From: Mark Gold [mgold@shelltown.net] Sent: Sunday, January 12, 2003 11:12 PM To: fdadockets@oc.fda.gov Subject: Docket # 02P-0317 Recall Aspartame as #4: Reported Aspartame Toxicity Reactions	a Neur	rotoxic Drug: File
Subject: Docket # 02P-0317 To: FDA Dockets Submittal From: Mark D. Gold		
12 East Side Dr., Suite 2-18 Concord, NH 03301 603-225-2110 Date: January 12, 2002		
Please find below Evidence File #4: Reported A Reported Aspartame Toxicity Eff	ects	ne Toxicity Effects
Q. What are the reported reactions to asparta How often are such effects seen? Answer	me inge	estion?
==> What are the reported reactions to asparta We will limit our discussion in this FAQ to re reactions to aspartame ingestion. Controlled	ported	toxicity
problems with aspartame ingestion will be disc FAQ. Toxicity reactions to aspartame can be d types: 1. Acute toxicity reactions occuring within 4 an aspartame-containing product.	ussed i ivided	in another into three
 Chronic toxicity effects occuring anywhere use to appearing a number of years (i.e., beginning of aspartame use. Potential toxicity effects that would be not appear to the second of the	1-20+ y	years) after the
the user to recognize the link to aspartam In an epidemiological survey which appeared in Applied Nutrition (Roberts 1988), 551 persons reported toxicity effects from aspartame inges	the Jo who hav tion we	ournal of ve ere
surveyed. The adverse effects found cover a sacute and chronic toxicity effects from aspart. What follows is a listing of the adverse healt which were found.	ame.	
Eye - Decreased vision and/or other eye problems (blurring, "bright flashes," tunnel vision	140	, ,
 Pain (or or both eyes) Decreased tears, trouble with contact lens, or both Blindness (one or both eyes) Ear	51 46 14	(8%)
- Tinnitus ("ringing," "buzzing") - Severe intolerance for noise - Marked impairment of hearing Neurologic - Headaches	73 47 25	(9%) (5%)
 Dizziness, unsteadiness, or both Confusion, memory loss, or both Severe drowsiness and sleepiness Paresthesias ("pins and needles," "tingling" or numbness of the limbs 	217 157 93) 82	(39%) (29%) (17%) (15%)
- Convulsions (grand mal epileptic attacks) - Petit mal attacks and "absences" - Severe slurring of speech - Severe tremors - Severe "hyperactivity" and "restless legs" - Atypical facial pain	80 18 64 51 43 38	(15%) (3%) (12%) (9%) (8%) (7%)
Psychologic-Psychiatric - Severe depression - "Extreme irritability" - "Severe anixiety attacks"	139 125 105	(25%) (23%) (19%)
- "Marked personality changes" - Recent "severe insomnia" - "Severe aggravation of phobias" Chest - Palpitations, tachycardia (rapid heart action	88 76 41 n), 88	(16%) (14%) (7%) (16%)
of both - "Shortness of breath" - Atypical chest pain - Recent hypertension (high blood pressure)	54 44 34	(10%) (8%) (6%)
Gastrointestinal - Nausea - Diarrhea - Associated gross blood in the stools (12) - Abdominal pain - Pain on swallowing	79 70 70 28	
Skin and Allergies - Severe itching without a rash - Severe lip and mouth reactions - Urticaria (hives)	44 29 25	(8%) (5%) (5%)
- Other eruptions - Aggravation of respiratory allergies Endocrine and Metabolic - Problems with diabetes: loss of control; precipitation of clinical diabetes;	48 10 60	(9%) (2%) (11%)
aggravation or simulation of diabetic complications - Menstrual changes Severe reduction or cessation of periods (- Paradoxic weight gain - Marked weight loss	45 22) 34 26	(6%) (5%) (6%)
- Marked Weight loss - Marked thinning or loss of the hair - Aggravated hypoglycemia (low blood sugar attacks) Other - Frequency of voiding (day and night), burning	32 25	(6%) (5%)
on urination (dysuria), or both - Excessive thirst - Severe joint pains - "Bloat" - Fluid retention and leg swelling	65 58 57 20	(12%) (11%) (10%) (4%)
- Increased susceptibility to infection There are other clinical reports in the scient aspartame-caused toxicity reactions including	Blument	iterature of thal (1997),
Drake (1986), Johns (1986), Lipton (1989), McC. Novick (1985), Watts (1991), Walton (1986, 198 (1985). Many pilots appear to be particularly susceptil aspartame ingestion. They have reported numero	auliffe 8), and ble to	e (1991), d Wurtman the effects of
effects including grand mal seizures in the co Nearly 1,000 cases of pilot reactions have been Aspartame Consumer Safety Network Pilot Hotling This susceptibility may be related to ingesting as suggested in a letter from Dr. Phil Moskal,	ckpit (n repor e (Stod g metha Profes	(Stoddard 1995). rted to the ddard 1995). anol at altitude ssor of
