

corneal opacities had been observed in rats receiving dosages of 40 mg/kg per day and 20 mg/kg per day of MER/29, and that in two dogs which had received 40 mg/kg per day of MER/29 for three months, observations had been made that one dog appeared to be blind and an ophthalmoscopic examination revealed an opacity of the crystalline lens and that the retina was not visible, and that the other dog appeared to have an eye infection and an ophthalmoscopic examination revealed a slight opacity of the crystalline lens and that the retina was not clearly visible. Violation of 18 U.S.C. 1001.

Seventh Count

1. On or about June 29, 1960, Dr. Frank J. Talbot, Medical Officer of the Food and Drug Administration of the Department of Health, Education and Welfare, wrote to The Wm. S. Merrell Company advising that Lauretta E. Fox had reported that certain test rats which had been administered MER/29, a new drug then subject to the provisions of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), had developed an opaque cornea and lens in the eyes during an experiment and requested that The Wm. S. Merrell Company comment upon such study.

2. On or about July 25, 1960, within the District of Columbia, the defendants, The Wm. S. Merrell Company, a body corporate, and William M. King, in a matter within the jurisdiction of a Department and agency 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 material statements and entries and knowingly and wilfully concealed and covered up, and caused to be concealed and covered up, by trick and scheme, material facts in that they caused to be submitted to the Food and Drug Administration of the Department of Health, Education and Welfare, at Washington, D.C., on or about July 25, 1960, in response to the request mentioned in paragraph 1 above, a memorandum, dated July 22, 1960 prepared by the defendant William M. King, concerning the Lauretta Fox study in which it was falsely and fraudulently stated that "thousands of rats have been involved in many different experiments with MER/29 here in our laboratories,"; that "in only one group of animals in one experiment and at only one time did we observe eye changes," and that "We have no evidence from our experience or from the literature that MER/29 would in itself, produce such changes", said defendants then and there well knowing that in addition to the eight corneal opacities, previously reported to the Food and Drug Administration in February 1960, at least three out of 35 rats being administered MER/29 since that date at a daily dosage of 20 mg per kg of body weight, and at least 25 out of 29 rats being administered MER/29 since that date at a daily dosage of 40 mg per kg of body weight, had developed corneal opacities, and that in a dog study completed in February 1960 opacities of the crystalline lens had been observed in two dogs which had received 40 mg/kg per day dosage of MER/29 for a period of three months, which facts were not disclosed in said memorandum but were knowingly and wilfully omitted therefrom and concealed from said Food and Drug Administration.

Eighth Count

1. On or about October 6, 1960, Dr. Frank J. Talbot, Medical Officer of the Food and Drug Administration of the Department of Health, Education and Welfare, inquired of The Wm. S. Merrell Company concerning the effect of MER/29, a new drug then subject to the provisions of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), upon the eyes of rats and concerning the rat studies of Lauretta Fox.

2. On or about October 12, 1960, within the District of Columbia, the defendant, The Wm. S. Merrell Company, a body corporate, 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 concealed and covered up and caused to be concealed and covered up by trick and scheme a material fact, in that at the aforesaid time and place the defendant did conceal and cover up and cause to be concealed and covered up in a matter within the jurisdiction of the Food and Drug Administration, the fact that in October 1959, The Wm. S. Merrell Company had initiated a toxicity study concerning the effect of MER/29 on rats which study was to be divided into three parts, one of three months', one of six months' and one