

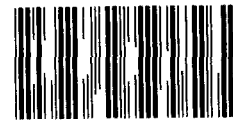
GAO

Briefing Report to the Honorable
Howard Metzenbaum
United States Senate

July 1986

FOOD AND DRUG ADMINISTRATION

Six Former HHS Employees' Involvement in Aspartame's Approval



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UNITED STATES GENERAL ACCOUNTING OFFICE

WASHINGTON, D.C. 20548

HUMAN RESOURCES
DIVISION

July 22, 1986

B-223552

The Honorable Howard Metzenbaum
United States Senate

Dear Senator Metzenbaum:

On May 23, 1985, you requested that we review the Food and Drug Administration's (FDA's) process for approving aspartame-- an artificial sweetener manufactured by G.D. Searle and Company. You identified a number of concerns about issues raised by an FDA task force, a panel of in-house scientists, and a Public Board of Inquiry relating to the quality and interpretation of Searle's animal tests on the safety of aspartame.

Your office requested that during our review, we obtain information on six former Department of Health and Human Services (HHS) employees, including (1) their contacts or involvement with Searle while employed by HHS and with FDA after they left their government positions and (2) their involvement in the FDA aspartame approval process. The employees were Robert Dormer, Sherwin Gardner, Arthur Hayes, M.D., Stuart Pape, Wayne Pines, and Howard Roberts, Ph.D. (App. I lists the positions these persons held during and after their employment with HHS.)

Your office also requested that we obtain information from the Department of Justice on former U.S. Attorney Samuel K. Skinner, including his contacts with Searle while a U.S. Attorney and his involvement in a 1977 Department of Justice investigation of Searle.

We agreed with your office to review and report on the former HHS employees before completing our work on the other matters contained in your letter. We did not develop information on Mr. Skinner or the Justice Department investigation of Searle because your office has initiated a separate investigation.

In doing our work, we reviewed available FDA files containing correspondence and memos (1) between FDA and Searle officials supporting FDA's decision to approve aspartame, (2) identifying meetings between FDA officials and persons outside the executive branch, and (3) disclosing employment histories and financial holdings of the six former HHS employees. We interviewed five of the six individuals regarding their roles in FDA's approval of aspartame and their postemployment activities relating to their contacts with FDA officials on aspartame. We also reviewed the federal standard-of-conduct regulations relating to postemployment activities of government employees. These regulations were discussed with HHS's Office of General Counsel, the Office of Government Ethics, and our Office of General Counsel.

Our review of available documentation showed that:

- Except for Mr. Dormer, the HHS employees were involved in the approval of aspartame.
- Of the five involved in aspartame's approval, all but Mr. Pines had contacts with Searle concerning aspartame while serving with the government. However, we believe the individuals carried out these contacts as part of their government duties, and our review of available personnel files and financial disclosure statements showed they had no financial interest in Searle while employed by HHS.
- All six individuals had contacts with FDA after leaving their government positions.
- Only Dr. Roberts, Mr. Pape, and Mr. Dormer have discussed aspartame with FDA since leaving the government. Although not requiring former government employees to decline employment with private organizations, federal postemployment regulations do place certain restrictions on such employees' contacts with their former agencies. As noted, Mr. Dormer was not involved in aspartame's approval; therefore, he is not restricted from discussing aspartame with FDA. Aspartame matters discussed at two meetings between Dr. Roberts, Mr. Pape, and FDA officials were, in our opinion, permissible under the postemployment statute because it allows former employees to inquire into the status of particular matters and to exchange factual information with government officials.

As arranged with your office, unless you publicly announce its contents earlier, we plan no further distribution of this briefing report until 30 days from its issue date. At that time, we will send copies to the Secretary of Health and Human Services, the Commissioner of FDA, the six former HHS employees discussed in this document, and other interested parties. We will also make copies available to others on request.

