DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington DC 20204

June 6, 1995

Re: FOI Request No. F95-17797

Dear

This is in response to your request of April 19, 1995, requesting a copy of the aspartame report (CDC/FDA - 1984), and the current report on aspartame complaints. Your request was forwarded to the Office of Premarket Approval in the Center for Food Safety and Applied Nutrition.

__X__ Enclosed are the records you requested.

Charges will be included in a monthly invoice if your requests total more than $10.00. If your monthly total is LESS than $10.00 the material is free. Please DO NOT send payment until you receive an invoice for the total monthly fee.

Reproduction $ 15.30 Search $ 24.00 Review $ _____
Other $ 3.00 Total $ 42.30.

THE ABOVE TOTAL MAY NOT REFLECT THE FINAL CHARGES FOR THIS REQUEST.

Sincerely yours,

Angela M. Artis
Office of Premarket Approval
Center for Food Safety
and Applied Nutrition

Enclosure

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Memorandum

Date: April 20, 1995

From: Chief, Epidemiology Branch (HFS-728)
Technical Information Specialist (HFS-728)

Subject: Summary of Adverse Reactions Attributed to Aspartame

To: Health Hazard Evaluation Board

Since 1980 the FDA has received 7232 complaints of adverse reactions attributed to the use of aspartame. Six hundred and forty-nine of the complaints that were received in the early 1980's have differences in the adverse reaction information collected as compared to the remaining reports. Because of these differences, the 649 complaints are generally not included in the summaries of adverse reactions attributed to aspartame. Excluding these 649 reports, from 1980 through 1994, CFSAN received 6583 complaints describing adverse reactions thought to be due to the consumption of aspartame. These complaints were either reported directly to CFSAN, or received from the Nutrasweet (Searle) Company, Aspartame Consumer Safety Network, 700 Club, health professionals, and other interested parties.

For the 4826 (73.3%) complainants who provided information on gender, 3666 (76%) were female and 1160 (24%) were male. For the 3271 (49.7%) complainants whose ages were provided, the peak age group for reports was 30-39 years old, with 847 (25.9%) complaints. All other ten year age groups provided less than 20% of reported complaints.

For the 4884 (74.3%) reports that included information on intensity of the reaction, 518 (10.6%) reactions were classified as severe and 4366 (89.4%) were classified as mild to moderate.

In some reports, adverse reactions were attributed to more than one product type. Diet soft drinks were implicated most frequently; with a total of 3021 (45.9%) complaints, followed by 1716 (26.1%) complaints attributed to table-top sweeteners. Each remaining product type was mentioned in less than 10% of all aspartame complaints (Table 1).

More than one symptom associated with aspartame was described by many complainants. Almost 90 different symptoms were described in total; with 1847 (28.1%) reports for headache being the most frequent, followed by 735 (11.2%) reports describing dizziness or problems with balance, 656 (10.0%)

describing a change in mood quality or level, 668 (10.0%) reports of vomiting and nausea, 468 (7.0%) reports of abdominal pain, 378 (5.7%) reports of a change in vision, and 347 (5.2%) reports of diarrhea. Other symptoms were reported by less than 5% of complainants (Table 2).

Of the 4274 (64.5%) reactions that could be classified in terms of consistency of the reaction following ingestion of aspartame, 1402 (32.8%) were Group A events, described as episodic and appeared to occur following consumption of more than one product containing Aspartame. An additional 1155 (27.0%) reports were classified as Group B reactions, because they occurred on multiple occasions following exposure to a specific Aspartame-containing product. A total of 786 (18.4%) reports were classified as group C reactions, with a single episode following consumption of one or more Aspartame-containing products. The remaining 931 (21.8%) reports were classified as Group D, because the adverse reaction did not occur every time the complainant consumed a specific product containing aspartame, or the reaction was deemed unlikely to have been associated with aspartame.

There has been a gradual decrease in reports of adverse reactions to aspartame received over time. Reports are entered into the ARMS system by the year they occur. The trend for reports of adverse reactions to Aspartame has declined from the 1985 peak, when over 1500 adverse reactions were reported to 15 reported reactions during 1997.

