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MORBIDITY AND MORTALITY WEEKLY REPORT

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Current Trends

Evaluation of Consumer Complaints Related to Aspartame Use

In February 1984, the U.S. Food and Drug Administration (FDA) requested CDC's assistance in evaluating consumer complaints that FDA had received about consumption of aspartame-containing products. The request followed an increase in aspartame-related complaints in the latter half of 1983. Complaints to the FDA increased from 108 in the first 6 months of 1983 to 248 in the last 6 months. This increase coincided with approval of aspartame for use in soft drinks in July 1983.

The CDC investigation had two major purposes: (1) to provide a basic descriptive analysis of the symptoms reported and the epidemiologic characteristics of the persons reporting those symptoms; and (2) to determine whether specific individual symptoms or constellations of symptoms were reported with enough consistency to indicate where further clinical studies, should they seem necessary, would be most productive. It was recognized from the outset that this investigation alone would be unlikely to establish any cause-and-effect relationship between the ingestion of aspartame and the occurrence of reported symptoms.

Application of criteria

The quality and type of evidence that may be obtained by a passive surveillance system does not allow definitive determination of whether given symptoms are or are not caused by the agent under question—in this case, aspartame. Passive surveillance implies that cases or reports are not actively solicited by the agency or organization concerned but, rather, are initiated on the part of the consumer or complainant. In such a passive surveillance system, serious problems may be more likely to be reported, even if they occur less often than mild problems. Problems occurring soon after use of a product are more likely to be thought to be caused by the product and, hence, reported. Thus, passive surveillance systems are more likely to detect rare and serious conditions and symptoms occurring shortly after use of a product than common symptoms or symptoms occurring at some longer period after product use. However, symptoms that are common in the general populace and are reported in a passive surveillance system are more likely to have occurred by chance in association with use of the product than are more rare symptoms.

Criteria originally developed to assess potential adverse reactions to medications were adapted to evaluate the likelihood that symptoms reported by individuals through this passive surveillance system could be due to aspartame consumption (*1,2*). However, application of these criteria was limited by a number of factors. For example, when evaluating reactions to medications, physician reports indicating concurrent illness and use of other medications are usually available. In the case of aspartame use, because few of the complainants sought medical aid, few physician reports containing information specific to the aspartame complaints were available. For this reason, information about other potential causes of symptoms, such as concurrent illnesses or medications, was often limited. Moreover, details relating to the

Table 6-3

Distribution of Neurological/Behavioral Symptoms By Subcategory, Group D Excluded*

Symptoms	Percent	Number
Headache	22%	41
Mood Alterations	21%	39
Insomnia	11%	20
Dizziness	10%	19
Fatigue	10%	18
Visual Impairment	4%	8
Numbness	3%	6
Hyperactivity	3%	5
Seizures	3%	5
Disorientation	2%	4
Lack of Concentration	2%	3
Ringing in Ears	2%	3
Memory Loss	2%	3
Drowsiness/Listlessness	1%	2
Fainting	1%	1
"Hallucinations"	1%	1
Loss of Balance	1%	1
Motor Dysfunction	1%	1
Sleepwalking	1%	1
Speech Impairment	1%	1
"Rush to Forehead"	1%	1
"Paranoia"	1%	1
Nightmares	1%	1
TOTAL SYMPTOMS†	105%	185
TOTAL COMPLAINANTS	100%	91

*Group D: Symptoms did not recur on rechallenge, or physician stated that the symptoms were unlikely to be due to aspartame.
(For complete definitions of Groups A-D, see pages 17-18.)

†Percent (%) may not total 100 due to rounding.

Appendix Table 8

Distribution of Remaining Cases*
By Neurological/Behavioral Symptoms

Symptoms	Percent	Number
Mood Alterations†	24%	104
Headache	20%	88
Dizziness	15%	63
Insomnia	7%	31
Fatigue	7%	30
Visual Impairment	6%	26
Memory Loss	4%	16
Seizures/Pre-seizures	3%	12
Numbness	2%	9
Fainting	2%	9
Disorientation	2%	9
Hallucinations/Pre-hallucinations	1%	6
Lack of Concentration	1%	6
Hyperactivity	1%	5
Motor Dysfunction	1%	5
Auditory Disturbances	1%	3
Ringing In Ears	<1%	2
Loss of Balance	<1%	1
Sleepwalking	<1%	1
Speech Impairment	<1%	1
Rush to Forehead	<1%	1
Paranoia	<1%	1
Nightmares	<1%	1
Behavioral Change	<1%	1
Personality Change	<1%	1
Loss of Sense of Taste	<1%	1
Drowsiness/Listlessness	0%	0
TOTAL NEUROLOGICAL/BEHAVIORAL SYMPTOMS		433

†*Mood Alterations:
- Agitation
- Anxiety
- Depression
- Hysteria
- Irritation
- Nervousness
- "Spaced-out"
- Suicidal
- Violent

*For comparison with neurological/behavioral cases selected for in-depth review, see Table 6-3, page 40.

