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ASPARTAME: AN ARTIFICIAL SWEETENER

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Donna V. Porter Analyst in Life Sciences Science Policy Research Division March 23, 1984

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ABSTRACT

Since 1973 when the Food and Drug Administration first approved the artificial sweetener, aspartame, for use in food products, some researchers have raised questions about possible health effects associated with its consumption. This paper provides an overview of the regulatory history and possible health problems associated with the use of aspartame.

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ASPARTAME: AN ARTIFICIAL SWEETENER

Aspartame is an artificial sweetener synthesized from two amino acids, aspartic acid and phenylalanine. It was discovered accidentally in 1965 by a scientist at G. D. Searle & Company (Skokie, Illinois) who was doing research on new drugs to treat ulcers. Since 1965, G. D. Searle & Company has conducted extensive testing in an attempt to demonstrate that aspartame is safe for most people when added to food products. On July 7, 1981, after considerable debate, the Food and Drug Administration (FDA) approved the use of aspartame in dry food products. On July 8, 1983, FDA approved the use of the sweetener in carbonated beverages. This report provides an overview of aspartame, discusses the regulatory history of artificial sweeteners and identifies some of the current controversy over this recently approved substance.

HEALTH ASPECTS OF ASPARTAME

In terms of caloric value, aspartame contains four calories per gram, the same as table sugar. However, because it has a sweetening power 180 times greater than table sugar, aspartame can be used in much smaller quantities to achieve the same level of sweetness. In practical terms, the amount of aspartame with an equivalent sweetening power of two teaspoons of sugar (32 calories) contains only 0.4 calories. 1/ Aspartame has a further advantage as a sweetening

^{1/} Jemison, Terry. Aspartame Firm Eyes Saccharin's Popularity. U.S. Medicine, v. 18, Sept. 15, 1982. p. 27.

agent because, unlike sugar, it does not provide a good medium in the mouth to encourage the growth of bacteria that cause dental caries.

When digested by humans, aspartame breaks down into its component parts, aspartic acid, phenylalanine, and small amounts of methanol. Although both of the amino acids and methanol are naturally present in a number of commonly eaten foods, concern about their health implications has been raised in the scientific community. 2/

A small proportion of the population suffers from the genetic disease called phenylketonuria (PKU), a condition which prevents the metabolism of the amino acid, phenylalanine. These individuals must restrict their intake of this amino acid in order to prevent its buildup in the brain which can lead to mental retardation. The intake of foods containing phenylalanine must be carefully monitored in individuals with this disorder.

Concerns have also been raised about the safety of aspartic acid. Animal studies have shown that extremely high doses of certain amino acids, such as aspartic acid, can cause focal brain lesions and associated neuroendocrine changes. The safety of aspartame has also been questioned in relation to the formation of brain neoplasms (tumors), the effect on neurotransmitters, and the production of methanol as a metabolic endproduct.

LEGISLATIVE HISTORY OF FOOD ADDITIVE POLICY

Federal policy concerned with food regulation began in the United States with the Pure Food and Drug Act of 1906, which stated that food is deemed adulterated "if it contains any added poisonous or other deleterious ingredients which may

^{2/} Aspartame; Commissioner's Final Decision. Federal Register, v. 46, no. 142, July 24, 1981. p. 38284-38308.

render such article injurious to health." The Federal Food, Drug, and Cosmetic Act of 1938 (FD&C Act) expanded the definition of adulterated food to include foods containing

any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health. 3/

In 1958, the Food Additive Amendment, which includes the controversial Delaney (anti-cancer) clause, was added to the FD&C Act. 4/ Three catagories of food additives are recognized by this Amendment:

1. Food additives generally recognized as safe (GPAS);

2. Food additives with prior sanction (approval); and

3. New food and color additives.

Under the anti-cancer clause, any food or color additive or animal drug that may be determined to cause cancer in man or animal is required to be banned from the market. The Amendment further states that the burden of proving an additive safe is the responsibility of the manufacturer. In seeking approval for aspartame, Searle & Company needed to demonstrate compliance with both general safety and anti-cancer provisions of the FD&C Act.

