of determining whether to permit the aforesaid supplemental New Drug Application for drug MER/29 to become effective, knowingly and wilfully concealed and covered up and caused to be concealed and covered up by trick and scheme material facts in a matter within the jurisdiction of the Food and Drug Administration of the Department of Health, Education, and Welfare, an agency and Department of the United States, in that by a letter dated December 28, 1961, said Richardson-Merrell, Inc., made a submission to the Food and Drug Administration of results of investigations, made to show whether or not the drug was safe for use and pertaining to the changes in the aforesaid brochure and representing thereby that it had submitted full reports of all such investigations as of that date, said defendants well knowing that as of December 28, 1961, there were certain reports of investigations, conducted by itself and by its former subsidiary The Wm. S. Merrell Company and data and information concerning the adverse and toxic reactions of MER/29 therapy in animals in the possession of Richardson-Merrell, Inc., which had not been submitted and the existence of which was concealed from said Food and Drug Administration, to wit:

(*a*) An investigation made by The Wm. S. Merrell Company, begun on or about June 23, 1959 with three female monkeys, to study the effect of dosages of 10 mg/kg per day of MER/29 upon the ovaries of such animals, in which it was observed (a) that one monkey had ovarian changes in the form of an increase in the number of ovarian follicles which did not appear to have matured to a state of ovulation, (b) that one monkey had developed severe leukopenia and agranulocytosis, and (c) that two monkeys had a depressed granulocyte count, atyptical lymphocytes and high leukocyte counts.

(*b*) An investigation made by The Wm. S. Merrell Company in which four female monkeys were started on a toxicity study on or about September 15, 1959 for the purpose of determining the effect of an administration of 5 mg/kg per day of MER/29 on ovarian morphology, at the end of which investigation no evidence of recent ovulation was found.

(*c*) A recovery toxicity investigation made by The Wm. S. Merrell Company with female rats, started on or about January 10, 1958 to determine the etiology of abnormal blood changes, in which it was observed that eight out of the ten rats being administered a dosage of 50 mg/kg per day of MER/29 had died as of January 27, 1958, and the surviving two rats whose dosage as of that date was reduced to 25 mg/kg per day of MER/29 had died as of February 3, 1958.

(*d*) A recovery toxicity investigation made by The Wm. S. Merrell Company with female rats, started on or about February 30, 1958 to determine the etiology of abnormal blood changes which had been observed in previous toxicity studies, the results of which showed that rats being administered MER/29 had developed abnormal blood changes in the form of binucleated lymphocytes, blood dyscrasias and an increase in raticulocytes.

(*e*) A toxicity investigation conducted by The Wm. S. Merrell Company between on or about October 26, 1959 and on or about November 1, 1960, during which period said drug was administered to rats at 20 mg/kg and 40 mg/kg per day and which rats developed eye opacities in a quantity and degree greater than those reported to the Food and Drug Administration on February 17, 1960.

(*f*) A toxicity investigation in rates conducted by Richardson-Merrell, Inc., which began on or about April 19, 1961, to determine the effect of MER/29 upon the eyes of rats during the course of which MER/29 and MER/29 plus Vitamins and Cholesterol was being administered to rats at a dosage of 40 mg/kg per day in which it was observed that on or about November 15, 1961 eye opacities had developed in all female rats being administered MER/29 and MER/29 plus Vitamins and Cholesterol at a dosage of 40 mg/kg per day, and opacities had developed in the eyes of 20 out of 24 male rats being administered MER/29 and MER/29 plus Vitamins and Cholesterol at a daily dosage of 40 mg/kg while none of the control rats had developed any eye changes in the aforesaid study.

A True Bill:

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Attorney of the United States in and for the District of Columbia.

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Foreman.