DOCUMENT LIST

1965: NUTRASWEET (ASPARTAME) DISCOVERED.

MARCH 5, 1973: SEARLE FILES PETITION FOR APPROVAL OF (NUTRASWEET) AS FOOD ADDITIVE.

JULY 16, 1974: FDA APPROVES NUTRASWEET AS FOOD ADDITIVE.

JULY 23, 1975: FDA ESTABLISHES SEARLE INVESTIGATION TASK FORCE TO EXAMINE CERTAIN ANIMAL STUDIES CONDUCTED BY SEARLE, INCLUDING TESTS ON NUTRASWEET.

DECEMBER 5, 1975: BEFORE NUTRASWEET COMES ON THE MARKET, FDA STAYS ITS APPROVAL "BASED ON THE COMMISSIONER'S CONCLUSION IN JULY, 1975 THAT THE INTEGRITY OF CERTAIN ANIMAL STUDIES CONDUCTED BY SEARLE WAS QUESTIONABLE." (DOC # 1, PG. 18)

MARCH 24, 1976: FDA'S SEARLE TASK FORCE OFFICIALLY REPORTS. CONCLUSIONS INCLUDE:

> "AT THE HEART OF FDA'S REGULATORY PROCESS IS ITS ABILITY TO RELY UPON THE INTEGRITY OF THE BASIC SAFETY DATA SUBMITTED BY SPONSORS OF REGULATED PRODUCTS. OUR INVESTIGATION CLEARLY DEMONSTRATES THAT, IN THE G.D. SEARLE COMPANY, WE HAVE NO BASIS FOR SUCH RELIANCE NOW." (DOC # 2, PG. 1)

"WE HAVE NOTED THAT SEARLE HAS NOT SUBMITTED ALL THE FACTS OF EXPERIMENTS TO FDA, RETAINING UNTO ITSELF THE UNPERMITTED OPTION OF FILTERING, INERPRETING, AND NOT SUBMITTING INFORMATION WHICH WE WOULD CONSIDER MATERIAL TO THE SAFETY EVALUATION OF THE PRODUCT. SOME OF OUR FINDINGS SUGGEST AN ATTITUDE OF DISREGARD FOR FDA'S MISSION OF PROTECTION OF THE PUBLIC HEALTH BY SELECTIVELY REPORTING THE RESULTS OF STUDIES IN A MANNER WHICH ALLAYS THE CONCERNS OF QUESTIONS OF AN FDA REVIEWER." (DOC # 2, PG. 1)

THE TASK FORCE AUDITED 25 SEARLE STUDIES, 11 OF WHICH WERE ON NUTRASWEET.

REPORT INCLUDED A RECOMMENDATION THAT THE FDA ASK THE U.S. ATTORNEY IN THE NORTHERN DISTRICT OF ILLINOIS TO INSTITUTE GRAND JURY PROCEEDINGS "UTILIZING COMPULSORY PROCESS IN ORDER TO IDENTIFY MORE PARTICULARLY THE NATURE OF VIOLATION AND TO IDENTIFY ALL THOSE RESPONSIBLE FOR SUCH VIOLATIONS." (DOC # 2, PG. 10)

APRIL 7, 1976: FDA WRITES TO U.S. ATTORNEY SKINNER CITING ITS TASK FORCE INVESTIGATION OF TESTS ON A NUMBER OF SEARLE FOOD ADDITIVES AND DRUGS. SKINNER IS INFORMED THAT FDA WANTS A GRAND JURY EMPANELED "TO INQUIRE INTO THE CAUSES AND SIGNIFICANCE OF THE DISCREPANCIES IN ANIMAL TEST DATA SUBMITTED IN SUPPORT OF SEARLE PRODUCTS." FORMAL REQUEST FOR GRAND JURY TO FOLLOW. (DOC # 3)

APRIL, 1976: SKINNER ASSIGNS BILL CONLON AND FRED BRANDING TO SEARLE INVESTIGATION. BILL CONLON WAS SKINNER'S DEPUTY CHIEF IN THE CIVIL DIVISION. BRANDING, AN ASSISTANT U.S. ATTORNEY, WAS CONLON'S SUBORDINATE.