REGULATION OF ARTIFICIAL SWEETENERS

In recent years, FDA has banned the use of several previously approved food additives, including some artificial sweeteners, on the grounds that these substances may have negative health effects. One example is cyclamate, the

- 3/ The Federal Food, Drug, and Cosmetic Act. Section 402 (a)(1).
- 4/ The Federal Food, Drug and Cosmetic Act. Section 409 (c)(3)(A).

primary artificial sweetener in use during the 1950s and 1960s. On October 21, 1969, FDA banned the use of cyclamate from foods, beverages, and drugs after studies with laboratory animals revealed that this artificial sweetener may cause bladder cancer. 5/ Since that time FDA has received a number of petitions to reverse this decision on the basis of new data. However, to date, all such requests have been denied.

Saccharin was the only non-nutritive artificial sweetener on the market from 1970 through 1981. A product of petroleum materials produced by Sherwin-Williams Paint Company, it has been under scientific scrutiny since its discovery in 1879. In 1977, FDA proposed a ban on saccharin after animal studies indicated that it too may cause bladder cancer in animals. <u>6</u>/ This proposed ban, however, was overruled by Congress because of strong public demand for an artificial sweetener to be available on the market. In November 1977, Congress imposed an 18-month moratorium against such a ban. <u>7</u>/ This moratorium was extended in May 1979 and again in August 1931. In April 1983, a 24-month extension of the moratorium was signed into law. The search for low-calorie sweeteners that do not pose health hazards has been stimulated by concerns about the cancer-causing potential of cyclamate and saccharin, and by the market demand for such an artificial sweetener.

5/ 34 Fed. Reg. 17063, Oct. 21, 1969.

6/ Saccharin and Its Salts: Proposed Rule Making. Federal Register, v. 42, no. 73, Apr. 15, 1977. p. 19996.

7/ Saccharin Study and Labeling Act--P.L. 95-203 (S. 1750), 1977.

REGULATORY HISTORY OF ASPARTAME

In an attempt to demonstrate the safety of aspartame, G.D. Searle & Company has subjected the artificial sweetner to extensive testing. On March 5, 1973, Searle reported its findings, together with a petition for approval, to FDA. According to the 1973 studies, aspartame does not have any negative health implications for the general population, but it is recommended that people who suffer from the rare condition phenylketonuria (PKU) not consume aspartame-containing products.

On July 26, 1974, FDA approved Searle's petition for aspartame as: a sweetener for table use; a tablet for hot beverages; an ingredient in cold cereals; a dry base sweetener for powdered beverages, instant coffee and tea, gelatins, fillings, and dessert toppings; and a flavoring agent in chewing gum. In reviewing the characteristics of aspartame, FDA imposed the following additional conditions on the marketing of this artificial sweetener:

- The label of any food containing aspartame must bear the statement "Phenylketonurics: contains Phenylalanine." (The purpose of this statement is to alert persons who must avoid foods containing phenylalanine.);
- 2. When aspartame is to be used as a table top sweetener, its label is required to bear instructions not to use aspartame in cooking or baking. (This statement is to inform the consumer that aspartame breaks down to an undesirable compound, diketopiperazine (DKP), when exposed to prolonged heat.); and
- 3. If a food containing aspartame claims to have special dietary uses, such as a low-calorie product, it is required to comply with FDA's special dietary food regulations. 8/

At the time of FDA's initial (1974) approval of aspartame, several formal objections were raised. Specifically, John W. Olney, M.D., Washington University

8/ Food Additives Permitted in Food for Human Consumption. Federal Register, v. 39, no. 145, July 26, 1974. p. 27320.

School of Medicine, St. Louis, and James S. Turner, Esq. representing Label, Inc. (Legal Action for Buyers' Education and Labeling) filed objections to aspartame's approval on the grounds that its use by children may cause brain damage and result in mental retardation, endocrine dysfunction, or both. On December 5, 1975, FDA placed a stay on the regulation allowing the marketing of aspartame and planned a comprehensive review of research data on aspartame. <u>9</u>/ On December 13, 1978, the results of a two year study of Searle's research investigations confirmed that the test experiments were valid. On June 1, 1979, FDA established a Public Board of Inquiry (Board) consisting of three independent scientists to clarify the following issues:

- Whether the ingestion of aspartame, either alone or together with glutamate, poses a risk contributing to mental retardation, brain damage, or undesirable effects on neuroendocrine regulatory systems;
- Whether the ingestion of aspartame may induce brain neoplasms (tumors) in the rat; and
- 3. Based on answers to the above questions,
 - a. Should aspartame be allowed for use in foods, or instead, should approval of aspartame be withdrawn?
 - b. If aspartame is allowed for use in foods, i.e., if its approval is not withdrawn, what conditions for use and label statements should be required, if any? 10/

After hearing and reviewing testimony from various scientists and groups, the Board issued its decision on October 1, 1980. Specifically, it concluded that aspartame consumption would not pose an increased risk of brain damage resulting in mental retardation or endocrine dysfunction. 11/ It did

9/ 40 Fed. Reg. 56907, Dec. 5, 1975.

