

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, atypical 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 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 January 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 developed abnormal blood changes in the form of binucleated lymphocytes, blood dyscrasias and an increase in reticulocytes.

E. A toxicity investigation in male and female rats which was conducted during the period between July 1959 through October 1959 by The Wm. S. Merrell Company to determine the effect of MER/29 on fertility and gestation, such rats having been administered 5 mg and 15 mg/kg per day of MER/29, in which it was observed that doses of 15 mg/kg per day reduced the conception rate when given prior to and during cohabitation, and

F. A toxicity investigation in male and female rats at dosages of 10 and 25 mg/kg per day of MER/29 which was conducted between on or about July 7, 1959 and October 1959 by The Endocrine Laboratories of Madison, Inc., Madison, Wisconsin, pursuant to a contract with The Wm. S. Merrell Company to determine the effect of MER/29 on fertility and gestation, in which it was observed that there was a reduced conception rate among rats receiving doses of 25 mg/kg per day of MER/29 during pregnancy, the size of the litter was reduced and there was an increase in rate of the deaths of the young during the 24-hour period after delivery.

Third Count

1. The Grand Jury realleges all of the allegations of the first paragraph of the Second Count of this indictment.

2. On or about February 17, 1960, within the District of Columbia, the defendants, The Wm. S. Merrell Company, a body corporate, Evert F. Van Maanen and William M. King, 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, knowingly and wilfully made and used, and caused to be made and used, a false writing and document knowing the same to contain false, fictitious and fraudulent statements and entries, in that on February 17, 1960, the defendants caused to be submitted to said Food and Drug Administration, at Washington, D.C., on behalf of said The Wm. S. Merrell Company, as an amendment to its New Drug Application for MER/29 (Triparanol), a new drug then subject to the provisions of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) and which was then a matter within the jurisdiction of the Food and Drug Administration, a writing containing reports of investigations that had been made to show whether or not the drug was safe for use, such writing containing the following false, fictitious and fraudulent statements and entries, to wit:

(a) The report of a six-month study in mongrel dogs receiving a dosage of 25 mg/kg per day of MER/29, which contained false and fraudulent statements and entries that three of the dogs had died early in the experiment and that two of the remaining dogs had maintained their body weight during the course of the study, when in truth and in fact, as the defendants well knew, the dead dogs had been replaced by three additional dogs and all of the dogs in the study had lost body weight.