Appendix Table 12

Distribution of Remaining Cases
By Miscellaneous Symptoms

Symptom	Number
Painful joints	11
Flu-like symptoms	8
Palpitations/racing heart	3
Chills/sweats	5
Sleepiness	4
Bladder dysfunction	3
Fever	3
Shortness of breath	3
Loss of hair	3
Coughing	3
Pressure in chest	2
Pressure in head	2
Increased appetite	2
Premature ventricular contractions	2
Pain in chest	2
Rise in blood glucose level	2
Loss of appetite	2
Strong odor in urine	2
Blood in urine	2
Urinary urge on awakening	1
Frequent urination	1
Extreme thirst	1
Swelling of ankles	1
Swelling in both hands	1
Rigid and stiff	1
Blackouts	1
Heart pain	1
Cramps on left side of body	1
Loss of strength	1
Numerous colds & infections	1
Back pain	1
Non-malignant tumor	1
Drop in blood pressure	1
Sensitivity to light	1
Hair growing on face (female)	1
Teeth crumbling	1
Unusual taste in mouth	1
Insulin shock	1
Charley horses	1
Cardiac arrest	1
Gray/black bar in left eye	1
Chipping of fingernails	1
Bitter taste	1
Earache	1
Lump in hip area	1
Rapid breathing	1
Left eye pain	1
TOTAL SYMPTOMS	92

CASES REVIEWED FOR DEMOGRAPHIC INFORMATION: TABLES

Appendix Table 1

Sex Distribution of Remaining Cases

Compared with Initial Cases Selected for In-Depth Review

Sex	Remaining Cases Percent	Cases Selected for Review Percent
Male	24%	25%
Female	76%	75%
TOTAL	100%	100%

EVALUATION OF CONSUMER COMPLAINTS RELATED TO ASPARTAME USE

EXECUTIVE SUMMARY:

In February 1984 the Food and Drug Administration (FDA) requested the assistance of the Centers for Disease Control (CDC) in evaluating consumer complaints the FDA had received related to consumption of aspartame-containing products. The request followed an increase in aspartame-related complaints in the latter half of 1983. Complaints to the FDA increased from 108 in the first 6 months of 1983 to 248 in the last 6 months. This increase coincided with approval of aspartame for use in soft drinks in July of that year.

The CDC investigation had two major purposes: first, to provide a basic descriptive analysis of the symptoms reported and the epidemiologic characteristics of the persons reporting those symptoms; and second, to determine whether specific individual symptoms or constellations of symptoms were reported with enough consistency to indicate where further clinical studies, should they seem necessary, would be most productive. It was recognized from the outset that this investigation alone would be unlikely to establish any cause and effect relationship between the ingestion of aspartame and the occurrence of reported symptoms.

SUMMARY AND CONCLUSION

In summary, the quality and type of evidence obtained by a passive surveillance system based on consumer complaints precludes definitive determination of whether these complaints are or are not caused by the agent under question--in this case, aspartame. However, it is possible under these circumstances to provide a basic descriptive analysis and to attempt to identify consistent patterns of report. Analysis of the demographic characteristics of the complainants revealed that the great majority were white women 20-60 years of age. This overrepresentation of women may reflect a greater use of aspartame-containing products, a greater tendency to report their symptoms, or a greater susceptibility to side effects from aspartame. Available data are not adequate to resolve this issue.

A wide variety of symptoms was reported. No specific constellation of symptoms was identified in relation to aspartame ingestion; however, a substantial number (25-30 percent) of individual complainants reported that their symptoms recurred after repeated consumption of aspartame-containing products without evidence of misuse or other alternative explanation. How many of the individuals who reported repeated episodes of symptoms after aspartame use had symptoms that were due to aspartame, we cannot determine. Whether the symptoms experienced by persons who chose not to use aspartame again were caused by aspartame is also not clear. In a few instances persons who had challenged themselves several times with aspartame-containing products found by the time of our reinterview that their symptoms were, in fact, not due to aspartame. These individuals had used aspartame without such symptoms subsequently or had come to alternative explanations for their symptoms.