10/ Aspartame; Ruling on Objections and Notice of Rearing Before a Public Board of Inquiry. Federal Register, v. 44, no. 107, June 1, 1979. p. 31717.

11/ Aspartame; Commissioner's Final Decision. Federal Register, v. 46, no. 142, July 24, 1981. p. 38286.

not, however, rule out the possibility of aspartame causing brain tumors and even suggested that the evidence may indicate that aspartame induces brain tumors in animals. Because of the unresolved question on the brain tumor issue, the Board did not recommend approval of Searle's food additive petition. 12/A study subsequently completed on the brain tumor issue resolved this question to the satisfaction of the agency.

After considering the results of experimental studies, comments from FDA staff, and the recommendations of the Board, on July 18, 1981, Arthur Hull Hayes, Jr., then Commissioner of FDA, ordered approval of the food additive petition for aspartame as outlined in the 1974 approval with the addition of one further condition. Searle is to monitor the actual use level of aspartame and provide this information to the FDA Bureau of Foods when requested. This approval became effective October 22, 1981. 13/

Until July 1983, aspartame could be used only in dry products. Aspartame was not previously approved for use in liquid media because it may break down into diketopiperazine (DKP) over time. However, on July 8, 1983, FDA amended the food additive regulations to allow for the use of aspartame in carbonated beverages and carbonated beverage syrup bases. In a petition that had been filed in October 1982, Searle & Company provided sufficient evidence to satisfy FDA that 1) the sweetener is sufficiently stable for the normal shelf-life of carbonated beverages, and 2) additional consumption of the sweetener will not cause toxicological problems. <u>14</u>/ Approval of Searle's petition has been delayed for several months while FDA studied scientific data and comments.

- 12/ Ibid., p. 38286.
- 13/ Ibid., p. 38288.

14/ Food Additives Permitted for Direct Addition to Food for Human Consumption; Aspartame. Federal Register, v. 48, no. 132, July 8, 1983. p. 31376-31382.

CURRENT STATUS OF ASPARTAME

Searle & Company markets aspartame under the trade names "Equal" for use at the table and "NutraSweet" for manufacturing purposes. Currently, Searle & Company has the exclusive right to produce aspartame. This right has been extended by an amendment to the patent regulations approved January 4, 1983. The amendment states that for products such as aspartame, whose approval for use is withdrawn and then reinstated, "the length of the patent's duration is to be measured from the date such stay of regulation of approval was imposed until such proceedings are finally resolved and commercial marketing permitted." 15/

At the present time, the carbonated beverage industry accounts for 70 percent of the market use of saccharin. <u>16</u>/ The diet soda industry could be a potentially profitable market for aspartame. Unlike saccharin, aspartame does not leave a bitter aftertaste and is an FDA-approved food additive. Use of saccharin in food products is legal because the moratorium enacted by Congress prevents FDA from banning its use. The FDA decision to approve aspartame for addition to carbonated beverages provides diet soda manufacturers a choice of two artificial sweeteners--aspartame and saccharin--for use in their products. The Coca-Cola Company and Royal Crown Cola Company were the first to contract with Searle to use aspartame in their diet soda products. By the end of 1983 both companies were manufacturing beverages containing a mixture of aspartame and saccharin. 17/ Other soft drink manufacturers have since contracted

17/ Ibid.

^{15/} USC 35 Sec. 11(a).

