

At this point, it should be noted that the raw data was not recorded on separate sheet in sequence, but was reported in four separate notebooks together with many other studies. These notebooks were labeled numbers 770 R, 799 R, 848 R, and 904 R. These were bound notebooks which contained carbon copies of the original data. These originals reportedly have been filed in the firm's library.

Upon review of the raw data, it was observed that animal M51, a male monkey first appeared on 6/19/58. This animal was started on MER 29 on 6/23/58. On page 19 of Notebook 904 R, it was stated that this animal was autopsied on 3/4/59. As submitted in the NDA, this animal had received sixteen months of medication with MER 29. Dr. King was asked to explain this discrepancy of approximately 8 months. He had no immediate explanation, in fact he could not explain this discrepancy. He searched through the earlier part of this study and could find no mention of animal M51. At this point, he asked one of his assistants to obtain the original weight charts on this study. Dr. King then presented a weight chart titled Fig. 8 on three monkeys receiving MER 29 and three control monkeys. A copy of this is attached. Dr. King looked over this weight chart, and admitted that monkey M51 had not been started on MER 29 at the beginning of the experiment (9/9/57). At this point, Dr. Goldenthal pointed out that the weight charts submitted with the NDA indicated that this animal had received MER 29 for sixteen months. In fact, monthly weights were given for this animal from zero to seventeen months.

Dr. King was asked to explain this discrepancy. Dr. King then asked his assistants to see if they could get more information on this point. During this time, Dr. Goldenthal pointed out that on this chart (Fig 8) that monkey #49 had a severe weight loss between 45 and 50 weeks of the experiment. At this point, Dr. King's assistant brought in four additional weight charts which were titled, "Monkeys Chronic Oral Toxicity WSM 5052 (MER 29) Body Weights". (Copies attached). Dr. King studied these charts for several minutes and then said these were the original weight charts of this monkey study. This study covered from 0 to 352 days. It is apparent that this is only the last year of the study rather than the full study. On the first sheet, it is indicated that monkey #51 was started on the drug (MER 29) on day 96. Dr. Goldenthal again asked Dr. King about the severe weight loss on monkey M49 on the last sheet of these charts between days 2/5/59 and 3/5/59. Dr. King could not explain this weight loss. Dr. King and Dr. Goldenthal then looked over the notebooks to find the source of these body weights. On page 100 of Notebook 848 R, the weights for monkey 49 on 2/5/59, 2/12/59 and 2/19/59 were given. On the continuation of this study on page 18 in Notebook 094 R, the weight of monkey 34 was given at 7.5 kilograms on the day of autopsy 3/5/59. These body weights in the notebook corresponded to the weights in the fourth page of the charts. Dr. Goldenthal asked Dr. King to explain the discrepancy between this data and the data reported in the NDA. In the NDA, animal 49 showed a weight gain in the last month of the study rather than a weight loss. Dr. King was unable to explain this discrepancy. It should be noted that this weight loss was from 9.9 kilograms to 7.5 kilograms or a loss of 2.4 kilograms equivalent to 5.3 lbs. Dr. Goldenthal asked Dr. King who prepared the four weight charts. Dr. King was also asked if he prepared them personally. Dr. King replied that he did not prepare the charts personally, but that he assumed that they were prepared by the two employees named Jo Jordan and B. Umberger whose names were signed at the bottom of the raw data sheets.

Dr. Goldenthal pointed out to Dr. King that monkey # M25 from data in the NDA was autopsied on July, 1958, monkey # M34 was autopsied on 2/19/59, monkey # M51 on 2/19/59, and monkey F49 on 2/26/59. Dr. Goldenthal asked Dr. King the meaning of the autopsy numbers. Dr. King replied that the first number 59 indicated the year of autopsy, and the second number indicated the number of the animal autopsied that year. Dr. Goldenthal asked Dr. King if the autopsy numbers were assigned in sequence as the monkeys were autopsied. Dr. King replied in the affirmative. Dr. Goldenthal then asked Dr. King why monkey F49, which the NDA states was autopsied on 2/26/59, actually had an autopsy number of 59-101, while animals M34 and M51 which the NDA states were autopsied on 2/19/59 actually had autopsy numbers of 59-102 and 59-103. Dr. King was unable to explain this break in normal sequence. Dr. King speculated that perhaps animal F49 had been planned to be autopsied earlier than animals M34 and M51. However, no satisfactory answer was given.