Thus, this investigation of consumer complaints of symptoms experienced after consumption of aspartame-containing products has identified no specific constellation of symptoms related to aspartame consumption. Nonetheless, some individual symptoms were reported with greater frequency than other symptoms, and 28 percent of individual complainants reported experiencing repeated episodes of symptoms after aspartame use. While some of these reports are undoubtedly due to mere coincidental occurrence of symptoms after aspartame consumption, and others may be due to the suggestibility of some persons, still others may be attributable to some as yet undefined sensitivity to aspartame in commonly consumed amounts. The only way that these possibilities could be thoroughly evaluated would be through focused clinical studies.

V-0002: Neurological/Behavioral, Group A

A 4-year-old white male had symptoms of insomnia, headache, aggressive behavior, and disorientation. His mother reported that he appeared "glassy eyed" and was "running around wildly...hitting his head against the wall," and that his speech was rapid and slurred. The symptoms first occurred while he was consuming 2-3 glasses of Kool Aid® or Wyler's® lemonade daily along with Halfsies® cereal 3 times per week. His symptoms stopped approximately 24 hours after he stopped ingesting these products. Since this time, the child has participated in a double-blind,* videotaped, observer-validated study. This study reportedly confirmed that the symptoms occur following aspartame ingestion. The symptoms have also consistently recurred on at least three occasions when the child was "accidentally" given three different foods with aspartame--hot chocolate, bubble gum, and cookies. The child's private pediatrician, who feels that the child's symptoms are due to aspartame, reported that he has observed that the child's symptoms have become more prolonged with increased exposure to aspartame.

Relevant Medical History: The child's mother reports that he is allergic to milk protein, but that he has no other allergies.

* The report of double-blind trial is based on verbal communication with the investigator. The results are being prepared for publication and are not available for review at the time.of this report.

V-0030: Neurological/Behavioral, Group A

A 7-year-old white male had symptoms of hyperactivity, irritability and agitation, extreme excitability, and insomnia. The parents first noticed symptoms in the child during a one-week period in which he was consuming 1-2 packets per day of the table-top sweetener, Equal®. During this period, the child's first-grade teacher called and asked the parents if he was on any medication because she had noticed that he had become inattentive, very talkative, and overactive. Intake of Equal® was discontinued, and 3 days later, his behavior had returned to normal at school and at home. Seven months later, the symptoms of hyperactivity, agitation, and excitability occurred with greater severity within 1 hour of ingesting another aspartame product (about 1 pint of Kool Aid®). The symptoms lasted about 16 hours and were accompanied by insomnia. The child was not referred to a physician about his symptoms.

Relevant Medical History: The child has had mild to moderate sensorineural hearing loss since birth. He also has had a reaction somewhat similar to the reported symptoms after taking on one occasion the medication Dimetapp® at 18 months of age.

V-0042: Neurological/Behavioral, Group B

A 30-year-old white female reported symptoms of severe headache, disorientation, and loss of depth perception. Her first symptom, which she described as a severe headache, occurred within 45 minutes of her first ingestion of an aspartame product (2 glasses of lemonade-flavored Crystal Light®), and lasted overnight. The next day, she ingested the same amount of this product and again had a similar experience. The following day, she drank several 14 oz. glasses of the product on an empty stomach. Two to 3 hours later, she became disoriented while driving her car and experienced "loss of depth perception," which made it difficult to drive. She also became confused about what street she was on. The disorientation and headache lasted throughout the afternoon (about 3 hours). Several days later she consumed the aspartame product again and had the same reaction. She then recognized a connection between the drink and her symptoms and stopped ingesting the product.

Relevant Medical History: None.

V-0090: Neurological/Behavioral, Group A

A 39-year-old white female complained of depression, memory loss, lethargy, irritability, dizziness, and headaches. The complainant's first use of aspartame-containing products was in March, 1983, when she began using approximately 8 packs of Equal® per day. During the symptomatic interval, the complainant added other aspartame-containing products to her diet, including Diet Coke® and Kool Aid®. The symptoms started in mid-April and increased in number and intensity in subsequent months. The first symptom to occur was lethargy. Over the ensuing months, irritability, dizziness, depression, and memory loss occurred. She states that when she stopped using aspartame-containing products in mid-September following a news report, the symptoms improved within 1 day and ceased within 1 week. The complainant subsequently rechallenged herself approximately 2 months later with Equal®, consuming 4 packets per day for approximately 3 days. She stated that she became dizzy on the third day and that the episode was "very frightening." After these symptoms appeared she stated that she stopped consuming Equal®, and approximately 24 hours later the symptoms subsided.

