

of the Federal Food, Drug & Cosmetic Act (21 U.S.C. 355), and had submitted as a part thereof, reports of investigations that had been made to show whether or not the drug was safe for use, said reports being submitted in an effort to persuade the Food and Drug Administration to permit said New Drug Application to become effective.

2. Among such reports was one reporting the results of a three-month toxicity study in rats being administered doses of MER/29 at the rate of 20 mg/kg per day and 40 mg/kg per day, in which it was reported that corneal opacities had been observed in the eyes of eight out of twenty rats which had been administered 40 mg/kg per day in the course of the investigation, such rats having been autopsied at the time of the report.

3. Said three-month toxicity study of the effect of the administration of MER/29 to rats at dosage levels of 20 mg/kg and 40 mg/kg per day was only one part of a continuing investigation which had been set up to continue for a period of one year; as of February 24, 1960, following the submission of the report pertaining to the three-month investigation, corneal opacities had been observed in the eyes of live rats being subjected to such continued investigation, corneal opacities being observed in 2 out of 38 rats used as controls, and in the eyes of one out of 35 rats being administered MER/29 in doses of 20 mg/kg per day, and in the eyes of 22 out of 36 rats being administered MER/29 in doses of 40 mg/kg per day.

4. On or about March 2, 1960, at Washington, D.C., the defendant, The William S. Merrell Company, a body corporate, knowingly and wilfully concealed and covered up, and caused to be concealed and covered up, by trick and scheme, a material fact in a matter within the jurisdiction of a department and agency of the United States, in that it knowingly and wilfully concealed and covered up and caused to be concealed and covered up in a matter within the jurisdiction of the Food and Drug Administration of the Department of Health, Education, and Welfare, to wit, the New Drug Application by The William S. Merrell Company for MER/29 (Triparanol) a new drug then subject to the provisions of section 505 of the Food, Drug and Cosmetic Act (21 U.S.C. 355) the fact that corneal opacities had been observed in the eyes of rats to which MER/29 was being administered at doses of 20 mg/kg per day and 40 mg/kg per day, by the trick and scheme of submitting to the Food and Drug Administration a letter dated February 29, 1960, from The William S. Merrell Company pertaining to said drug in which it was stated, with respect to corneal opacities in rats which had previously been reported in the amended New Drug Application for drug MER/29, that "Corneal changes have now been found in the control animals." but which omitted any statement that additional corneal opacities had been observed in the eyes of live rats to which MER/29 was being administered for experimental purposes during the month of February 1960, as alleged in paragraph three of this count, and that the control animals were different from those which had been used in its previously reported three-month study. Violation of 18 U.S.C. 1001.

Sixth Count

On or about March 7, 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 a Department and agency of the United States, knowingly and wilfully concealed and covered up, and caused to be concealed and covered up, by trick and scheme, material facts, in that at the aforesaid time and place during a meeting with representatives of the Food and Drug Administration of the Department of Health, Education, and Welfare to discuss the toxicity of 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), for which a New Drug Application had been filed with said Food and Drug Administration, and which was then a matter within the jurisdiction of the Food and Drug Administration, the defendants did submit to said Food and Drug Administration a document and writing entitled "Summary of Toxicity Studies" and did discuss the results of animal and clinical investigations of MER/29 which The Wm. S. Merrell Company had made to show whether or not the drug was safe for use, but the defendants wilfully and knowingly failed and omitted to make known, either in said summary or in their oral conversations, the fact that The Wm. S. Merrell Company was then conducting a chronic toxicity study in rats in which during the month of February 1960