APRIL 15, 1976: BRANDING TO SKINNER. SEARLE HAS PROPOSED A MEETING WITH JUSTICE IN WASHINGTON "REGARDING THE FDA REFERRAL FOR CRIMINAL INVESTIGATION OF THE G.D. SEARLE COMPANY." BRANDING REQUESTS AUTHORIZATION TO ATTEND. (DOC # 4)

OCTOBER 20, 1976: FDA HOLDS ADMINISTRATIVE HEARING ON G.D. SEARLE INVESTIGATION WHERE SEARLE PRESENTS ARGUMENTS AGAINST FURTHER PROCEEDINGS. FDA DECIDES TO PROCEED WITH RECOMMENDATTION FOR CRIMINAL INVESTIGATION.

JANUARY 10, 1977: FDA WRITES A 33 PAGE LETTER TO SKINNER RECOMMENDING GRAND JURY INVESTIGATION OF G.D. SEARLE "FOR CONCEALING MATERIAL FACTS AND MAKING FALSE STATEMENTS IN REPORTS OF ANIMAL STUDIES CONDUCTED TO ESTABLISH THE SAFETY OF THE DRUG ALDACTONE AND THE FOOD ADDITIVE ASPARTAME (NUTRASWEET)". (DOC # 1, PG. 1)

LETTER CITES 1970 SEARLE STRATEGY MEMO IN WHICH SEARLE COMMITS ITSELF TO OBTAINING FAVORABLE REVIEW OF NUTRASWEET BY FDA PERSONNEL BY SEEKING TO DEVELOP IN THEM A "SUBCONSCIOUS

SPIRIT OF PARTICIPATION IN THE SEARLE STUDIES." MEMO SAYS SEARLE WANTS TO GET THE FDA IN THE HABIT OF SAYING "YES." FDA SAYS THEY WANT "THE TRUTH NOT PSYCHOLOGICAL WARFARE." (DOC # 1, PG. 26)

LETTER ALSO STRESSES IMPORTANCE OF SAFETY DATA ON NUTRASWEET SINCE "IF ULTIMATELY APPROVED FOR MARKETING, THIS SWEETENING AGENT CAN REASONABLY BE EXPECTED TO BE PART OF THE DAILY DIET OF EVERY AMERICAN." "THE POTENTIAL COMMERCIAL VALUE OF ASPARTAME (NUTRASWEET) IS ENORMOUS." (DOC # 1, PG. 18, PG. 26)

FDA CITES TWO NUTRASWEET STUDIES FOR SPECIAL ATTENTION. A PRIMATE STUDY WHERE MONKEYS WHICH HAD SIEZURES WERE NEVER GIVEN AUTOPSIES AND A TOXICITY STUDY ON HAMSTERS. (DOC # 1, PGS. 18-26)

SEARLE SUBMITTED THESE STUDIES TO THE FDA ON OCTOBER 10 AND DECEMBER 8, 1972. <u>SO, THE STATUTE OF LIMITATIONS ON ANY PROSECUTION (5 YEARS) WOULD EXPIRE ON OCTOBER 10 AND DECEMBER 8, 1977</u>.

FINALLY, THE FDA MADE IT CLEAR THAT THE GRAND JURY INVESTIGATION COULD COVER OTHER SEARLE TESTS WHOSE CREDIBILITY WAS BROUGHT INTO QUESTION BY THE 1976 TASK FORCE REPORT. "OUR SELECTION OF APPARENT VIOLATIONS, DOES NOT, OF COURSE, LIMIT THE INQUIRY BY YOUR OFFICE OR BY THE GRAND JURY." (DOC # 1, PG 30).