^{16/} Personal Communication with Neil Sweig, Health Care Industry Analyst for Shearson/American Express. New York City, N.Y. on Aug. 9, 1983.

for the use of aspartame in order to remain competitive. It is currently estimated that the majority of diet carbonated beverages contain aspartame, either alone or in combination with saccharin. 18/

According to a representative at Searle & Company, a number of food companies are filing petitions with FDA requesting approval to use aspartame in other liquid media, such as juices, jams, yogurt, and toothpaste. Because FDA has approved the use of the sweetener in carbonated beverages, it is expected that approval for use in these products will also be granted. 19/

In September 1983 Searle filed a petition with FDA proposing that the food additive regulations be amended to provide for the safe use of aspartame as a sweetener available to the consumer in bulk package form. 20/ In December 1983 the agency proposed to declare aspartame suitable for use as an active ingredient in human drug products provided that the label and labeling of the drug products declare the presence and amount of the component phenylalanine that is contained in the drug product per dosage unit. 21/

Research continuing at Searle & Company is directed at developing less expensive methods of producing aspartame. A cost comparison of aspartame with sugar and saccharin reveals that aspartame is the most costly of the three sweeteners. For a sweetening power equivalent of a pound of sugar,

18/ The CU Cola Challenge. Consumer Reports, Feb. 1984. p. 68.

19/ Personal communication with Dick McGraw, Public Relations Office at G. D. Searle & Co. Glenview, Ill. on July 20, 1983.

20/ G. D. Searle & Co. Filing of Food Additive Petition. Notice. Federal Register, v. 48, no. 175, Sept. 8, 1983. p. 40562.

21/ Aspartame as an Inactive Ingredient in Human Drug Products; Labeling Requirements: Proposed Rule. Federal Register, v. 48, no. 237, Dec. 8, 1983. p. 54993. aspartame costs 45 cents, sugar costs 29 cents, and saccharin cost 1.3 cents. $\underline{22}/$ By reducing the cost of aspartame, the final cost of the food products to which it is added would be reduced. In order to reduce the cost of the raw materials, Searle has recently contracted with a genetic engineering firm to supply phenylalanine. The genetic engineering firm's new process is expected to produce this key ingredient more rapidly and at lower cost than it has been produced in the past. 23/

In spite of FDA's approval, aspartame is not entirely free from questions concerning its safety. The Center for Science in the Public Interest has asked FDA to respond

to questions of aspartame safety for use in hot foods, the possibility of nitrosamine formation, the safety of formation of methyl alcohol through breakdown of aspartame; the toxicity of diketopiperazine, and the adequacy of label warnings for phenylketonurics and other people who need to avoid phenylalanine, and, therefore, aspartame. $\frac{24}{7}$

Dr. Woodrow Monte, Assistant Professor of Food Science at Arizona State University, reports numerous accounts from consumers who have felt their consumption of products containing aspartame had caused such complaints as grand mal seizures, suicidal deep depression, severe headaches, mental disorientation, loss of equilibrium, speech impairment, confusion, fatigue, vaginal spotting, menses changes mimicking early onset of menopause, visual impairment, dizziness and even a possibility of brain abscesses and fetal abnormalities. He concludes that 1) these complaints can be explained by toxic effects of the various components of aspartame affecting the body either alone or together, and

 $\frac{24}{}$ New Questions on Aspartame's Safety Raised by CSPI. Food Chemical News, Feb. 14, 1983. p. 4.

 $[\]frac{22}{26}$, Bylinski, Gene. The Battle for America's Sweet Tooth. Fortune, July 26, 1982. p. 30.

 $[\]underline{23}/$ Genex Joins Searle to Make Sweeteners. Washington Post, Aug. 16, 1983. p. D7.

?) that many of the complaints are to be found in Searle's own studies done with humans and primates. 25/

Dr. William Pardridge, Associate Professor of Medicine at UCLA, has questiones FDA on two points concerning aspartame: 1) the intended dose in mg/kg/day, and 2) what constitutes a harmful effect of the compound in the food supply. Dr. Pardridge contends that FDA has underestimated the projected usage of aspartame even before it has been approved for use in all possible food products. FDA has estimated that a typical daily dose of aspartame will be 8 to 10 mg/kg, the allowable daily intake will be 23 mg/kg and the 99th percentile of aspartame intake will be 34 mg/kg/day. 26/ Pardridge believes a more typical daily intake of aspartame will be in the order of 30 to 50 mg/kg/day, particularly in children. 27/ His second concern deals with the neurotoxic criteria being used to judge the possible harmful effect of the aspartame intake. He suggests that the measurements of mental retardation, EEG abnormalities and seizures are inappropriate and that new criteria should be established that include a) subtle changes in human prenatal development; b) behavioral changes; and 3) subtle effects on neuroendocrine physiology. . Dr. Pardridge contends that while these issues remain hypothetical at this time, there is sufficient evidence in the medical literature to suggest that a given dose of phenylalanine in people can cause neurochemical changes in the brain.