The complainant consulted three physicians during this time. Only her family physician was available for interview, and he stated that he "had no reason to doubt the judgment of the complainant."

Relevant Medical History: The patient has a past history of thyroid disease as well as a past history of migraine headaches for which she was on Valium® and Cafergot® at the time of the symptoms. Thyroid screen at the time of the symptoms was reported to be normal. The only other medical condition reported was an allergy to ampicillin and compazine.

M-0328: Neurological/Behavioral, Group C

A 17-year-old white female reported symptoms of lethargy, depression, severe mood swings, and suicidal tendencies. (The parents of the complainant were interviewed because they did not wish their daughter to be subjected to the stress of talking to the investigator.) They reported that the symptoms began within 2 weeks of first regular use of a product containing aspartame. (At a different interview, the complainant's parents reported that she used one-half packet of Equal® per day for approximately 2 months prior to the first recorded symptoms.) The complainant's parents also reported that, during the symptomatic period, the complainant consumed eight 12-ounce cans of Diet Coke® per day, one-half packet of Equal® per day, two quarts of Crystal Light® drink per day, and one quart of Crystal Light® iced tea per week.

The parents described their daughter previous to the symptomatic episode as "healthy, vibrant, and positively motivated, with a genius I.Q. in excess of 170." They stated that she was a "straight-A" student who was very athletic and always "diet conscious" and that artificially sweetened drinks were the only "non-nutritious" foods that she ingested.

The parents described the complainant during the symptomatic episode as a "weak, fragile, depressed person who has lost her sense of independence and her spirit." They reported that the complainant was seen by several physicians during her symptomatic episode for uncontrollable mood swings, lethargy, and "plan to commit suicide." In February 1984, an osteopathic physician diagnosed an impairment of liver and kidney function of unknown etiology. The physician treated the complainant with megadoses of vitamins B and C.

V-0404: Neurological/Behavioral, Group B

A 33-year-old white male physician reported symptoms of a severe, bitemporal vascular headache. His first symptoms occurred about 15 minutes after his first substantial ingestion (16 oz.) of Carnation® hot chocolate.

His symptoms first occurred about 1 month after he began ingesting aspartame products: diet soft drink (Pepsi Free®), hot chocolate (Carnation®), and table-top sweetener (Equal®); however, he reported that he used these products very intermittently and in low quantities.

On the occasion of his first substantial ingestion of Carnation® hot chocolate, the symptoms lasted 3 hours. They recurred the next day when he "experimented" by again drinking 16 oz. of the same product on an empty stomach. The latency and duration of symptoms was the same as the first episode. The complainant reported that his symptoms were dose-related in that he experienced a severe headache with two cups of hot chocolate, a headache of lesser intensity with one cup, and no symptoms with one-half cup of Diet Pepsi ®. The complainant, a staff psychiatrist, did not see a physician about his symptoms.

Relevant Medical History: The complainant has had similar symptoms after ingesting Chinese food containing monosodium glutamate.

V-0415: Neurological/Behavioral, Group C

A 62-year-old white male reported symptoms of acute depression with thoughts of suicide. These symptoms occurred approximately 10 days after beginning daily ingestion of an aspartame product (table-top sweetener, Equal®). The symptoms continued up until approximately 3 days after he discontinued use of this product. (Complainant was not sure of exact time frames.) He has not consumed this product since and has not had recurrence of symptoms. The complainant did not see a physician about his symptoms and stated that he never experienced these symptoms prior to using this product.

Relevant Medical History: None.

S-0565: Neurological/Behavioral and Gastrointestinal, Group A

The mother of a 7-year-old white male reported that her son had abdominal pain, headache, fever, and hyperactivity. His first symptoms occurred within 4 hours after consuming Diet Coke®. The symptoms lasted for 12 hours. Approximately 1 week later he was given a Featherweight® dessert mix and had the same symptoms with the same latency and duration. Approximately 1 week after this second incident he consumed Alba® hot chocolate mix and experienced a third, identical episode.

Relevant Medical History: The complainant is under treatment for food allergies (sugar, spinach, fruits) and allergies to dust and molds. Allergy shots are given every 8 weeks.