We plan to continue reviewing the FDA aspartame approval process and other matters identified in your request. If you have any questions or wish to discuss the information provided, please contact me on 275-6207.

Sincerely yours,

A handwritten signature in cursive script that reads "David P. Baine".

David P. Baine
Associate Director

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ABBREVIATIONS

FDA	Food and Drug Administration
HHS	Department of Health and Human Services

SIX FORMER HHS EMPLOYEES'

INVOLVEMENT IN ASPARTAME'S APPROVAL

We obtained information on six former Department of Health and Human Services (HHS) employees, including (1) their contacts or involvement with Searle while employed by HHS and with the Food and Drug Administration (FDA) after they left their government positions and (2) their involvement in the aspartame approval process. The employees were Robert Dormer, Sherwin Gardner, Arthur Hayes, M.D., Stuart Pape, Wayne Pines, and Howard Roberts, Ph.D. (App. I lists their positions during and after their employment with HHS.)

Aspartame--an artificial sweetener about 180 times as sweet as sugar--is a white, odorless, crystalline powder composed of 2 amino acids--L-aspartic acid and L-phenylalanine. G.D. Searle and Company developed aspartame in 1965. It was approved by FDA for use in dry foods in July 1981 and for use in carbonated beverages in June 1983.

SCOPE OF WORK

For the six former HHS employees, we obtained information from FDA's:

- Division of Management Services' chronological files on Searle for the period January 1964 to July 1985--nearly 2 years after Dr. Hayes' resignation as FDA Commissioner. This file includes correspondence and memos of meetings and telephone contacts between FDA and Searle officials on all Searle products regulated by FDA.
- Center for Food Safety and Applied Nutrition (formerly the Bureau of Foods) official files on aspartame. These files contain the animal and clinical tests submitted by Searle since 1969 on aspartame and correspondence relating to such tests.
- Docket Management Branch files on aspartame. This is the official file supporting FDA's decision to approve aspartame. It also contains information used by the Public Board of Inquiry, which was convened in January 1980 to hear objections on aspartame's use in dry foods.

--Public calendar from January 1, 1978,¹ to August 8, 1985. The public calendar is a record of meetings between FDA officials and persons outside the executive branch.

--Division of Human Resources Management files on post-employment activities of former employees. Except for former employees transferring within HHS, this office, since 1971, has annually surveyed former senior FDA employees within a year after they leave the agency to determine their place of employment.

In addition, for the six former HHS officials, we reviewed personnel files and available financial disclosure statements² for the period of their HHS employment (see app. I) to determine their places and dates of employment, government positions, and financial holdings. We also obtained and reviewed former Commissioner Hayes' appointment calendar, as kept by his staff assistant, for his term (from Apr. 13, 1981, to Sept. 3, 1983) and his telephone log from July 1982 to September 1983. The staff assistant could not locate the telephone log for the period before July 1982. The log included only calls that Dr. Hayes was to return.

We interviewed Dr. Roberts, Mr. Pape, and Mr. Dormer regarding their roles in FDA's approval of aspartame and their postemployment activities relating to their contacts with FDA officials on aspartame. As requested by Senator Metzenbaum's office, we asked Dr. Roberts and Mr. Pape to provide copies of all their communications with FDA since leaving the agency and with their current employers while they were with FDA. We also asked Mr. Pape to provide copies of all of his communications concerning aspartame or with Searle since he joined Patton, Boggs, and Blow. Both declined to provide the documents, citing the extensive resources needed to comply with the request and the availability of many of these documents in FDA's files. In addition, Mr. Pape said that copies of communications since he joined Patton, Boggs, and Blow could not be made available to us because of the attorney/client relationship. As discussed with your office, we also asked Mr. Pape and Dr. Roberts the reasons why (1) the National Soft Drink Association drafted a letter

¹We reviewed the public calendar to identify meetings between the six former employees and FDA. The first of the six employees left FDA in 1978.