Microbiology, Biochemistry, and Pathology, Cha of Pathology, Director of Public Health Labora or it may simply be that some pilots tend to it of aspartame during a flight. Whatever the ca about aspartame dangers have appeared in pilot The Aviation Consumer (1988), Aviation Medical	tories ngest l se, num ing jou	(Moskal 1990), large quantities merous warnings urnals including
Pacific Flyer (1988), CAA General Aviation (19 Digest (1989), General Aviation News (1989), P Canadian General Aviation News (1990), Nationa Association Digest (NBAA Digest 1993), Interna Air Shows (ICAS 1995), and the Pacific Flyer (89), Av lane & l Busin tional 1995).	viation Safety Pilot (1990), ness Aircraft Council of Both the U.S.
Air Force's magazine "Flying Safety" and the U "Navy Physiology" published articles warning a of aspartame including the cumlative deliterio and the greater likelihood of birth defects. The the ingestion of aspartame may make pilots more seigures and vertige (US Air Force 1992)	bout th us effe he arti	he many dangers ects of methanol icles note that
Countless other toxicity effects have been rep 1995), other independent organizations (Missio Stoddard 1995), and independent scientists (e. seizures were reported to Dr. Richard Wurtman,	n Possi g., 80	ible 1996, cases of
Samples of some aspartame toxicity reactions resolutions in the Aspartame (Nutrassection on the Aspartame of the Aspartame (Nutrassection of the Aspartame of the Asparta	eported weet) T	d on the
Frequently, aspartame toxicity is misdiagnosed This has yet to be reported in the scientific been reported countless times to independent o scientists (Mission Possible 1994, Stoddard 19 it has been reported that chronic aspartame in	literat rganiza 95). I gestion	ture, yet it has ations and In other cases, n has triggered
or worsened certain chronic illnesses. Nearly patient and physician assume that these worsen simply a normal progression of the illness. So the case, but many times it is chronic asparta	100% o ing con ometime me pois	of the time, the nditions are es that may be soning.
According to researchers and physicians studyi effects of aspartame, the following list conta of chronic illnesses which may be caused or wo long-term ingestion of aspartame. (Mission Pos 1995)*:	ins a s rsened sible 1	selection by the chronic,
Brain tumors Multiple scler Epilepsy Chronic faigue Parkinson's Disease Alzheimer's Mental retardation Lymphoma Birth defects Fibromyalgia Diabetes Arthritis (inc	syndro	
Diabetes Arthritis (inc Chemical Sensitivities Attention Defi *Note: In some cases such as MS, the seve mimic the illness or exacerbate the but do not cause the disease.	cit Dis	sorder
Also, please note that this is an incomplete l ingestion of a very slow poison (as discussed beneficial to anyone who has a chronic illness	in othe	er FAQs) is not
Finally, potential toxicity effects from aspar cancer (as seen in pre-approval research) and and nervous system development will be discussed as the seen?	effects ed in o	s on fetal brain other FAQs.
Until recently approximately 90% of aspartame : United States (Monsanto 1994). Other countrie with aspartame, but it will be some time until full effects of aspartame toxicity on the gene U.S. has some history of significant use, we want to the frequency of effects in the U.S.	s are not they be ral pop	now being inundated begin to feel the bulation. Since the
to the frequency of effects in the U.S. There have been well over 7,000 aspartame toxi received by the U.S. Food and Drug Administrat aspartame was first approved) until 1995 (DHHS From this figure, we can estimate the number of	city re ion bet 1993,	eactions officially tween 1982 (after DHHS 1995).
reactions observed. FDA officials believe that as little as 1% of adverse drug reactions are reported to the FDA 1993). Using a reported rate of 1%, we would	the ser (Kessl	rious ler te that there
have been 700,000 recognized aspartame toxicity since 1982. However, there are a number of signature that must be made before we can accept this estable. 1. Most physicians are aware of the Adverse Remonitoring System (ARMS) and are encourage.	gnifica timate. eaction d by th	ant adjustments n ne FDA
to report serious adverse drug reactions (Physicians are not encouraged by the FDA to toxicity reactions to the FDA (Food 1995). public is generally unaware of ARMS and mu report adverse reactions to the FDA. There	Kessler o repor The l ch less efore,	r 1993). rt aspartame lay s likely to this would
lower the estimated reporting rate below 1 small adjustment and estimate a 0.88% reports. 2. It was pointed out by James Turner, Esq. in FDA Commissioner Frank Young that no progretoxicity reactions was created until February.	rting r n a let am to m ary 198	rate. tter to the then monitor aspartame 84, two years after