In summary, the number of adverse reaction complaints received by the FDA; and the nature of these reports in terms of demographic distribution, severity, strength of association with the product, and symptoms remain comparable to those from previous analyses.

Donna M. Gray

95-08-08 14:38:11

PROGRAM: SFDFITZ.COUNT

SEARCH IS: MODULE=SFDFITZ AND KEY=ASPM AND NOT ASPO
DATA LIMIT IS: MODULE=SFDFITZ
FIELD COUNTED IS: SYMPTOMS

92 documented symptoms on t FDA report - from coma and seizures to blindness and death.

SYMPTOMS FOR ASPARTAME

COUNT	%RECORD	%OCCUR	SYMPTOMS DECODED
1862	28.28%	19.03%	HEADACHE
737	11.19%	7.53%	DIZZINESS OR PROBLEMS WITH BALANCE
656	9.96%	6.70%	CHANGE IN MOOD QUALITY OR LEVEL
651	9.88%	6.65%	VOMITING AND NAUSEA
457	6.94%	4.67%	ABDOMINAL PAIN AND CRAMPS
364	5.52%	3.72%	CHANGE IN VISION
331	5.02%	3.38%	DIARRHEA
291	4.42%	2.97%	SEIZURES AND CONVULSIONS —
256	3.88%	2.61%	MEMORY LOSS
242	3.67%	2.47%	FATIGUE, WEAKNESS
230	3.49%	2.35%	OTHER NEUROLOGICAL
226	3.43%	2.31%	RASH
201	3.05%	2.05%	SLEEP PROBLEMS
191	2.90%	1.95%	HIVES
186	2.82%	1.90%	CHANGE IN HEART RATE
175	2.65%	1.78%	ITCHING
174	2.64%	1.77%	CHANGE IN SENSATION (NUMBNESS, TINGLING)
174	2.64%	1.77%	GRAND MAL —
115	1.74%	1.17%	LOCAL SWELLING
114	1.73%	1.16%	CHANGE IN ACTIVITY LEVEL
112	1.70%	1.14%	DIFFICULTY BREATHING
108	1.64%	1.10%	ORAL SENSORY CHANGES
107	1.62%	1.09%	CHANGE IN MENSTRUAL PATTERN
100	1.51%	1.02%	OTHER SKIN
98	1.48%	1.00%	OTHER
93	1.41%	0.95%	LOCALIZED PAIN AND TENDERNESS
91	1.38%	0.93%	OTHER UROGENITAL
74	1.12%	0.75%	CHANGE IN BODY TEMPERATURE
74	1.12%	0.75%	DIFFICULTY SWALLOWING
68	1.03%	0.69%	OTHER METABOLIC
67	1.01%	0.68%	JOINT AND BONE PAIN
66	1.00%	0.67%	SPEECH IMPAIRMENT
59	0.89%	0.60%	OTHER GASTROINTESTINAL
57	0.86%	0.58%	CHEST PAIN
51	0.77%	0.52%	OTHER MUSCULO-SKELETAL
50	0.75%	0.51%	FAINTING
43	0.65%	0.43%	SORE THROAT
43	0.65%	0.43%	OTHER CARDIOVASCULAR
39	0.59%	0.39%	CHANGE IN TASTE
37	0.56%	0.37%	DIFFICULTY WITH URINATION
37	0.56%	0.37%	OTHER RESPIRATORY
36	0.54%	0.36%	EDEMA
36	0.54%	0.36%	CHANGE IN HEARING
35	0.53%	0.35%	ABDOMINAL SWELLING