25/ Monte, Dr. Woodrow. Statement filed with Motion for Temporary Restraining Order. Jan. 1984.

<u>26</u>/ Food Additives Permitted for Direct Addition to Food for Human Consumption. Aspartame. Federal Register, v. 48, no. 132. July 8, 1983. p. 31377.

27/ Pardridge, William, M.D., Letter to Sanford Miller, Director of Bureau of Foods, Food and Drug Administration. Nov. 23, 1983.

Dr. Richard J. Wurtman, Professor of Neuroendocrine Regulation at Massachusetts Institute of Technology, has also raised questions concerning aspartame's safety. Specifically, he has reported that combining aspartame and glucose may alter brain neurotransmitter levels and, in turn, affect behavior. 28/

In July 1983 James Turner, on behalf of himself and the Community Nutrition Institute (CNI), and Dr. Monte filed with FDA objections to the July 8, 1983 regulation approving the use of aspartame in carbonated beverages. The objections contended that numerous safety issues had not been adequately considered by the agency before promulgation of the regulation, and requested that a stay be placed on the regulation pending examination of those issues in a public hearing. FDA denied the request to stay the effectiveness of the carbonated beverage regulation on the grounds that the objections failed to create significant doubts about the safety of the sweetener to warrant such a move. <u>29</u>/ The agency has also denied the request for a public hearing on the safet; issues related to the regulation allowing the use of aspartame in carbonated beverages and carbonated beverage syrup bases. After reviewing the objections, FDA concluded that the safety issues raised had been fully dealt with in earlier proceedings and that there was a lack of adequate new data to convene a public hearing at this time. 30/

In December 1983 Mr. Turner, CNI, the Arizona Dietetic Association, the Central Arizona District Dietetic Association, and Dr. Monte fil d a motion

- 29/ 48 Fed. Reg. 52899, Nov. 23, 1983.
- 30/ 49 Fed. Reg. 6672, Feb. 22, 1984.

^{28/} Wurtman, Richard J. Letter to the Editor: Neurochemical Changes Following High-Doses of Aspartame with Dietary Carbohydrates. New England Journal of Medicine, v. 309, no. 7. Aug. 18, 1983. p. 429-430.

in the U.S. district court to compel the agency to hold hearings on the safety of adding the sweetener to carbonated beverages and to prohibit the sale of carbonated beverages containing aspartame until the hearings are held. In the motion the parties asked that the court direct FDA to include at the hearings evidence bearing on the quality of the scientific studies relied upon by FDA to support the safety of aspartame as well as other evidence challenging the safety of aspartame. 31/

On January 24, 1984, Turner et al. filed a motion for a Temporary Restraining Order, asking the l 3. District Court for the District of Columbia to stop FDA "from continuing to permit the addition of the food additive aspartame to any food products, including diet sodas, powdered drinks, cereals and deserts sold in the U.S. and the use of aspartame as food until such time as FDA convenes and concludes a public hearing on the safety of aspartame." <u>32</u>/ The group believes that new evidence has accumulated that serious harm is being suffered by consumers of food products containing aspartame, establishing the fact that the continued use of aspartame in the food supply poses a serious imminent hazard to food consumers. <u>33</u>/ The court turned down the motion citing a lack of sufficient evidence to bar the sale of aspartame and aspartame-containing products. <u>34</u>/

34/ No Ruling on Aspartame TRO Motion: Parker Takes Issue "Under Advisement." Food Chemical News, Feb. 27, 1984. p. 9.

^{31/} Turner, James. CNI To Halt Sale of Aspartame. Food Chemical News, Jan. 30, 1984. p. 30.

<u>32</u>/ U.S. District Court for the District of Columbia. Motion for Temporary Restraining Order, Preliminary Injunction, Prohibitory and Mandatory Injunction. Civil Action No. 83-3846. Community Nutrition Institute et al. v. Dr. Mark Novitch. Filed Jan. 24, 1984.

^{33/} Ibid.

