

of twelve months' duration, and that, during the period between February and on or about October 10, 1960, examinations had been made of the rats' eyes which disclosed that the number of corneal opacities was increasing in rats receiving a daily dose of 20 mg/kg and 40 mg/kg of MER/29 and that by September 1960 nearly all of the rats remaining on the study of the 40 mg/kg per day dosage had developed some degree of blindness; said material facts being concealed and covered up by the trick and scheme of submitting by letter to the Food and Drug Administration at Washington, D.C., dated October 10, 1960, in response to its inquiry as set forth in paragraph 1, a carbon copy of a letter to Lauretta E. Fox dated September 29, 1960, in which it was falsely stated and represented that the results of Lauretta Fox' study, indicating involvement of the cornea and lens of the rats' eyes, "are most surprising to us," and that "Our pathologist states that he has never seen such involvement of the lens", The Wm. S. Merrell Company wilfully and intentionally omitting, in its letter to the Food and Drug Administration and in the carbon copy of the letter to Lauretta Fox enclosed therein, to disclose the true facts which it well knew, as set out above, concerning the existence of its continuing toxicity study in rats and the observation of corneal opacities in the eyes of rats during the period from February to October 1960.

Ninth Count

1. On or about September 23, 1960, Dr. Frank J. Talbot, Medical Officer of the Food and Drug Administration of the Department of Health, Education and Welfare, requested The Wm. S. Merrell Company to incorporate in its labeling a discussion of the effect on pregnant rats of large doses of MER/29, a new drug then subject to the provisions of section 505 of the Food, Drug, and Cosmetic Act (21 U.S.C. 355), and stating that the labeling for MER/29 should include a contraindication of the drug in women of the childbearing age, and also that, if the drug were prescribed for such women, a pregnancy test should be made every three months.

2. On or about October 10, 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 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, in that at the time and place aforesaid the defendants concealed and covered up, and caused to be concealed and covered up, the fact that The Wm. S. Merrell Company had conducted various investigations in animals to ascertain the effect of the administration of MER/29 upon the ovaries of female monkeys and upon the fertility and gestation of female rats and the effect of said drug upon the offspring of female rats to which it had been administered, said investigations being more particularly described as follows:

(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 that one monkey had ovarian changes similar to the changes observed in the ovaries of a monkey on a previous MER/29 toxicity study.

(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 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/kg 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.

(d) 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