95-08-08 14:38:11 PROGRAM: BFDFITZ.COUNT

SYMPTOMS FOR ASPARTAME

30	0.45%	0.30%	CHANGE IN SALIVA OUTPUT
30	0.45%	0.30%	CHANGE IN URINE VOLUME
30	0.45%	0.30%	CHANGE IN PERSPIRATION PATTERN
30	0.45%	0.30%	EYE IRRITATION
30	0.45%	0.30%	UNSPECIFIED
26	0.39%	0.26%	MUSCLE TREMORS
26	0.39%	0.26%	PETIT MAL —
25	0.37%	0.25%	CHANGE IN APPETITE
22	0.33%	0.22%	CHANGE IN BODY WEIGHT
22	0.33%	0.22%	NOCTURNAL
20	0.30%	0.20%	CHANGE IN THIRST OR WATER INTAKE
18	0.27%	0.18%	UNCONSCIOUSNESS AND COMA
18	0.27%	0.18%	WHEEZING
16	0.24%	0.16%	CONSTIPATION
16	0.24%	0.16%	OTHER EXTREMITY PAIN
15	0.22%	0.15%	PROBLEMS WITH BLEEDING
15	0.22%	0.15%	UNSTEADY GAIT
15	0.22%	0.15%	COUGHING
15	0.22%	0.15%	BLOOD GLUCOSE DISORDERS
14	0.21%	0.14%	BLOOD PRESSURE CHANGES
14	0.21%	0.14%	CHANGES IN SKIN AND NAIL COLORATION
13	0.19%	0.13%	CHANGE IN HAIR OR NAILS
11	0.16%	0.11%	EXCESSIVE PHLEGM PRODUCTION
10	0.15%	0.10%	SINUS PROBLEMS
10	0.15%	0.10%	SIMPLE PARTIAL SEIZURES —
8	0.12%	0.08%	HALLUCINATIONS
7	0.10%	0.07%	ANY LUMPS PRESENT
6	0.09%	0.06%	SHORTNESS OF BREATH ON EXERTION
6	0.09%	0.06%	EVIDENCE OF BLOOD IN STOOL OR VOMIT
5	0.07%	0.05%	DYSMENORRHEA
4	0.06%	0.04%	DENTAL PROBLEMS
4	0.06%	0.04%	CHANGE IN SMELL
4	0.06%	0.04%	DEATH
4	0.06%	0.04%	OTHER BLOOD AND LYMPHATIC
4	0.06%	0.04%	ECZEMA
4	0.06%	0.04%	COMPLEX PARTIAL SEIZURES —
3	0.04%	0.03%	SWOLLEN LYMPH NODES
3	0.04%	0.03%	HEMATURIA
2	0.03%	0.02%	SHORTNESS OF BREATH DUE TO POSITION
2	0.03%	0.02%	DIFFICULTIES WITH PREGNANCY
2	0.03%	0.02%	(CHILDREN ONLY) DEVELOPMENTAL RETARDATION
2	0.03%	0.02%	CHANGE IN BREAST SIZE OR TENDERNESS
1	0.01%	0.01%	ANEMIA
1	0.01%	0.01%	CHANGE IN SEXUAL FUNCTION
1	0.01%	0.01%	SHOCK
1	0.01%	0.01%	CONJUNCTIVITIS
1	0.01%	0.01%	DILATING EYES
1	0.01%	0.01%	FEBRILE

DISTRIBUTION BASED ON 6683 RECORDS AND 9781 OCCURRENCES OF SYMPTOMS

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Memorandum

Date May 23, 1996

From Technical Information Specialist (HFS-728)

Subject Summary of Adverse Reactions Attributed to Aspartame

To Health Hazard Evaluation Board

Since 1980, the FDA has received 7244 complaints of adverse reactions attributed to the use of aspartame. Six hundred and forty-nine of the complaints that were received in the early 1980's have differences in the adverse reaction information collected as compared to the remaining reports. Because of these differences, the 649 complaints are generally not included in the summaries of adverse reactions attributed to aspartame. Excluding these 649 reports, from 1980 through 1995, CFSAN received 6595 complaints describing adverse reactions thought to be due to the consumption of aspartame. These complaints were either reported directly to CFSAN, or received from the Nutrasweet (Searle) Company, Aspartame Consumer Safety Network, 700 Club, health professionals, and other interested parties.

For the 4929 (75.0%) complainants who provided information on gender, 3742 (76%) were female and 1187 (24%) were male. For the 3338 (50.6%) complainants whose ages were provided, the peak age group for reports was 30-39 years old, with 864 (25.9%) complaints. All other ten year age groups provided less than 20% of reported complaints.

For the 4990 (76.0%) reports that included information on intensity of the reaction, 533 (10.7%) reactions were classified as severe and 4457 (89.3%) were classified as mild to moderate.