JANUARY 24, 1977: SKINNER CALLS MEETING IN U.S. ATTORNEY'S OFFICE TO DISCUSS "OUR NEXT STEP." (DOC # 5)

JANUARY 26, 1977: SEARLE'S LAW FIRM, SIDLEY AND AUSTIN, WRITES TO SKINNER REQUESTING MEETING "PRIOR TO THE SUBMISSION TO A GRAND JURY OF ANY MATTERS RELATING TO THIS COMPANY" (SEARLE). (DOC # 6)

FEBRUARY 2, 1977: LAWYERS FROM SIDLEY AND AUSTIN MEET WITH SKINNER. BRANDING TOOK NOTES. (DOC # 7) NEWTON MINOW, A PARTNER AT SIDLEY AND AUSTIN, ATTENDS THE MEETING EVEN THOUGH HE IS NOT LISTED BY JUSTICE AS HANDLING THE SEARLE CASE. IT IS MINOW WHO OFFERS SKINNER A JOB AT SIDLEY AND AUSTIN. (DOC # 8).

FEBRUARY 7, 1977: SIDLEY AND AUSTIN WRITE TO BRANDING TO CONFIRM THAT A MEETING WILL BE HELD IN THEIR OFFICES TO CONDUCT "A CALM AND ORDERLY BUT DETAILED FACTUAL REVIEW." REFERENCE IS MADE TO THE FACT THAT SKINNER WANTED SIDLEY AND AUSTIN TO ADDRESS INITIALLY MATTERS RELATING TO ALDACTONE. (DOC # 9)

MARCH 8, 1977: SKINNER WRITES CONFIDENTIAL MEMO ON SEARLE CASE. (DOC # 10) CITES HIS "PRELIMINARY EMPLOYMENT DISCUSSIONS WITH SIDLEY AND AUSTIN", THE LAW FIRM DEFENDING SEARLE IN THE INVESTIGATION, AND THE FACT THAT IT IS "INAPPROPRIATE FOR ME TO MAKE ANY DECISION IN THAT MATTER (SEARLE INVESTIGATION) WHILE I REMAIN IN OFFICE."

SKINNER STATES IT IS HIS UNDERSTANDING THAT CONLON AND BRANDING WILL DO ANY PRELIMINARY WORK THAT IS NECESSARY -- BUT THAT A DECISION AS TO WHETHER OR NOT A GRAND JURY INVESTIGATION SHOULD BE CONDUCTED WILL AWAIT THE APPOINTMENT OF THE NEW U.S. ATTORNEY.

THE MEMO ALSO STATES:

"I HAVE ADVISED THE COUNSEL FOR G.D. SEARLE COMPANY (SIDLEY AND AUSTIN) OF MY DECISION TO RECUSE MYSELF IN THIS MATTER, BUT I WOULD APPRECIATE IT IF YOU WOULD KEEP THE FACT OF MY PRELIMINARY DISCUSSIONS CONFIDENTIAL TO AVOID ANY UNDUE EMBARRASSMENT UPON THE FIRM OF SIDLEY AND AUSTIN." (EMPHASIS SUPPLIED).

APRIL 13, 1977: OFFICIAL MEMO FROM KOCORAS TO SKINNER. (DOC # 11) CITES CONVERSATIONS WITH BRANDING AND CONLON. STATES "IT IS MY OPINION THAT A GRAND JURY INVESTIGATION BE UNDERTAKEN AT THE EARLIEST PRACTICABLE TIME." KOCORAS SAYS THE INVESTIGATION SHOULD NOT AWAIT THE APPOINTMENT OF A NEW U.S. ATTORNEY. FOR TWO REASONS.

1. THE APPOINTMENT DATE IS UNCERTAIN. MAY NOT TAKE PLACE WITHIN NEXT TWO MONTHS.

2. "IT WOULD BE INAPPROPRIATE TO REFRAIN FROM CONDUCTING NECESSARY INVESTIGATION BY THE GRAND JURY DURING THE SUBSTANTIAL PERIOD OF TIME BETWEEN NOW AND MR. SULLIVAN'S APPOINTMENT."

KOCORAS TELLS SKINNER "IN LIGHT OF YOUR RECUSAL, THIS MEMORANDUM IS SOLELY TO ADVISE YOU OF MY DECISION TO PROCEED."

[TWO POINTS SHOULD BE NOTED HERE. FIRST, THE GRAND JURY INVESTIGATION DOES NOT PROCEED AT THIS TIME. SECOND, THE STATUTE OF LIMITATIONS ON THE TWO NUTRASWEET TESTS CITED BY THE FDA EXPIRES IN OCTOBER-DECEMBER OF 1977. SO, THERE WAS A REAL URGENCY ASSOCIATED WITH THE INVESTIGATION.]