²HHS retains financial disclosure statements for 6 years. Robert Dormer and Howard Roberts resigned from their government positions in March 1979 and October 1978, respectively. Therefore, their financial statements had been destroyed.

raising concerns with FDA's approval of aspartame in carbonated beverages and (2) the Association decided to not send the letter to FDA.

In addition, we reviewed the information on Mr. Pines and Dr. Hayes given to you in August 1985 by Burson-Marsteller, a public relations firm employed by Searle. According to this information, Mr. Pines works for, and Dr. Hayes acts as a consultant to, Burson-Marsteller. We have not, nor do we plan to, interview Mr. Pines because the information provided to your office indicates that he had only limited involvement in the approval of aspartame. We interviewed Dr. Hayes and Mr. Gardner on their postemployment activities relating to their contacts with FDA officials on aspartame and discussed with them specific issues relating to their involvement with the approval of aspartame.

To identify possible postemployment regulation violations, we reviewed the federal standard-of-conduct regulations for government employees, and we talked with officials from HHS's Office of General Counsel, the Office of Government Ethics, and our Office of General Counsel. We also interviewed FDA officials identified by the Senator's office to (1) determine Dr. Hayes' postemployment contacts relating to aspartame and (2) clarify discussions between Dr. Roberts, Mr. Pape, and FDA officials.

FEDERAL POSTEMPLOYMENT RESTRICTIONS

The postemployment statute, 18 U.S.C. 207, was enacted in 1962 and amended by the Ethics in Government Act of 1978. The act's purpose is to preserve and promote public confidence in the integrity of federal officials through financial disclosure, postemployment restrictions, and independent investigations of alleged wrongdoing by government officials.

The statute places four basic restrictions on postemployment activities of government employees. These restrictions limit the activities of former government employees but do not require former employees to decline employment with private organizations.

The following two restrictions, in effect since 1963, apply to all former government employees. The statute:

- Permanently bars former employees from acting as another person's representative to the government in a particular matter involving specific parties in which they participated personally and substantially as a government employee (18 U.S.C. 207(a)).
- Prohibits, for 2 years, former employees from acting as another person's representative to the government in a particular matter involving specific parties for which

they had official responsibility within their last year of government service (18 U.S.C. 207(b)(i)).³

The other two restrictions, added by the 1978 Ethics in Government Act and implemented in 1979, apply to former "senior" employees. This designation includes (1) those who are paid at rates of the executive schedule and (2) those in the Senior Executive Service or paid at rates equal to or greater than GS-17 who have not been exempted on the basis that they lack significant decision-making or supervisory responsibilities. The statute:

--Prohibits former senior employees, for 2 years, from assisting in representing another person to the government by personal presence in a particular matter involving specific parties in which they had participated personally and substantially as a government employee (18 U.S.C. 207(b)(ii)).

--Prohibits former senior employees, for 1 year, from appearing before their former agency or, with intent to influence, making a written or oral communication to their former agency on any matter pending before or of interest to the agency (18 U.S.C. 207(c)).

Of the six former HHS employees, only Dr. Hayes and Mr. Pines are covered by the latter two restrictions. The positions held by former FDA Deputy Commissioner Sherwin Gardner and former Bureau of Foods Deputy Director Howard Roberts have now been designated as senior employee positions. The designation for the FDA Deputy Commissioner position became effective February 28, 1980, and the designation for the Bureau of Foods Deputy Director position became effective November 14, 1980 (5 C.F.R. 727). Neither former employee is subject to the senior employee restrictions since the designation took effect, respectively, 2-1/2 months after Mr. Gardner resigned and 25 months after Dr. Roberts resigned. The positions held by the two other former employees were not designated as "senior employee" positions.

INFORMATION OBTAINED ON FORMER HHS EMPLOYEES

Our review of FDA's files disclosed that Dr. Hayes, Mr. Gardner, Dr. Roberts, and Mr. Pape had 25 contacts with Searle officials while working for HHS (see app. II). We believe these contacts were carried out as part of their official duties as government employees. We did not identify any contacts with Searle by Mr. Dormer or Mr. Pines.