In some reports, adverse reactions were attributed to more than one product type. Diet soft drinks were implicated most frequently; with a total of 3070 (46.6%) complaints, followed by 1760 (26.7%) complaints attributed to table-top sweeteners. Each remaining product type was mentioned in less than 10% of all aspartame complaints (Table 1).

More than one symptom associated with aspartame was described by many complainants. Ninety-one different symptoms were described in total; with 1898 (28.8%) reports for headache being the most frequent, followed by 745 (11.3%) reports describing dizziness or problems with balance, 675 (10.2%)

complaints describing a change in mood quality or level, 666 (10.1%) reports of vomiting and nausea, 463 (7.0%) reports of abdominal pain, 371 (5.6%) reports of a change in vision, and 338 (5.1%) reports of diarrhea. Other symptoms were reported by less than 5% of complainants (Table 2).

Of the 4226 (64.1%) reactions that could be classified in terms of consistency of the reaction following ingestion of aspartame, 1393 (32.9%) were Group A events, described as episodic and appeared to occur following consumption of more than one product containing Aspartame. An additional 1150 (27.2%) reports were classified as Group B reactions, because they occurred on multiple occasions following exposure to a specific Aspartame-containing product. A total of 755 (17.9%) reports were classified as group C reactions, with a single episode following consumption of one or more Aspartame-containing products. The remaining 928 (22.0%) reports were classified as Group D, because the adverse reaction did not occur every time the complainant consumed a specific product containing aspartame, or the reaction was deemed unlikely to have been associated with aspartame.

There has been a gradual decrease in reports of adverse reactions to aspartame received over time. Reports are entered into the ARMS system by the year they occur. The trend for reports of adverse reactions to Aspartame has declined from the 1985 peak, when over 1500 adverse reactions were reported to 11 reported reactions during 1995.

In summary, the number of adverse reaction complaints received by the FDA; and the nature of these reports in terms of demographic distribution, severity, strength of association with the product, and symptoms remain comparable to those from previous analyses.

Donna M. Gray

Donna M. Gray

1776

Table 1. Distribution of reactions attributed to aspartame by product type.

PRODUCT TYPE	NO. OF COMPLAINTS	% OF RECORDS	% OF COMPLAINTS
Diet Soft Drinks	3070	46.6%	38.0%
Table Top Sweetener	1760	26.7%	21.8%
Puddings - Gelatins	638	9.7%	7.9%
Lemonade	416	6.3%	5.1%
Other	362	5.5%	4.5%
Kool Aid	341	5.2%	4.2%
Chewing Gum	334	5.0%	4.1%
Hot Chocolate	323	4.9%	4.0%
Iced Tea	323	4.9%	4.0%
Frozen Confections	146	2.2%	1.8%
Cereal	122	1.8%	1.5%
Sugar Substitute Tablets	75	1.1%	0.9%
Breath Mints	63	0.9%	0.8%
Punch Mix	45	0.7%	0.6%
Fruit Drinks	24	0.4%	0.3%
Chewable Multi-Vitamins	9	0.1%	0.1%
Non-Dairy Toppings	8	0.1%	0.1%
Fruit, Dried	2	0.003%	0.02%

Table 2. Symptoms attributed to Aspartame in complaints submitted to FDA.[1]

REPORTED SYMPTOMS	NO. OF COMPLAINTS	% OF REPORTS	% OF COMPLAINTS
Headache	1898	28.8%	19.0%
Dizziness/ Poor equilibrium	745	11.3%	7.5%
Change in Mood	675	10.2%	6.7%
Vomiting or Nausea	666	10.1%	6.6%
Abdominal Pain and Cramps	463	7.0%	4.7%
Change in Vision	371	5.6%	3.7%
Diarrhea	338	5.1%	3.4%
Seizures and Convulsions	297	4.5%	3.0%
Memory Loss	271	4.1%	2.7%
Fatigue, Weakness	251	3.8%	2.5%
Other Neurological	233	3.5%	2.3%
Rash	227	3.4%	2.3%
Sleep Problems	204	3.1%	2.0%
Hives	194	2.9%	2.0%
Change in Heart Rate	191	2.9%	1.9%
Itching	177	2.7%	1.8%
Change in Sensation (Numbness, Tingling)	176	2.7%	1.8%
Grand Mal	174	2.6%	1.7%
Local Swelling	119	1.8%	1.2%
Difficulty Breathing	116	1.8%	1.2%
Change in Activity Level	115	1.7%	1.2%
Oral Sensory Changes	112	1.7%	1.1%
Change in Menstrual Pattern	107	1.6%	1.1%
Other Skin	102	1.5%	1.0%
Symptoms reported by less than 100 complainants	1754	--------	17.6%