APRIL 25, 1977: FDA LETTER TO BRANDING INFORMING HIM OF FDA FURTHER INSPECTION OF NUTRASWEET TESTS TO BE CONDUCTED AT SEARLE. ADVISED BRANDING THAT INSPECTION MAY GENERATE INQUIRIES ABOUT "PENDING RECOMMENDATION" (GRAND JURY). ALSO TELLS BRANDING HE CAN CONTACT THE HEAD OF THE FDA INVESTIGATION TEAM, DR. BRESSLER, TO KEEP IN TOUCH WITH DEVELOPMENTS. (DOC # 12)

MAY 4, 1977: FDA LETTER TO BRANDING RESPONDING TO SEARLE CHRONOLOGY OF EVENTS ON ALDACTONE WHICH THE U.S. ATTORNEY'S OFFICE HAD FORWARDED TO FDA. FDA SAYS "VERY LITTLE IS NEW AND NONE OF IT JUSTIFIES WITHHOLDING THIS MATTER FROM GRAND JURY AS RECOMMENDED IN OUR ORIGINAL TRANSMITTAL LETTER." (DOC # 13)

MAY 25, 1977: BRANDING TO FDA. NOTES ANOTHER MEETING WITH SIDLEY AND AUSTIN, "THE SUBSTANCE OF THE MEETING WAS ESSENTIALLY THE SAME AS THE EARLIER MEETING (FEBRUARY 16, 1977) WITH MR. SKINNER PRIOR TO HIS REMOVING HIMSELF FROM ACTIVE PARTICIPATION IN THIS MATTER."

"AS BILL CONLON MAY HAVE ADVISED YOU VIA TELEPHONE, THREE ISSUES WERE RAISED IN 'DEFENSE' OF SEARLE'S POSITION..." BRANDING THEN ITEMIZES THE ISSUES AND REQUESTS WRITTEN RESPONSE FROM FDA. (DOC # 14)

JUNE 2, 1977: FDA WRITES LETTER TO JUSTICE'S KOCORAS RESPONDING TO 3 SEARLE DEFENSES. AGAIN STATES THESE DEFENSES ARE "NOT NEW." FDA'S LEVINE SAYS HE HOPES THAT KOCORAS RESERVATIONS "ARE ELIMINATED." IF ANY RESERVATIONS STILL EXIST, LEVINE OFFERS TO FLY TO CHICAGO "WHERE WE WOULD HAVE THE BENEFIT OF THE KIND OF EXCHANGE AND PROBING FOLLOW-UP THAT CANNOT BE ACHIEVED IN WRITTEN COMMUNICATION." (DOC # 15)

JULY 1, 1977: SAMUEL SKINNER LEAVES U.S. ATTORNEY'S OFFICE, JOINS SEARLE'S LAW FIRM, SIDLEY AND AUSTIN.

JULY 19, 1977: SULLIVAN BECOMES NEW U.S. ATTORNEY.

JULY 20, 1977: FDA CHIEF COUNSEL, MERRILL, WRITES TO SULLIVAN. (DOC # 16) STATES THAT HE HAS NOT HEARD FROM JUSTICE IN CHICAGO ABOUT GRAND JURY INVESTIGATION. CITES ALL THE RESPONSES FDA HAS GIVEN TO SEARLE'S DEFENSE AS RELAYED BY JUSTICE. NOTES SKINNER'S DEPARTURE TO SIDLEY AND AUSTIN, "WHICH HAS REPRESENTED SEARLE ON THE MATTERS INVOLVED IN THE CASE." ASKS SULLIVAN TO "PROCEED EXPEDITIOUSLY."

ALSO TELLS SULLIVAN THAT ANOTHER SEARLE TEST ON NUTRASWEET WHICH WAS REVIEWED BY FDA INSPECTORS RAISES ISSUES WHICH "COULD REQUIRE SUBMISSION TO THE GRAND JURY."

