

October 30, 2009: Over 8 years ago I spoke to Jerome Bressler and thanked him for speaking out in this report. He told me the report was worse than what I had read because when the FDA had retyped it they left out the worst 20%, two mouse studies, and a cover letter. Doctors H. J. Roberts and Russell Blaylock both spoke to Bressler and got the same information.

Dr. Roberts wrote his Senator, Bill Nelson on November 27, 2001 stating that important information had been withheld. He said, "Specifically, I need original copies of the two (2) mouse studies done at Searle Laboratories, which were reviewed by the inspection team of the Chicago District of the Center for Food Safety & Applied Nutrition between April – September 1977.

Jane Kirby for Melinda Plaisier, Associate Commissioner for Legislation wrote Senator Bill Nelson on April 18, 2002 and said: "Additionally, some documents are considered confidential under FDA's FOI regulations and in some instances the Agency cannot acknowledge the existence of such documents."

The rest of the Bressler Report was kept under FDA seal for 3 decades. The investigation of these studies was the epitome of other Searle studies, sloppy, inefficient and never showed safety. The Bressler Report itself is revealing the things that Searle did so the FDA would not find out how unsafe aspartame is. They not only filtered out neoplasms but even excised brain tumors from rats, putting them back in the study and then resurrecting them on paper when they died. The report found that 98 of the 196 animals died during one of Searle's studies and weren't autopsied until later dates, in some cases over one year after they died. Records for approximately 30 animals showed substantial differences between original observations on pathology sheets and the observations on pathology sheets submitted to the FDA. There were numerous other inconsistencies. A uterine polyp and ovarian neoplasms were found in animals but not reported or diagnosed in Searle's reports. The FDA investigators found dose-related uterine polyps in 15% of 34 animals.

It was obvious even with fraud aspartame couldn't be proven safe and on January 10, 1977 in a 33 page letter, FDA Chief Counsel Richard Merrill recommended to U.S. Attorney Sam Skinner that a grand jury investigate Searle for "apparent violations of the Federal Food, Drug and Cosmetic Act, 21 USC 331 (e), and the False Reports to the Government Act, 18 U.S.C. 1001, for "their willful and knowing failure to make reports to the Food and Drug Administration required by the Act, 21 USC 355 (i) and for concealing material facts and making false statements in reports of animal studies conducted to establish the safety of (aspartame)."

U.S. Prosecutor Sam Skinner as well as William Conlon hired on with the defense team and the statute of limitations expired.

Finally in 1980 the FDA Board of Inquiry revoked the petition for approval which would have been signed into law if Searle had not sued. Donald Rumsfeld, CEO of Searle, hired to get aspartame approved, was on Reagan's transition team. FDA Commissioner Jere Goyan at 3:00 AM was called by a member of the transition team and fired. Reagan wrote an Executive Order making the FDA powerless to do anything about aspartame including signing the revoked petition into law until he could get Arthur Hull Hayes there as the new FDA Commissioner to over-rule the Board of Inquiry. Then the Executive Order was expunged from the record, which is illegal. This is mentioned in the movie, Sweet Misery: A Poisoned World, [www.soundandfury.tv](http://www.soundandfury.tv)

So science never proved aspartame safe. It proved only fraud. But you hear the manufacturer constantly claiming there were 200 studies that proved safety. Informants say when Rumsfeld came to work for Searle people working there and knowing what was going on were fired and the studies were removed.

Jan Marie Kinnard, wrote in Feb, 2008 that she was the one who was hired to shred the Searle studies, and send a copy to France. She said: "They were the lab results from the tested rats and other animals. The results were outrageous. This stuff killed everything it touched."

The investigation of the two mouse studies the FDA did not want the public to read was kept from the record all these years. I even wrote FDA Freedom of Information and was told too it was confidential. When I stated it was not confidential but a matter of public record I was told that the information had been destroyed.

[http://www.mpwhi.com/fda\\_gate.htm](http://www.mpwhi.com/fda_gate.htm)

Fortunately Dr. John Olney back in the 1970's had been able to get a copy of the deleted information and still had these records, which are now scanned in below to complete the Bressler Report. In one conversation with Jerome Bressler he said even Dr. Collins, chief FDA scientist's signature had been deleted from the report. He said the Bressler Report was not complete without it. An attempt to get Dr. Collins to speak on the subject was unsuccessful.

So below you will see the rest of the report and understand these mouse studies are just representative of the way Searle did studies, and there is no way for aspartame to ever be proven safe.