aspartame approval began (Turner 1984). The least 1,200 reported reactions (probably means should use 8,200 toxicity reaction reports freedom of Information act request determine FDA offices had been told that only "serio	his wou uch mor . In a ned tha us" com	uld probably add at re), so that we addition, a at the regional mplaints should
be forwarded to the FDA headquarters (Turn- complaints were complaints where the illne to require the attention of a physician. Set between 1984 (when the monitoring system be estimate an additional 300 toxicity reactions reported for a total of 8,500.	ss was Since t egan) a	severe enough this happened and 1985, we can
 In 1987, it was brought out at U.S. Congre the FDA had been transferring aspartame to to the AIDS Hotline (Turner 1987). In add by James Turner, Esq. of Community Nutrition there were numerous cases of people calling 	xicity ition, on Inst	reaction calls it was reported titute (CNI) that
toxicity reaction and they were told that between aspartame and adverse reactions and taken by the FDA. While this may not effe after the start of 1988, it would signific rate before that time. Let us make another	there w d no ot ct the antly e	was no connection ther information was reporting rate effect the reporting
estimate a 0.78% reporting rate. 4. Perhaps the biggest reduction in the reporthe fact that Commissioner Kessler's estim for adverse drug reactions involves only "reactions. The rate for reporting *all* d	ting ra ated 1% serious	ate comes from % reporting rate s" adverse
reactions. The rate for reporting *all* d reporting were done) would almost certain! Therefore, if we cut our current estimated 0.78% in half, the estimated reporting rate reactions to aspartame (including serious more than 0.39%.	y be no report e for *	o more than 0.5%. ting rate of *all* toxicity
During the first couple of years that aspartam there was publicity that would likely have inc rate. However, since the FDA did not have a m place until February 1984, the estimated incre	reased onitori ased nu	the reporting ing system in umber of reports
will not be that much. I will reduce the number to 7,500 to take this into account. ********************** We now have approximately 7,500 reports at an rate of 0.39%. This totals approximately 1.9	estimat million	ted reporting n *recognized*
aspartame toxicity reactions in the U.S. betwee These reactions run anywhere from mild to very ***********************************	en 1982 seriou	2 and 1995. us illnesses. 9 million
represents only those toxicity reactions that users and/or healthcare practitioners. Quite histories were people suffered for long time a connection. For example: "I have suffered from Migraines for years.	often, nd did As soon	I encounter case not make the n as I gave up
Nutrasweet my migraines disappeared. All t MRI'sfor nothing." "Since I last wrote my brother has been off then. My brothers lupus type of symptoms	nutris	sweet since tely went
away. My brother has been a physician for his doctor (a specialist) who has been seen the significant difference and wants paper on this my brothers physician has prescribing getting off nutrisweet for his	treatin to writ now st other	ng him has te a research tarted patients."
Therefore, I believe that in addition to the e people in the U.S. who have recognized asparta in themselves (from serious to mild), there are number who are suffering from some of the sympo and that they do not recognize that chronic as cause or at least a contribuatory factor. I we	me toxi e many toms me partame	icity reactions times that entioned above e use is the
least* 7.6 million others are suffering from so aspartame use (many mild symptoms, but many se do not recognize the connection. In addition to the estimated 1.9 million recognize	ome sym rious o nized r	mptoms related to ones as well) and reactions and 7.6
million unrecognized reactions in the U.S., it note that aspartame has been used in significa for a relatively short time. A U.S. Department report noted that it wasn't until approximately was used in significant amounts in the U.S. (U. aspartame had been used for only nine (9) year	nt amou t of Ag y 1987 SDA 198 s in si	unts in the U.S. griculture that aspartame 88). Therefore, ignficant amounts
through 1995. When one considers that the dam often silent and cumulative (much like chain-s can see that a couple of generations of aspart	age fro	om aspartame is cigarettes), one