AUGUST 10, 1977: CHARLES MCCONACHIE, CONSUMER AFFAIRS ANTITRUST, JUSTICE DEPARTMENT IN WASHINGTON WRITES TO SULLIVAN. (DOC # 17) CITES JULY 20, 1977 LETTER FROM CHIEF COUNSEL OF FDA ASKING FOR GRAND JURY INVESTIGATION OF THE "PRIOR PRACTICES OF THIS FIRM" (SEARLE). MCCONACHIE STATES HIS SUPPORT FOR THAT REQUEST. SAYS IT SHOULD BE UNDERTAKEN "AS SOON AS POSSIBLE."

SAYS HIS DIVISION IS RESPONSIBLE FOR CONDUCT AND SUPERVISION OF LITIGATION ARISING OUT OF ACTIONS RELATED TO FDA. HIS JOB TO ENSURE THESE CASES ARE HANDLED ON "AN EXPEDITED BASIS." "I AM BECOMING CONCERNED AT THE AMOUNT OF TIME WHICH HAS TRANSPIRED BETWEEN FDA'S JANUARY, 1977, REFERRAL LETTER AND THE PRESENT. I KNOW OF NO REASON WHY THE GRAND JURY SHOULD NOT AT LEAST INVESTIGATE."

AUGUST 18, 1977: MEMO TO FILE. (DOC # 18) MEETING BETWEEN SULLIVAN, BRANDING AND OTHER DEPARTMENT OF JUSTICE PEOPLE WITH SIDLEY AND AUSTIN. SULLIVAN ADVISES HE WILL SUBMIT ALDACTONE TO GRAND JURY. SIDLEY AND AUSTIN ASK IF GRAND JURY WILL INVOLVE ALL ISSUES RAISED BY FDA INCLUDING NUTRASWEET. SULLIVAN SAID AT THIS TIME ONLY ALDACTONE.

(NOTE: THIS IS AS CLOSE AS WE CAN COME TO THE DATE NUTRASWEET WAS DROPPED FROM THE INVESTIGATION.)

SULLIVAN ALSO SPOKE OF "PROCEDURES DESIGNED TO PERMIT PROMPT RESOLUTION OF THIS MATTER WITHOUT INCONVENIENCE AND UNDUE HARM TO THE PARTIES (SEARLE). MIGHT BE APPROPRIATE FOR NON-GOVERNMENTAL COUNSEL TO PROPOSE PROCEDURES THEY FELT WOULD BE APPROPRIATE." SULLIVAN SUGGESTED RECEIPT OF SUBPOENAS BY COUNSEL. ALSO SUGGESTED COUNSEL CONSIDER OTHER "POSSIBLE SAFEGUARD PROCEDURES" AND RETURN IN A WEEK TO PRESENT SUGGESTIONS.

SEPTEMBER 13, 1977: LAWYERS FOR SOME OF THE TARGETS OF THE INVESTIGATION WRITE TO BRANDING SETTING UP A MEETING AT WHICH "NO WASHINGTON PERSONNEL WILL BE PRESENT." (DOC # 19)

OCTOBER 3, 1977: FILE MEMO FROM CONLON ON "OFF THE RECORD" MEETINGS WITH SIDLEY AND AUSTIN LAWYERS REGARDING THE GRAND JURY INVESTIGATION. (DOC # 20)

OCTOBER 10, 1977: STATUTE OF LIMITATIONS EXPIRES ON 52-WEEK MONKEY STUDY WHERE MONKEYS THAT HAD SIEZURES WERE NEVER GIVEN AUTOPSIES. THIS IS ONE OF THE TWO TESTS SPECIFICALLY CITED IN FDA LETTER RECOMMENDING GRAND JURY INVESTIGATION OF NUTRASWEET ON JANUARY 10, 1977.