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[www.mpwhi.com](http://www.mpwhi.com), [www.dorway.com](http://www.dorway.com) and [www.wnho.net](http://www.wnho.net)  
Aspartame Toxicity Center, [www.holisticmed.com/aspartame](http://www.holisticmed.com/aspartame)

The missing 20% has been added to the end of  
the Report.

DW #50

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ESTABLISHMENT INSPECTION ENDORSEMENT		Page	of	Page
1. ESTABLISHMENT	a. ESTABLISHMENT NAME Searle Laboratories Div. of G.D. Searle & Co.	b. DISTRICT Chicago	c. CENTRAL FILE NO.	
	d. ESTABLISHMENT ADDRESS (Include Zip Code, Area Code and Telephone No.) 4901 Searle Parkway Skokie, IL 60576		e. DATE INSPECTED 4/25/77-8/A/	
2. ROUTING	a. HEADQUARTERS UNIT TO WHICH REFERRED (Use organizational symbol) Bureau of Foods, HFF-330 Attn: Mr. Richard Ronk	HEADQUARTERS USE ONLY c. DATE REFERRED PROFILE NOT NEEDED BY <i>HR</i> DATE 8-1		
	b. REASON FOR REFERRAL To Be Reviewed by the Bureau of Foods	d. AF NUMBER		
3. DISTRICT REMARKS	a. DISTRICT ENDORSEMENT  This top priority investigation was made to compare all available raw and summary data, along with all related material including methodologies, against the FDA submission. This inspection covers one study.  E-77/78 (P.T. 988573), SC-19192: 115 Week Oral Tumorigenicity Study in the Rat - Diketopiperazine  Study E-77/78 was initiated on November 8, 1971. The FDA submission is dated September 1974.  Three hundred and sixty weanling albino rats, Charles River CD strain, 130 of each sex, were used. The rats were divided into twelve housing groups, (six groups per sex), thirty rats in each housing group. Each housing group was composed of a random distribution of Control, Low, Mid, and High Dose animals. The rats were fed Diketopiperazine (SC-19192) at 0, 0.75, 1.5, and 3.0 grams per kilogram of body weight per day respectively  Our investigation of this study shows that no homogeneity tests were performed on any batches of the diet. We found evidence that the diets were not homogeneous.  Two unidentified infectious disease outbreaks were reported in the FDA submission. In both instances the control and treated animals were reportedly affected with equal frequency and severity. All morbid rats were injected with potassium penicillin G. Our review of the records show a third occurrence of infectious disease and penicillin administration took place, which was not reported in the submission to FDA.  We found an additional polyp of the uterus in the mid dose group which was not diagnosed or reported in the submission			
	b. REVIEWING OFFICER (Name and title) Jerome Bressler	c. SIGNATURE <i>Jerome Bressler</i>	d. DATE 8/7/77	
c. DISTRIBUTION C: CHI-DO CC: HFF-330, HFF-1, HFO-1, HFA-224, HFR-5140				

ENDORSEMENT  
4/25/77 to 8/4/77  
JSA/DME/JT/LF

-2-

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by Searle. The finding of one additional uterine polyp increases the incidence in the mid dose to 5 polyps of 34 animals (15%). The incidence of polyps of the uterus appears to be dose related.

Serum cholesterol determinations were done at days 796 and 798 (terminal bleeding), but not included in the submission to FDA. The submission reported a significant decrease in serum cholesterol that was more perceptible toward the end of the study and may have been dose related. Therefore, the exclusion of data from days 796 and 798 could be significant.

In some instances raw data was not available for review especially in the areas of clinical chemistry and microscopic pathology. In other instances there were inconsistencies in the raw data making it difficult to authenticate the study. As the investigation proceeded we learned that not all of the data was under seal. We discovered a number of documents. It is quite probable that there are still some laboratory notebooks missing. The majority of the responsible individuals that worked on this study are no longer with Searle.

FOLLOW-UP: To be reviewed by the Bureau of Foods

4/25/77 to 8/4/77

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SUMMARY OF FINDINGS

Authentication of this study was performed primarily by comparing available raw data with the submission to FDA. This was a problem, at times, due to the lack of some data and difficulty in locating other material. The majority of material relating to Aspartame was already under FDA seal at Searle. However, during this investigation we discovered various documents and notebooks that were not.

