Discrepancies such as the following were uncovered: Notebooks and weight charts indicated that a marked loss of weight occurred in one monkey during the last five weeks of the reported study; the data submitted in the New Drug Application indicated that there was a weight increase of this monkey during that period. We could not find the record of autopsy for another monkey in this study. According to the NDA, a third monkey had received MER/29 for 16 months, whereas the firm's notebook and charts indicated that this monkey had received MER/29 for only 8 months. The laboratory records on three of the monkeys showed three different dates for the autopsy of these animals. Moreover, the autopsy dates given in the New Drug Application did not correspond to those found on the charts and notebooks. Delving further into the records, I discovered reports on another monkey which had been treated with MER/29, apparently as part of a second toxicity study in this species. Only one monkey study had been mentioned in the New Drug Application. The officials of the firm responsible for these studies were asked if they could explain the discrepancies. They had no immediate explanation.

Before leaving the firm that day, we were asked if we were satisfied with the results of our visit. We replied that while we had received the utmost cooperation, we had discovered some discrepancies in the monkey studies which had not been explained to our satisfaction. The senior officials of the firm indicated that they would discuss our findings with their personnel in an attempt to clarify the matter. We indicated that we would return on the following day.

On the morning of April 10, 1962, we again visited the firm. A conference was held with company representatives. An official told us that, although they had worked late into the evening, they were still unable to find any explanation for the discrepancies which we had noticed on the previous day. We met further with the officials of the firm who were directly involved with these studies and they, too, indicated they had been unable to explain the discrepancies.

On April 11, 1962, a memorandum summarizing our findings was sent to our Division of Regulatory Management. I indicated that we had found certain discrepancies between the chronic monkey studies submitted in Merrell's New Drug Application and those found in their laboratory records. We felt that these discrepancies did not represent an oversight on the part of the William S. Merrell Company, but constituted evidence of the submission of fradulent and misleading data to the FDA. I indicated that the net effect of these misleading data was to make the drug appear less toxic to monkeys than was actually the case. These data were of particular significance at the time of our consideration of the NDA, when representatives of the William S. Merrell Company had vigorously maintained that evidence of safety obtained in these monkey studies outweighed any questionable findings in lower species, i.e., rats and dogs. It was apparent that the discrepancies uncovered in our visit supported the allegation by the former Merrell employee that fradulent monkey data had been submitted to the Food and Drug Administration.

On the basis of these findings, I recommended that the NDA be suspended. Moreover, I felt that sufficient evidence had been obtained to support prosecution of the William S. Merrell Company and the individuals involved and recommended such action.

On April 12, 1962, representatives of the firm met with FDA and advised us that they were immediately withdrawn MER/29 from the market. They requested that we suspend the New Drug Application. On May 22, 1962, a formal order suspending the New Drug Application for MER/29 was signed by the Commissioner of Food and Drugs.

Subsequently, as our investigation continued, we found that two of the reports of rat toxicity studies submitted in the New Drug Application contained falsified data. Regarding a six-week, two-dosage level study, the William S. Merrell Company reported in the NDA that four of the eight females at the high dosage (75 mg/kg) had died during the course of the experiment. Examination of Merrell's notebooks revealed that *no* females at that dosage level were alive at the end of six weeks. Seven of the female rats had died, and the eighth had been sacrificed. The firm's failure to report truthfully the results of this experiment resulted in further complications. Final organ weights and hematological values were reported in the NDA for these animals at the six-week period. In checking the firm's laboratory records, no organ weights or hematological values were found for these animals. This is not surprising since the animals did not survive for these determinations. The values which were reported were