

(b) The report of a three-month study with five beagle dogs receiving a dose of 40 mg/kg per day of MER/29, which contained false and fraudulent statements and entries, as follows;

(1) that microscopic examination of dog No. 69 had disclosed a reduction of the number of mature spermatocytes in the seminiferous tubules and a paucity of spermatozoa in the vas, when in truth and in fact, as the defendants well knew, no spermatocytes were so found and vitally important portions of the gonads had undergone marked tubular and interstitial atrophy;

(2) that between the sixth week of the study and its conclusion dog No. 69 had gained weight when in truth and in fact, as the defendants well knew, it had lost weight;

(3) that the evaluation of the dog study was difficult because of the existence of concomitant diseases in The Wm. S. Merrell Company's dog colony and particularly the outbreak of distemper in October 1959, when in truth and in fact, as the defendants well knew, the original study which started on October 21, 1959, had been discontinued on October 30, 1959, and a new study begun on November 3, 1959, with different dogs, which had not contacted distemper during the aforesaid outbreak.

(c) The report of a four-month study in three adult mongrel dogs receiving a dose of 10 mg/kg per day of MER/29, which contained false, fictitious and fraudulent statements and entries, as follows;

(1) that the administration of MER/29 at a dosage of 10 mg/kg of MER/29 did not affect the peripheral blood values of these dogs and that the hematologic values for dog No. 57 during the study showed the initial and final hemoglobin in grams per 100 cc as 11.8 and 14.2 respectively, and the initial and final hematocrit percentum packed cells as 34 and 40 respectively, when in truth and in fact, as the defendants well knew, the initial and final hemoglobin values for dog No. 57 remained at 9.0 grams, and the initial and final hematocrit values for dog No. 57 were 27 and 32 percentum respectively;

(2) that although dog No. 58 showed an initial weight loss when the drug administration was started, it showed a gain for the remainder of the study so that the loss amounted to approximately one kilogram (2.2 lbs.), when in truth and in fact, as the defendants well knew, dog No. 58 had lost 3.7 pounds during the last week of the study.

Fourth Count

On or about February 8, 1960, within the District of Columbia, the defendants, The Wm. S. Merrell Company, a body corporate, Harold W. Werner and Evert F. Van Maanen knowingly and willfully made, and caused to be made, false, fictitious and fraudulent statements and representations of material facts in a matter within the jurisdiction of a Department and agency of the United States, in that on said date The Wm. S. Merrell Company submitted to the Food and Drug Administration of the Department of Health, Education and Welfare, at Washington, D.C., a letter dated February 4, 1960 enclosing a revised brochure for MER/29 (Triparanol), a new drug then subject to the provisions of section 505 of the Federal Food, Drug, and Comestic Act (21 U.S.C. 355) and which was then a matter within the jurisdiction of the Food and Drug Administration, in which letter was falsely and fraudulently stated and represented that a caution statement reading, "Since cholesterol plays an important role in the development of the fetus, the drug should not be administered during pregnancy" had been inserted in the brochure "purely on theoretical grounds", when in truth and in fact, as the said defendant well knew, investigations and experiments had been conducted by said The Wm. S. Merrell Company, and by an independent laboratory pursuant to its request, the results of which disclosed that the administration of the drug to animals had resulted in adverse and deleterious effects upon the ovarian cycle, the rate of conception, the size of litters and the ability of the offspring to survive.

Fifth Count

1. At the times mentioned herein, the William S. Merrill Company had submitted to the Food and Drug Administration of the Department of Health, Education and Welfare, a New Drug Application, and amendment thereto, for MER/29 (Triparanol), a new drug then subject to the provisions of section 505