1. Some consumers described more than one symptom attributed to Aspartame.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date June 26, 1997

From Technical Information Specialist (HFS-728)

Subject Summary of Adverse Reactions Attributed to Aspartame

To Health Hazard Evaluation Board

Since 1980, the FDA has received 7259 complaints of adverse reactions attributed to the use of aspartame. Six hundred and forty-nine of the complaints that were received in the early 1980's have differences in the adverse reaction information collected as compared to the remaining reports. Because of these differences, the 649 complaints are generally not included in the summaries of adverse reactions attributed to aspartame. Excluding these 649 reports, from 1980 through 1996, CFSAN received 6610 complaints describing adverse reactions thought to be due to the consumption of aspartame. These complaints were either reported directly to CFSAN, or received from the Nutrasweet (Searle) Company, Aspartame Consumer Safety Network, 700 Club, health professionals, and other interested parties.

For the 4949 (74.9%) complainants who provided information on gender, 3758 (76%) were female and 1191 (24%) were male. For the 3343 (50.6%) complainants whose ages were provided, the peak age group for reports was 30-39 years old, with 864 (25.8%) complaints. All other ten year age groups provided less than 20% of reported complaints.

For the 5014 (75.8%) reports that included information on intensity of the reaction, 537 (10.7%) reactions were classified as severe and 4477 (89.3%) were classified as mild to moderate.

In some reports, adverse reactions were attributed to more than one product type. Diet soft drinks were implicated most frequently; with a total of 3077 (46.6%) complaints, followed by 1764 (26.7%) complaints attributed to table-top sweeteners. Each remaining product type was mentioned in less than 10% of all aspartame complaints (Table 1).

More than one symptom associated with aspartame was described by many complainants. Ninety-one different symptoms were described in total; with 1900

(28.7%) reports for headache being the most frequent, followed by 749 (11.3%) reports describing dizziness or problems with balance, 679 (10.3%) complaints describing a change in mood quality or level, 669 (10.2%) reports of vomiting and nausea, 466 (7.0%) reports of abdominal pain, 374 (5.7%) reports of a change in vision, and 345 (5.2%) reports of diarrhea. Other symptoms were reported by less than 5% of complainants (Table 2).

Of the 4243 (64.1%) reactions that could be classified in terms of consistency of the reaction following ingestion of aspartame, 1395 (32.9%) were Group A events, described as episodic and appeared to occur following consumption of more than one product containing Aspartame. An additional 1151 (27.1%) reports were classified as Group B reactions, because they occurred on multiple occasions following exposure to a specific Aspartame-containing product. A total of 766 (18.0%) reports were classified as group C reactions, with a single episode following consumption of one or more Aspartame-containing products. The remaining 931 (21.9%) reports were classified as Group D, because the adverse reaction did not occur every time the complainant consumed a specific product containing aspartame, or the reaction was deemed unlikely to have been associated with aspartame.

There has been a gradual decrease in reports of adverse reactions to aspartame received over time. Reports are entered into the ARMS system by the year they occur. The trend for reports of adverse reactions to Aspartame has declined from the 1985 peak, when over 1500 adverse reactions were reported to 16 reported reactions during 1996.

In summary, the number of adverse reaction complaints received by the FDA; and the nature of these reports in terms of demographic distribution, severity, strength of association with the product, and symptoms remain comparable to those from previous analyses.

Donna M. Gray

Donna M. Gray

Table 1. Distribution of reactions attributed to aspartame by product type.