CASE REPORTS: COMPLAINTS SUBMITTED AS SEIZURES

V-0092: Neurological/Behavioral (Seizure-Type Activity) Group C

The complainant, a 37-year-old white male, had been using an aspartame-containing product for 6 months prior to the reported episode. His last ingestion of an aspartame-containing product (Equal®) was reported to be 24 hours prior to the episode. He stated that he was riding a horse, the horse bolted, and he lost consciousness and fell, striking his head. He said that witnesses told him he had a seizure, although the attending physician was not a witness to his seizure. He also stated that he was not under care or hospitalized for any medical problems at the time of the incident or within the past two years, he was on no medications at the time of the incident, and he has no history of seizures.

Call to complainant on August 7, 1984, revealed that he has not used aspartame-containing products since his accident, and that he has had no further symptoms.

Relevant Medical History: No known medical problems.

V-0095: Neurological/Behavioral (Seizure-Type Activity) Group C

The complainant, a 39-year-old white male, started using a product containing aspartame in June of 1982. On June 29, 1983, he reportedly had his first seizure. This was followed by other seizures on October 28, November 11, November 25, November 27, 1983, and January 11 and February 2 of 1984. This person reports drinking an average of 40 cups of coffee per day and has sweetened most of them with Equal®. This person saw a physician on numerous occasions and was hospitalized for his conditions.

Since his first seizure this person has been treated with Triavil®, Dilantin®, Ludiomil®, Tranxene®, Elavil®, Haldol®, Valium®, and Mellaril®. He was diagnosed as having anxiety disorder with panic attacks.

Relevant Medical History: There appears to be the possibility of organic brain syndrome, and the complainant is currently under psychiatric treatment.

V-0097: Neurological/Behavioral (Seizure-Type Activity) Group C

The complainant, a 31-year-old white female, started using aspartame-containing products in May of 1983. She reported that she began sleepwalking in mid-July of that year. On July 28, 1983, she awoke to find herself bruised and sore. According to her physician, the complainant had had an epileptic seizure for which he prescribed Dilantin. Another physician was consulted who agreed with the seizure diagnosis but did not classify it as "epileptic," stating that it may not have been "organic related."

Complainant did not approve release of her medical records to the FDA for review. We recontacted her on August 8, 1984, and learned that she has not used aspartame since the time of her complaint, that she has had no subsequent seizures, and that she is not on any seizure medication.

Relevant Medical History: None.

M-0320: Neurological/Behavioral (Seizure-Type Activity) Group C

The complainant, a 26-year-old white female, had been using aspartame-containing products for approximately 3 months prior to the reported seizure that occurred on January 12, 1984. Within 24 hours prior to the incident, complainant had consumed Equal®, Diet Coke®, and aspartame-sweetened Kool-Aid® and fruit punch.

The complainant was standing at the time of the symptoms, which included a "tingly" feeling, tunnel vision, lightheadedness and seizure. A CAT scan and an EEG performed after the episode were within normal limits. The initial medical diagnosis was orthostatic hypotension associated with inappropriate adrenergic effect and secondary seizure. Another physician was consulted for a second opinion. He indicated that, since the tests were normal, he could not rule out a connection between the use of aspartame and the seizure-type episode, but that he was not familiar with the aspartame issue.

We contacted the complainant by telephone on August 7, 1984, and learned that she has had no further episodes. She has avoided aspartame-containing foods, her weight has been stable, she has not been on any diet plan, and her health has been good.

Relevant Medical History: This person was on a 1000-1200 calorie diet and exercise plan and lost 24 pounds between October 4, 1983, and January 12, 1984.

M-0323: Neurological/Behavioral (Seizure-Type Activity) Group D

The complainant, a two-year-old white female, was first given aspartame-containing products--Equal® on her breakfast cereal and sugar-free Kool-Aid® mix to drink--on January 7, 1983. The date of her first seizure was January 30, 1983. She also had seizures on February 2, 1983, May 25, 1983, and August 8, 1983. The parents reported that not all aspartame ingestions have been associated with seizure activity.

A pediatrician and a neurologist both stated that they did not consider the four seizure episodes to be aspartame-related. Both physicians were unsure of etiology, but each suggested that the convulsions were a common variety of "febrile seizures." They prescribed phenobarbital elixir.

We contacted the father on August 7, 1984, and learned that she has had no further seizures while on phenobarbital, that she has had no further exposure to aspartame, and that her health and her growth and development are normal.

Relevant Medical History: None.

