14</sup>

14 Note that just as expected 92% of independent scientific peer reviewed  
15 studies show that there are problems with aspartame, while only those  
16 funded or controlled by industry ever said it was safe. In fact, if  
17 you eliminate 6 studies the FDA had something to do with (after the  
18 FDA became loyal to Commissioner Hayes decision to approve aspartame),  
19 and one pro-aspartame summary, 100% of the independent scientific peer  
20 reviewed studies show aspartame's toxic and carcinogenic problems.

21 According to the Ecologist Magazine, aspartame was even listed with  
22 the pentagon in an inventory of prospective biochemical warfare  
23 weapons submitted to Congress.<sup>15</sup>

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25 <sup>13</sup> [http://www.wnho.net/mh\\_aspartame\\_letter.htm](http://www.wnho.net/mh_aspartame_letter.htm)

<sup>14</sup> <http://www.dorway.com/peerrev.html>

<sup>15</sup> [http://www.mpwhi.com/ecologist\\_september\\_2005.pdf](http://www.mpwhi.com/ecologist_september_2005.pdf)

1 Soffritti, lead researcher on three long-term aspartame studies, was  
2 recently honored at New York's Mt Sinai School of Medicine with the  
3 Irving J Selikoff Award for his outstanding contributions to the  
4 identification of environmental and industrial carcinogens and his  
5 promotion of independent scientific research. Dr. Soffritti explains:  
6 The first ERF study (2005) was conducted on 1800 Sprague-Dawley rats  
7 (100-150/per sex/per group). In order to simulate daily human intake,  
8 aspartame was added to the standard rat diet in quantities of 5000,  
9 2500, 100, 500, 20, 4, and 0 mg/Kg of body weight. Treatment of the  
10 animals began at 8 weeks of age and continued until spontaneous death.  
11 The results show that APM causes a statistically significant, dose-  
12 related increase of lymphomas/leukemias and malignant tumors of the  
13 renal pelvis in females and malignant tumors of peripheral nerves in  
14 males. These results demonstrate for the first time that APM is a  
15 carcinogenic agent, capable of inducing malignancies at various dose  
16 levels, including those lower than the current acceptable daily intake  
17 (ADI) for humans (50 mg/kg of body weight in the US, 40 mg/kg of body  
18 weight in the EU).  
19 The second ERF study (2007) was conducted on 400 Sprague-Dawley rats  
20 (70-95/per sex/per group). In order to simulate daily human intake,  
21 aspartame was added to the standard rat diet in quantities of 100, 20,  
22 and 0 mg/Kg of body weight. Treatment of the animals began on the 12th  
23 day of fetal life until natural death. The results of the second study  
24 show an increased incidence of lymphomas/leukemias in female rats with  
25 respect to the first study. Moreover, the study shows that when  
lifespan exposure to APM begins during fetal life, the age at which

1 lymphomas/leukemias develop in females is anticipated. For the first  
2 time, a statistically significant increase in mammary cancers in  
3 females was also observed in the second study. The results of this  
4 transplacental carcinogenicity bioassay not only confirm, but also  
5 reinforce the first experimental demonstration of APMs multipotential  
6 carcinogenicity.

7 On August 1, 1985 the FDA's own toxicologist, Dr. Adrian Gross, told  
8 Congress<sup>16</sup> at least one of Searle's studies "has established beyond ANY  
9 REASONABLE DOUBT that aspartame is capable of inducing brain tumors in  
10 experimental animals and that this predisposition of it is of  
11 extremely high significance. ... In view of these indications that the  
12 cancer causing potential of aspartame is a matter that had been  
13 established WAY BEYOND ANY REASONABLE DOUBT, one can ask: What is the  
14 reason for the apparent refusal by the FDA to invoke for this food  
15 additive the so-called Delaney Amendment to the Food, Drug and  
16 Cosmetic Act?"

17 The Delaney Amendment makes it illegal to allow any residues of cancer  
18 causing chemicals in foods. In his concluding testimony Gross asked,  
19 "Given the cancer causing potential of aspartame how would the  
20 FDA justify its position that it views a certain amount of aspartame  
21 as constituting an allowable daily intake or 'safe' level of it? Is  
22 that position in effect not equivalent to setting a 'tolerance' for  
23 this food additive and thus a violation of that law? And if the FDA  
24  
25

1 itself elects to violate the law, who is left to protect the health of  
2 the public?"<sup>16</sup>

3 To fulfill its obligation to protect the public in matters of food and  
4 drug safety, the FDA must invoke the "Delaney amendment" and revoke  
5 its approval of aspartame.<sup>17</sup>

6 The undersigned certifies, that, to the best knowledge and belief of  
7 the undersigned, this petition includes all information and views on  
8 which the petition relies, and that it includes representative data  
9 and information known to the petition which are unfavorable to the  
10 petition.

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14 \_\_\_\_\_  
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17 Santa Fe, NM 87505  
18 505 955 8560

14 \_\_\_\_\_  
Date

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25 <sup>16</sup> Congressional Record SID835:131 (August 1, 1985)

<sup>17</sup> Food, Drug, and Cosmetic Act §409(c)(1)(3)(A).