In some cases original data could be recorded in several areas, making it difficult, and sometimes impossible to determine which was actually the original. This was a particular problem in dealing with dates of deaths, as some conflicted on the "source" documents. Many of the responsible individuals involved with the study, including stability testing of DKP, are no longer employed by Searle. Dr. K.S. Rao, Study Monitor, the only individual who could have possibly answered some questions, had left Searle. He was contacted, but permission for an interview was refused by his attorney. Due to the absence of various individuals it was not always possible to accurately determine methods used in some analyses and operations carried out in conducting this study. In a number of areas, including chemistry, statistics, diet preparation and feeding, it was necessary to use assumptions, or information supplied by current employees who were not involved with the study.

At the beginning of this investigation, Mr. James R. Phelps, Vice-President and General Counsel for G.D. Searle & Co., advised us that an attorney and scientific coordinator would have to be present at all times to protect their interest in the data. This did not present any insurmountable problems, but on several occasions an attorney would question our request for data, stating that it was not relevant for authentication. At no time did we make any statement to the effect that our goal was to authenticate the study. Two memos were discovered dealing with reaction of animals to the diet. This was a significant factor in the study. Permission to copy them was initially refused, but finally granted after Searle was contacted by FDA General Counsel. We were not allowed to make xerox copies of any documents for about two and one-half weeks, due to Searle's concern over confidentiality. This was eventually reconciled between Searle and FDA General Counsel.

The major discrepancies concerning Study PT 988S73, SC-19192: 115 Week Oral Tumorigenicity Study in the Rat, are as follows:

A. Design & Conduct of Study

- 1) Control and treated animals were randomly distributed on the same rack. (See diagram of housing group attached as exhibit 7.)
- 2) No ear clips or other methods of uniquely identifying each animal were used. Identification consisted of two types of cards attached to the front of each cage.
- 3) Compound inventory cards were deficient in that only one of 18 such cards stated the purpose (study 988S73) for withdrawing the compound from inventory. Three of the cards did not include the date withdrawn, amount withdrawn, or signature of requestor. Therefore it was impossible to reconcile the amount withdrawn and the amount used. (See exhibit #28.)
- 4) Food jars were not individually identified, yet all the filled jars for a given housing group (control, low, mid, and high dose) were placed on a mobile cart, which was wheeled to the housing rack. The position of the jar (in rows) on the cart was the only means of identifying the proper dose level. The arrangement of the food cups on the cart is shown in exhibit #8.
- 5) A total of 79 "observations for drug effects" records were not signed or initialed.
- 6) Observation records indicated that animal A23LM was alive at week 88, dead from week 92 through week 104, alive at week 108, and dead at week 112.
- 7) Records indicated that at the scheduled 104 week bleeding, animal E2CM was substituted for AllCM. Records also indicated that animal AllCM was alive on this date and therefore should have been bled as scheduled.
- 8) Records indicated that penicillin was administered to four rats beginning on May 16, 1973, and continuing daily through May 28, 1973. This third occurrence of infectious disease and penicillin administration was not reported in the submission to FDA.

- 9) In many cases the actual number of tissues embedded was less than the 24 (control and high dose) or 19 (low and mid dose) specified in the final histology lab protocol dated 1/21/74.
- 10) Ophthalmoscopic examination records were present for animals H26MF and J29CM, yet the findings were not reported in the submission to FDA. Two other discrepancies of this type were noted.
- 11) Records indicate that a tissue mass measuring 1.5 X 1.0 cm was excised from animal B3HF on 2/12/72, and that a "skin incision over mass" was performed on animals C22LM and G25LM on Feb. 10, 1972.

B. Stability and Homogeneity of DKP in Diet Mixture

- 1) There were no batch records to show the quantities of DKP and basal diet weighed, type of mixer used, mixing time, dates, or names of individuals performing the weighing and blending operations.
- 2) There was no evidence that any tests had been done to determine the blending characteristics of the mixer, or to validate the mixing time.
- 3) No homogeneity tests were performed on any batches of diet used in the study, and two stability study assay reports (A7738) and A7739) indicated that samples were not homogeneous. (See exhibit #29.)
- 4) A stability study was conducted with DKP in 1972. However, the 115 week rat study employed Basal Diet from week 62 to its conclusion, and no stability studies had been conducted with Basal Diet.
- 5) Methods of assay for DKP in the diet were deficient in that: The titration method was discontinued after 1 week of the stability study. Some of the TLC photographs showed no DKP reference standards and photographs also showed that there was something in the basal diet itself producing a spot on the TLC plate which had an Rf value corresponding to DKP. Only one solvent system was used for development of the TLC Plates. Some of the chromatograms showed poor separation.