³Before July 1, 1979, the prohibition on former government employees acting as another person's representative was limited to 1 year.

These 25 contacts between the four employees and Searle included discussions concerning the approval of aspartame's use in dry foods, correspondence regarding a contract for a third-party review of Searle's animal tests on aspartame, telephone contacts to discuss procedural requirements for the Public Board of Inquiry on aspartame, and meetings between FDA and Searle officials to discuss the delay in FDA's approval of aspartame in soft drinks. In our review of former Commissioner Hayes' phone log and appointment calendar, we found no indications of phone contacts with Searle, and the only meeting with Searle identified in his appointment calendar was included in FDA's public calendar, as required by FDA staff guidelines.

Information we obtained showed that, except for Mr. Dormer, all the individuals were involved in the approval of aspartame and all have had contacts with FDA since leaving their government positions. According to FDA records, of the individuals involved in the approval of aspartame, Mr. Pape and Dr. Roberts, after leaving HHS, had two contacts with FDA relating to aspartame, as discussed below. Since both were involved in issues relating to aspartame's approval while employed by HHS, Mr. Pape and Dr. Roberts are subject to the lifetime ban of 18 U.S.C. 207(a) relating to that same matter (see p. 7).

An FDA memorandum of a January 27, 1984, meeting indicates that Mr. Pape and Dr. Roberts met with FDA officials to discuss the status of a number of projects involving both artificial and natural sweeteners. The discussion on aspartame related to the status of a court hearing on aspartame and information that the state of Arizona was going to begin collecting and analyzing products containing aspartame for methanol content. Two current FDA employees present at the meeting stated that (1) there was no attempt by Dr. Roberts or Mr. Pape to get FDA involved in state matters and (2) the content of FDA's response to the court hearing was not disclosed.

On August 15, 1984, Mr. Pape and Dr. Roberts again met with FDA officials. The FDA memorandum of this meeting indicates that the labeling of sweetener ingredients on food products was discussed. Aspartame was mentioned as an example of an artificial sweetener, but the discussion centered on specifying the precise sweetener ingredients (such as sugar and corn syrup) on food labels. A current FDA employee present at this meeting confirmed that aspartame might have been mentioned at this meeting but was not discussed. These meetings took place 7 months and 14 months after aspartame was approved for use in carbonated beverages.

In our opinion, the above meetings, in which aspartame was discussed, were permissible under the postemployment regulations because the regulations allow questions on the status of particular matters and the exchange of factual information. The

postemployment statute's implementing regulations (5 C.F.R. 737.5(b)(5)(1985)) provide:

". . . Communications which do not include an 'intent to influence' are not prohibited. Moreover, acting as agent or attorney in connection with a routine request not involving a potential controversy is not prohibited. For example, the following are not prohibited: a question by an attorney as to the status of a particular matter; a request for publicly available documents; or a communication by a former employee, not in connection with an adversary proceeding, imparting purely factual information."

Information about each former employee is summarized below.

Dr. Hayes

In July 1981, former FDA Commissioner Hayes approved the use of aspartame in dry foods. Dr. Hayes served as Commissioner from April 1981 to September 1983. After he resigned as Commissioner, he was the Provost and Dean of the New York Medical College until July 1986 when he became the President of E.M. Pharmaceutical, a division of E.M. Industries. During this time, he was also a Senior Scientific Consultant with Burson-Marsteller. According to documentation provided by Burson-Marsteller, Dr. Hayes has not consulted with Searle through Burson-Marsteller. Dr. Hayes advised us that he has never been asked by Burson-Marsteller to provide consulting services to Searle and before becoming FDA Commissioner he did not perform any services for Searle. Dr. Hayes added that he has met only once with Searle officials; the meeting, in 1983 while he was still FDA Commissioner, was attended by both FDA and Searle officials to discuss FDA's decision relating to aspartame's use in soft drinks. This meeting was recorded in FDA's Public Calendar (see p. 6).