The motion for a Temporary Restraining Order was resubmitted on February 15, 1984, by Turner et al., along with new evidence available since the initial motion was turned down by the Court. 35/ At a February 23, 1984 hearing, the judge stated he was taking the issue under advisement and that a ruling would be made at a later date. On March 22, 1984, Judge Barrington Parker ruled that the plaintiffs would have to turn to the U.S. court of appeals for aid because the FDA decision to deny the request for a hearing had effectively removed his jurisdiction over the matter. 36/ In the meantime on March 8, 1984, Arizona regulators refused to ban the sale of carbonated beverages sweetened with aspartame. The State had been asked by Dr. Monte to ban the sweetener because it can deteriorate into methanol (methyl alcohol) under certain conditions. The Arizona health department concluded that FDA has looked into the methanol question adequately. 37/

FDA has responded to these safety questions in much the same way they responded to similar issues in 1981. The agency believes that at normal consumption levels, aspartame does not cause harm to any segment of the population

³<u>36</u>/ Parker Rules He Has No Jurisdiction in Aspartame Case. Food Chemical News. Mar. 26, 1984. p. 55.

 $\frac{37}{}$ Arizona Refuses To Ban Sale of Drinks that Use Searle's Aspartame. Wall Street Journal, Mar. 9, 1984. p. 6.

<u>35</u>/ U.S. District Court for the District of Columbia. Motion for Temporary Restraining Order, Preliminary Injunction, Prohibitory and Mandatory Injunction. Civil Action No. 83-3846. Community Nutrition Institute et al. v. Dr. Mark Novirch. Filed Feb. 15, 1984.

other than phenylketonurics. <u>38</u>/ However, FDA and the Centers for Disease Control (CDC) have been investigating complaints from the use of aspartame. A standardized questionnaire is being used in FDA field offices to follow up investigations of complaints by contacting consumers and their attending physicians, particularly for cases reported since June 1983. 39/

Because of the continuing concerns by some individuals about the safety of aspartame, legislation was introduced in the 98th Congress to control its use. As introduced by Rep. Gejdenson on October 6, 1983, H.R. 4112 would require the Secretary of Health and Human Services to establish, through regulations, maximum concentration levels for aspartame as a food additive. <u>40</u>/ The bill was referred to the House Committee on Energy and Commerce. To date no action has been taken on the bill.

Aspartame has found its way into the American market place as an approved food additive. The future of this closely watched sweetener, however, is yet

<u>39</u>/ FDA Issues Questionnaire To Follow Up on Aspartame Complaints. Food Chemical News, Mar. 12, 1984. p. 13.

<u>40</u>/ Gejdenson, Sam. Aspartame: Not A Sure Bet. Remarks in the House of Representatives. Congressional Record, v. 129, Oct. 7, 1983. p. 4864.

^{38/} U.S. Dept. of Health and Human Services. Food and Drug Administration. Aspartame in Carbonated Beverages Questioned. FDA Talk Paper T84-4. Jan. 20, 1984.

A	PPENDIX 1. ASPARTAME: SELECTED CHRONOLOGY OF EVENTS
DATE	EVENT
1965	Aspartame discovered
1969 (Oct.)	Cyclamate banned
1973 (Mar.)	Searle files petition for approval of aspartame as food additive
1974 (July)	FDA approves aspartame as a food additive
1975 (Dec.)	FDA places stay on regulation allowing marketing of aspartame
1977 (July)	FDA proposes ban on saccharin
(Nov.)	Congress imposed 18 months moratorium against ban on saccharin
1978 (Dec.)	Study on Searle's research investigations confirms validity of experiments
1979 (June)	FDA established Public Board of Inquiry to examine aspartame issue
1980 (Oct.)	Public Board of Inquiry reports
1981 (July)	FDA approves aspartame for use in dry products
1983 (July)	FDA approves aspartame for use in carbonated beverages; Objections filed with FDA requesting stay on regulation allowing use in carbonated beverages and requesting public hearing
(fall)	First carbonated beverages with aspartame sold
(Oct.)	H.R. 4112 introduced to require Secretary of Health and Human Services to set maximum concentration levels for aspartame as a food additive
(Nov.)	FLA denies request to stay carbonated beverage regulation on aspartame
(Dec.)	Motion filed to compel FDA to hold public hearing
1984 (Jan.)	Motion filed to require FDA to stop all uses of aspartame and compel the agency to hold a public hearing
(Feb.)	Motion denied for lack of sufficient evidence FDA denies request for a public hearing; Court hearing on resubmitted motion for Temporary Restraining Order taken under advisement with ruling to be made sometime in the future
(Mar.)	FDA and CDC investigating reported cases of adverse effects from the consumption of aspartame Judge Parker rules U.S. district court has no jurisdiction in aspartame case.