have developed in June, 1961, and to have continued to increase in number and develop in degree to the point that on or about November 15, 1961 eye opacities had developed in all female rats being administered MER/29 and MER/29 plus Vitamins and Cholesterol at a dosage of 40 mg/kg per day, and opacities had developed in the eyes of 20 out of 24 male rats being administered MER/29 and MER/29 plus Vitamins and Cholesterol at a daily dosage of 40 mg/kg while none of the control rats had developed any eye changes in the aforesaid study.

Eleventh Count

On or about October 26, 1961, within the District of Columbia the defendants, Richardson-Merrell, Inc., a body corporate, and Evert F. Van Maanen, 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 statements and entries, in that at the time and place aforesaid, the defendant Richardson-Merrell, Inc., for the purpose and with the intent of influencing the Food and Drug Administration of the Department of Health, Education and Welfare in the exercise of its function of passing upon and approving the issuance of a warning letter by said Richardson-Merrell, Inc., to the medical profession concerning MER/29, a new drug subject to the provisions of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), submitted to the Food and Drug Administration of the Department of Health, Education and Welfare a report from E. F. Van Maanen to Dr. Werner, dated October 24, 1961, entitled "Chronic Study with MER/29 In Dogs Progress Report," said progress report containing the following statements and entries which the defendants knew to be false, fictitious and fraudulent, to wit:

1. A statement that on or about October 18, 1961, the fundi of the eyes of dogs Nos. 158, 166 and 171 appeared normal, when in truth and in fact, as the defendants well knew, there was an inability to visualize the fundus of the left eye and difficulty in visualizing the fundus of the right eye of dog No. 158, in dog No. 166 spoke-like striations persisted bilaterally, and in dog No. 171 striations were seen at the innercanthus aspect of both eyes.

2. A statement that on or about October 18, 1961, the eyes of the surviving dogs Nos. 148, 149 and 169 which were being administered MER/29 plus Vitamins and Cholesterol were all normal, when in truth and in fact, as the defendants well knew, on or about October 18, 1961, these dogs had developed the following eye changes:

(*a*) *Dog No. 148.*—Striations had been observed at the inner-canthus aspect of both eyes deep to the cornea.

(*b*) *Dog No. 149.*—Left eye showed slight fluorescent reflections at 9 o'clock.

(*c*) *Dog No. 169.*—Striations had been seen in the left eye extending inward ½ mm. at 9 o'clock and in the right eye at 3 o'clock.

Twelfth Count

1. Between December 22, 1961 and December 29, 1961, The Wm. S. Merrell Company, Division of Richardson-Merrell, Inc., had pending before the Food and Drug Administration of the Department of Health, Education, and Welfare a supplemental New Drug Application for 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), which proposed changes in statements in the brochure of said drug pertaining to the safety of the drug and possible adverse and toxic effects arising from its use. During the aforesaid period there were submitted to the Food and Drug Administration at Washington, D.C., as a part of said Application, reports of investigations made to show the safety of MER/29, and data and information pertaining to the possible adverse and toxic reactions of the drug, said Richardson-Merrell, Inc., representing that said reports of investigations, data and information were full and complete and constituted all of the data and information in its possession relating to the safety of the aforesaid drug and possible adverse and toxic reactions due to the drug in both animals and humans which it had observed or was reported to it.

2. On or about December 29, 1961, within the District of Columbia, the defendants, Richardson-Merrell, Inc., a body corporate, Harold W. Werner, Evert F. Van Maanen and William M. King, for the purpose and with the intent of influencing the Food and Drug Administration in the exercise of its function