We found no record of Dr. Hayes contacting FDA after he resigned as Commissioner in September 1983. In this regard Dr. Hayes advised us that he has not represented Searle or any manufacturer before FDA, nor has he discussed aspartame with any FDA officials since he resigned as Commissioner. Current FDA officials confirmed that Dr. Hayes has not discussed aspartame with them since he resigned. Other than his meeting with us on May 9, 1986, Dr. Hayes stated that he has not discussed aspartame with anyone.

Sherwin Gardner

Mr. Gardner served as FDA's Deputy Commissioner between October 1973 and December 1979, and as Acting Commissioner at various times. He signed the initial approval for aspartame's

use in dry foods in July 1974,⁴ and selected the panel members for the Public Board of Inquiry on aspartame.

FDA records indicated that Mr. Gardner resigned from FDA in 1979 and became a Vice President with Grocery Manufacturers of America, Inc. As that organization's representative, Mr. Gardner has met with FDA officials 20 times. None of these meetings were identified as pertaining to aspartame. Although four of these meetings occurred within a year of his resignation, Mr. Gardner was not subject to the 1-year no-contact ban of 18 U.S.C. 207(c) since he resigned before February 28, 1980, the effective date of the senior employee designation of his former position (see p. 8). Mr. Gardner's contacts with FDA during the year after his resignation pertained to freedom of information requests and a request for an FDA speaker at a Grocery Manufacturers of America seminar. Mr. Gardner advised us that he has not discussed aspartame with any FDA official since he resigned.

Stuart M. Pape

Mr. Pape served as HHS's Associate Chief Counsel for Foods from October 1976 to March 1979 and as a Special Assistant to the FDA Commissioner from March to December 1979. Mr. Pape said that while with FDA, he participated in general meetings and/or discussions on aspartame and the Public Board of Inquiry. Mr. Pape currently works for the law firm of Patton, Boggs, and Blow and, in this capacity, has provided counsel to the National Soft Drink Association. Mr. Pape drafted the Association's letter opposing the approval of aspartame in soft drinks but said the letter was never sent because the Association resolved the concerns expressed in the letter.

FDA records indicated that Mr. Pape met with FDA officials 10 times since he resigned; the first meeting was almost 3 years after he left FDA. At two meetings (Jan. 27 and Aug. 15, 1984), aspartame was discussed. These meetings are discussed on page 9.

Dr. Howard R. Roberts

In January 1972, Dr. Roberts started at FDA in the Division of Mathematics in the Bureau of Foods and also served in the Bureau's Office of the Director. In 1975 he became the Deputy Director, Bureau of Foods, and also served as Acting Director of the Bureau. He was involved in a number of issues

⁴On December 5, 1975, the regulation approving the use of aspartame in dry foods was suspended because of discrepancies in Searle's data and research summaries submitted to FDA. The use of aspartame in dry foods was re-approved on July 18, 1981.

concerning aspartame's approval, including the Public Board of Inquiry and a review of Searle studies by the Universities Associated for Research and Education in Pathology. When he left FDA in 1978, he became the Vice President for Science and Technology for the National Soft Drink Association.

FDA records indicated that he met with FDA officials nine times since he resigned; the first meeting took place 3 years after he left FDA. At two meetings (Jan. 27 and Aug. 15, 1984), also attended by Mr. Pape, aspartame was discussed. These meetings are discussed on page 9.