PRODUCT TYPE	NO. OF COMPLAINTS	% OF RECORDS	% OF COMPLAINTS
Diet Soft Drinks	3077	46.6%	38.0%
Table Top Sweetener	1764	26.7%	21.8%
Puddings - Gelatins	639	9.7%	7.9%
Lemonade	416	6.3%	5.1%
Other	364	5.5%	4.5%
Kool Aid	342	5.2%	4.2%
Chewing Gum	334	5.0%	4.1%
Hot Chocolate	324	4.9%	4.0%
Iced Tea	324	4.9%	4.0%
Frozen Confections	148	2.2%	1.8%
Cereal	122	1.8%	1.5%
Sugar Substitute Tablets	75	1.1%	0.9%
Breath Mints	63	0.9%	0.8%
Punch Mix	45	0.68%	0.6%
Fruit Drinks	24	0.36%	0.3%
Chewable Multi-Vitamins	9	0.1%	0.1%
Non-Dairy Toppings	8	0.1%	0.09%
Fruit, Dried	2	.03%	0.02%

June 26, 1997

Table 2. Symptoms attributed to Aspartame in complaints submitted to FDA.[1]

REPORTED SYMPTOMS	NO. OF COMPLAINTS	% OF REPORTS	% OF COMPLAINTS
Headache	1900	28.7%	18.9%
Dizziness/ Poor Equilibrium	749	11.3%	7.5%
Change in Mood	679	10.3%	6.8%
Vomiting or Nausea	669	10.1%	6.7%
Abdominal Pain and Cramps	466	7.0%	4.6%
Change in Vision	374	5.7%	3.7%
Diarrhea	345	5.2%	3.4%
Seizures and Convulsions	298	4.5%	3.0%
Memory Loss	273	4.1%	2.7%
Fatigue, Weakness	251	3.8%	2.5%
Other Neurological	233	3.5%	2.3%
Rash	227	3.4%	2.3%
Sleep Problems	205	3.1%	2.0%
Hives	194	2.9%	1.9%
Change in Heart Rate	193	2.9%	1.9%
Change in Sensation (Numbness, Tingling)	178	2.7%	1.8%
Itching	177	2.7%	1.8%
Grand Mal	174	2.6%	1.7%
Local Swelling	119	1.8%	1.2%
Difficulty Breathing	117	1.8%	1.2%
Change in Activity Level	115	1.7%	1.1%
Oral Sensory Changes	112	1.7%	1.1%
Change in Menstrual Pattern	107	1.6%	1.1%
Other Skin	103	1.6%	1.0%
Localized Pain and Tenderness	101	1.5%	1.0%
Symptoms reported by less than 100 complainants	1678	.25%	16.7%

1. Some consumers described more than one symptom attributed to Aspartame.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington DC 20204

JUN 25 1998

F98-14628

Dear

In response to your request of May 18, 1998 for number of complaints to the FDA on aspartame received in the years 1996, 1997, and through this date 1998.

XX Enclosed are the records you requested for 1996 and 1997. Complaints for the year 1998 have not yet been complied.

___ We have searched our files and find no responsive information.

___ Your request is also being referred to one of our component offices.

___ In order to help reduce processing time and costs, certain material has been deleted from the record(s) furnished to you because a preliminary review of the records indicated that the deleted information is not required to be publicly disclosed. If, however, you desire to review the deleted material, please make an additional request at the following address: Food and Drug Administration, Freedom of Information Staff, HFI-35, 5600 Fishers Lane, Rockville, MD 20857. Should the Agency then deny this information, you would have the right to appeal such denial. Any letter of denial will explain how to make this appeal.

Charges will be included in a monthly invoice if your request(s) total more than $15.00. If your monthly total is LESS than $15.00, the material is free. Please DO NOT send payment until you receive an invoice for the total monthly fee.

Reproduction $.80 Search $40.00 Review 0 Other 0 Total: $40.80

THE ABOVE TOTAL MAY NOT REFLECT THE FINAL CHARGES FOR THIS REQUEST.

Sincerely yours,

FOI OFFICER
Executive Operations Staff
Center for Food Safety
and Applied Nutrition

Enclosure