OCTOBER 12, 1977: SULLIVAN TO CONLON, BRANDING, REIDY. SULLIVAN SAYS CONLON WILL "NECESSARILY HAVE TO REDUCE OR END HIS INVOLVEMENT" IN SEARLE INVESTIGATION DUE TO "PRESS OF ADMINISTRATIVE DUTIES." REIDY TO TAKE OVER. (DOC # 21)

OCTOBER 26, 1977: MCCONACHIE TO SULLIVAN. WE HAVE NOT BEEN KEPT ADVISED OF ANY GRAND JURY INVESTIGATION. GET US INFORMATION. (DOC # 22)

NOVEMBER 7, 1977: SULLIVAN TO BRANDING ON SULLIVAN'S (DOC # 23) CONVERSATION WITH MCCONACHIE. "I TOLD MCCONACHIE AT GREAT LENGTH HOW WE HAVE REPEATEDLY ASSURED THE LAWYERS FOR SEARLE THAT WE DO EVERYTHING IN OUR POWER TO KEEP THE GRAND JURY INVESTIGATION SECRET."

IT SHOULD BE NOTED HERE THAT JUSTICE WILL NOT GIVE ANY DETAILS ABOUT THE GRAND JURY INVESTIGATION, WHEN IT WAS COMMENCED, HOW MANY WITNESSES WERE PRESENTED ETC. ALL WE KNOW FOR SURE IS THAT THE GRAND JURY INVESTIGATION, SUCH AS IT WAS, INVOLVED ONLY ALDACTONE, NOT NUTRASWEET.

DECEMBER 8, 1977: STATUTE OF LIMITATIONS EXPIRES ON HAMSTER TOXICITY TEST. THE SECOND TEST CITED BY FDA IN ITS JANUARY 10, 1977 LETTER SEEKING A GRAND JURY INVESTIGATION OF NUTRASWEET.

DECEMBER, 1977 - DECEMBER, 1978: PERIOD IN WHICH GRAND JURY ACTION IS TAKEN ON ALDACTONE. NO DOCUMENTS ON GRAND JURY AVAILABLE.

DECEMBER, 1978: SULLIVAN DECIDES NOT TO PROSECUTE SEARLE. INVESTIGATION DROPPED.

JANUARY 5, 1979: BILL CONLON LEAVES U.S. ATTORNEY'S OFFICE TO JOIN SIDLEY AND AUSTIN.

JANUARY 29, 1979: SULLIVAN WRITES TO FDA FORMALLY STATING HIS REASONS FOR NOT PROSECUTING SEARLE ON ALDACTONE. (DOC # 24)

POSTSCRIPT

JUNE, 1979: FDA ESTABLISHES PUBLIC BOARD OF INQUIRY TO RULE ON SAFETY ISSUES SURROUNDING NUTRASWEET.

OCTOBER, 1980: PUBLIC BOARD OF INQUIRY REPORTS NUTRASWEET SHOULD NOT BE APPROVED PENDING FURTHER BRAIN TUMOR TESTS.

"THE BOARD HAS NOT BEEN PRESENTED WITH PROOF OF A REASONABLE CERTAINTY THAT ASPARTAME (NUTRASWEET) IS SAFE FOR USE AS A FOOD ADDITIVE UNDER ITS INTENDED CONDITIONS OF USE." (DOC # 25).

MAY, 1981: THREE OF THE SIX IN-HOUSE FDA SCIENTISTS ADVISING FDA COMMISSIONER HAYES ON WHETHER NUTRASWEET SHOULD BE APPROVED (THE SO-CALLED COMMISSIONER'S TEAM) ADVISE AGAINST APPROVAL. THEY STATE THAT THREE SEARLE TUMOR TESTS ARE

UNRELIABLE (ONE INVOLVING DKP, AN NUTRASWEET BREAK-DOWN PRODUCT). QUESTIONS WERE ORIGINALLY RAISED ABOUT THESE TESTS BY THE FDA SEARLE INVESTIGATIVE TASK FORCE REPORT IN 1976, THE REPORT WHICH WAS TO FORM THE BASIS FOR A GRAND JURY INVESTIGATION OF NUTRASWEET. (DOC # 26)

JULY, 1981: COMMISSIONER HAYES OVERRULES PUBLIC BOARD OF INQUIRY AND APPROVES NUTRASWEET FOR DRY PRODUCTS.

JULY 8, 1983; NUTRASWEET APPROVED FOR USE IN CARBONATED BEVERAGES. (OVER 20 BILLION DIET SOFT DRINKS CONSUMED LAST YEAR).