The FDA and NutraSweet have claimed that the number of reported adverse reactions have declined substantially since the mid-1980s (Pauli 1995, Butchko 1994). In addition, the FDA recently claimed that the number of reported toxicity reactions for 1995 was only 11 (WSJ 1996)! It is important to realize that during the mid-1970s the FDA was investigating wrong-doings of the aspartame manufacturer and stated the facts exactly as they found them:

"[The manufacturer] lied and they didn't submit the real nature of their observations because had they done that it is more than likely that a great number of these studies would have been rejected simply for adequacy. What Searle did, they took great pains to camouflage these shortcomings of the study. As I say filter and just present to the FDA what they wished the FDA to know and they did other terrible things for instance animals would develop tumors while they were under study. Well they would remove these tumors from the animals."

[FDA Toxicologist and Task Force member, Dr. Andrian

During the late 1970s and early 1980s, a number of key government and FDA officials left their jobs to work with companies related to the aspartame industry (GAO 1986). This included key FDA officials such as the head of the FDA Bureau of Foods becoming a Vice President of the National Drink Association and the FDA Commissioner becoming a

high-paid consultant for the manufacturer's PR firm, Burston Marsteller (Gordon 1987). After this period of time, there was no scientific evidence and no amount of serious toxicity reports that

could get the FDA to seriously consider funding independent, properly-conducted (e.g., chronic exposure) research. That appearance of the FDA being under the total control of the

I include these comments about the FDA to demonstrate why no independent scientist familiar with the aspartame issue takes statements from the FDA such as "11 reported reactions in 1995"

seriously. There are many people, including myself who have received that many toxicity reaction reports in a single day during 1995. The reality is that independent organizations have noted that aspartame toxicity reaction reports given to them have *increased* every year since the late 1980s (Stoddard 1995). It is also important to note that in mid-1995, the FDA admited that it had stopped recording aspartame toxicity reactions (Food 1995). That may have something to do with why the numbers that the FDA reported

manufacturer, Monsanto, continues to this day.

to the Wall Street Journal (WSJ 1996) were so small!

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