Wayne L. Pines

In 1972, Mr. Pines started as a publications officer at FDA and became Associate Commissioner for Public Affairs in 1979. In correspondence to the Senator's office, Mr. Pines said his only involvement with aspartame while he was with FDA was that his office announced its approval for use in dry foods in 1981. In 1982, Mr. Pines transferred to the National Institute of Mental Health and about a year later resigned from government service. Mr. Pines now works for Burson-Marsteller. Mr. Pines said he has only peripherally participated in the Searle account while at Burson-Marsteller and he recruited Dr. Hayes as a consultant. FDA records indicated that Mr. Pines met with FDA officials twice since he left government service in 1983. Neither meeting was identified as pertaining to aspartame, and both took place over a year after his leaving the National Institute of Mental Health.

Robert A. Dormer

From 1976 to 1979, Mr. Dormer was employed as a trial attorney in HHS's Food and Drug Division. Mr. Dormer said he had no involvement with aspartame or Searle while with HHS. Mr. Dormer worked for the law firm of Rogers, Hoge, and Hills for about a year and now is employed by the law firm of Hyman, Phelps, and McNamara--which provides legal advice to Searle. One of the partners, Mr. James Phelps, was the former General Counsel for Searle. While with Hyman, Phelps, and McNamara, Mr. Dormer became involved as Searle's legal representative in the Community Nutrition Institute's suit for a hearing in the U.S. court of appeals on aspartame's approval in soft drinks.⁵ FDA records indicated that Mr. Dormer has met with FDA officials four times since he resigned; two meetings pertained to the Community Nutrition Institute's suit, and the other two did not pertain to aspartame or Searle.

⁵Community Nutrition Institute, et al., Petitioners v. Dr. Mark Novitch, Acting Commissioner, Food and Drug Administration, Respondent G.D. Searle and Co., Intervenor, No. 84-1153, U.S. Court of Appeals.

SUMMARY OF EMPLOYMENT
OF FORMER HHS EMPLOYEES

	<u>Tenure</u>	
	<u>From</u>	<u>To</u>
<u>Arthur H. Hayes, Jr., M.D.</u>		
Commissioner, FDA	Apr. 1981	Sept. 1983
Provost and Dean of the New York Medical College	Sept. 1983	July 1986
President, E.M. Pharmaceutical, A Division of E.M. Industries	July 1986	Present
Senior Scientific Consultant, Burson-Marsteller	Nov. 1983	Present
<u>Sherwin Gardner</u>		
Commissioners' Office	Oct. 1970	Mar. 1973
Acting Commissioner, FDA	Mar. 1973	July 1973
Commissioner's Office	July 1973	Oct. 1973
Deputy Commissioner, FDA	Oct. 1973	Dec. 1976
Acting Commissioner, FDA	Dec. 1976	Apr. 1977
Deputy Commissioner, FDA	Apr. 1977	Dec. 1979
Vice President, Science and Technology, Grocery Manufacturers of America	Dec. 1979	Present
<u>Stuart Pape</u>		
Attorney, Office of General Counsel, HHS	Aug. 1974	Mar. 1979
Special Assistant to the Commissioner, FDA	Mar. 1979	Dec. 1979
Patton, Boggs, and Blow (Attorneys at Law)	Dec. 1979	Present
<u>Howard Roberts, Ph.D.</u>		
Division of Mathematics, Bureau of Foods, FDA	Jan. 1972	Mar. 1974
Office of the Director, Bureau of Foods, FDA	Mar. 1974	Nov. 1975
Deputy Director, Bureau of Foods, FDA	Nov. 1975	Oct. 1978
Vice President for Science and Technology, National Soft Drink Association	Oct. 1978	Present

	Tenure	
	<u>From</u>	<u>To</u>
<u>Wayne L. Pines</u>		
Publications Officer, FDA Product Safety Letter, Inc. (a weekly newsletter)	Feb. 1972	Nov. 1974
Public Information Officer, FDA	Nov. 1974	July 1975
Associate Commissioner for Public Affairs, FDA	July 1975	Apr. 1979
Special Assistant to the Director, National Institute of Mental Health, HHS	Apr. 1979	May 1982
Burson-Marsteller	May 1982	Apr. 1983
	Apr. 1983	Present
<u>Robert A. Dormer</u>		
Trial Attorney, Food and Drug Division, Office of General Counsel, HHS	Oct. 1976	Mar. 1979
Rogers, Hoge, and Hills, Attorneys at Law	Mar. 1979	Mar. 1980
Hyman, Phelps, and McNamara, Attorneys at Law	Mar. 1980	Present

CONTACTS BETWEEN FORMER HHS
EMPLOYEES AND SEARLE OFFICIALS

FDA records showed the following contacts between the six former HHS employees and Searle officials while the former employees served in government positions.