M-0330: Neurological/Behavioral (Seizure-Type Activity) Group D

The complainant, a two-year-old white male, was given an aspartame-containing product on December 13, 1983, and 30 minutes after ingestion, had a grand mal seizure. Similar incidents occurred on December 24, 1983, and January 4, 1984. The child was hospitalized December 13-14, 1983, and given phenobarbital. His physician stated that the first seizure appeared to be a febrile seizure, and the subsequent ones have been typical of epilepsy.

Relevant Medical History: None known.

T-0350: Neurological/Behavioral (Seizure-Type Activity) Group A

The complainant, a 37-year-old white female, first used an aspartame-containing product in January of 1984. Within 24 hours she experienced "an aura of familiarity, anxiety, and nausea." During the week of January 15-21, 1984, she drank four more Diet Cokes®, and each time she had the same experience. She did not see a physician for the reported incidents.

During a follow-up call, the complainant said that she has avoided aspartame-containing products and has not had seizures, with the exception of one time early in July when she inadvertently drank three-fourths of a can of Diet 7-Up containing aspartame. Twenty-six hours after drinking the 7-Up, she had the same symptoms in mild form. She believes aspartame acts as a trigger for her symptoms and that possibly other similar compounds have acted as triggers in the past when she had similar symptoms unrelated to aspartame.

Relevant Medical History: She was diagnosed at age 19 as having jacksonian seizures, but has had little medical follow-up since that time. Complainant reports that she has averaged about two symptom episodes, which were similar in character, per year since age 19. She has been on no medication for her condition.

V-0458: Neurological/Behavioral (Seizure-Type Activity) Group C

The complainant is a 33-year-old white female who first used an aspartame-containing product in June or July of 1983. Approximately 3 months later, on October 9, 1983, the complainant experienced a seizure. Four months later, on February 9, 1984, she experienced another seizure, following which she stopped using Equal®. Her physician's diagnosis was idiopathic epilepsy. He did not know if it was related to aspartame use. Prior to this, complainant reported that she was not under a physician's care nor hospitalized within the past 2 years.

Since the reported episodes the complainant has not used aspartame-containing products, has been in good health, and has remained symptom-free.

Relevant Medical History: None.

S-0558: Neurological/Behavioral (Seizure-Type Activity) Group D

The complainant, a 32-year-old white female, reported that her first regular use of an aspartame-containing product was in June of 1983, 6 months prior to her first symptom episode. In the 24 hours before the reported incident, she consumed 32 oz. of Kool Aid® with aspartame and 24 oz. of Diet Coke®. She reported that her symptoms included headache, neck pain, nausea, dizziness, and a "movement disorder" of her right arm. The medical record from her neurology consultation indicated a diagnosis of "myoclonus without stereotypic pattern," which could have been associated with a functional disorder as well as "true neurologic disease." The physician did not know if the symptoms were related to aspartame use. Complainant did not report similar symptoms after consuming an aspartame-containing product at any other time.

Relevant Medical History: At the time of the incident, complainant was under treatment for hypertension with Minipress®. She reported being on an extremely low calorie diet and had lost 60 pounds in six months. At the time of her episode, she had completed a 4-day fast followed by drinking alcohol with her friends and taking Norgesic® and Darvocet® in addition to Minipress®. She was not able to be reached for follow-up information.

period, and the second 4 months after the first seizure. In this case, since the complainant did not have a seizure until after 3 months of chronic aspartame use, and no history of challenge-rechallenge episodes are available, It is difficult to relate these two seizures to the use of aspartame. In the case of V-0097, the complainant refused to release her medical records, but the history indicates that this complainant also had been using aspartame for at least 2 months prior to the onset of symptoms.

In summary, from the review of the first nine cases containing reports of seizures we could not find convincing evidence that any of the documented seizures had a high probability of being due to ingestion of aspartame-containing products. It is unclear whether the one case that fell into Group A is actually a case of seizure activity, as the history does not fully support this impression and there was no medical diagnosis available. The two cases in which there were no alternative diagnoses or etiology also did not have very convincing time frames regarding to aspartame use and seizure onset, although there may have been a dose effect involved. Seizure activity commonly occurs without a documentable etiology, and this compounds the difficulty of assessing case reports linking aspartame use with seizures. Without benefit of more intensive medical follow-up, we cannot rule out the possibility that aspartame may in some cases act as a trigger for seizure activity, but there is not sufficient evidence from these nine cases to raise our suspicions that this is a likely possibility.