- On July 3, 1974, former Deputy Commissioner Gardner, Dr. Roberts, and four other FDA employees (including former Commissioner Alexander Schmidt) met with two Searle officials to discuss the status of the aspartame approval for dry foods.
- On July 11, 1974, Dr. Roberts and another FDA official talked with a Searle official to inform him that aspartame would be approved in dry foods.
- On April 25, 1975, Dr. Roberts and two other Bureau of Foods officials met with two Searle officials and a General Foods official to discuss animal studies on a breakdown product in aspartame.
- On November 10 and 19, 1975, Dr. Roberts talked to a Searle official about the status of a hearing requested by objectors to aspartame's approval in dry foods.
- On February 12, 1976, Dr. Roberts and one other FDA official met with two Searle officials to discuss the status of an FDA investigational review of aspartame tests.
- On August 4, 1976, Searle representatives met with Mr. Pape, Dr. Roberts, and eight other FDA employees to discuss the third-party review of Searle's animal studies.
- On January 5, 1977, former Acting Commissioner Gardner wrote to Searle regarding a contract for a third-party review of Searle's animal tests on aspartame.
- On February 1, 1977, Searle wrote to former Acting Commissioner Gardner and on February 10, 1977, former Acting Commissioner Gardner wrote to Searle regarding "leaks" of information on the negotiations for a third-party review of Searle's tests on aspartame.
- On July 8, 1977, Dr. Roberts met with a Searle official to discuss the status of contract negotiations for a third-party review of aspartame tests.

- On July 28, 1977, a Searle official called Dr. Roberts to set up a meeting to discuss the contract for a third-party review of aspartame tests.
- On August 4, 1977, Dr. Roberts and four other FDA officials met with two Searle officials and three officials from Universities Associated for Research and Education in Pathology, Inc., to discuss a contract for a third-party review of aspartame tests.
- On March 3, 1978, Dr. Roberts and three other FDA officials met with three Searle officials and three officials from the organization conducting the third-party review of tests on aspartame, to discuss the status of that review.
- On July 3 and 12, 1979, a Searle lawyer called Mr. Pape to discuss procedural requirements for a Public Board of Inquiry on aspartame.
- On July 25, 1979, former Acting Commissioner Gardner wrote to Searle regarding procedures for selecting the members of the Public Board of Inquiry.
- On July 31, 1979, former Acting Commissioner Gardner wrote to Searle to inform it of the status of the selection of board members for the Public Board of Inquiry.
- On September 13, 1979, a Searle official wrote to Acting Commissioner Gardner and others involved in the Public Board of Inquiry concerning the selection of Board members.
- On October 19, 1979, former Acting Commissioner Gardner responded to Searle's September 28, 1979, letter regarding procedural matters for the Public Board of Inquiry.
- On August 6, 1982, Searle wrote to former Commissioner Hayes about an inaccuracy regarding aspartame's approval in an FDA letter to a private organization, and on October 13, 1982, former Commissioner Hayes responded to Searle's letter.
- On June 13, 1983, former Commissioner Hayes and five other FDA officials met with Searle officials to discuss the delay in FDA's decision relating to the use of aspartame in soft drinks.

--On June 17, 1983, Searle wrote to former Commissioner Hayes to thank him for meeting with them on June 13 and to ask again that a decision be made soon on aspartame's use in soft drinks.

(108872)

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