

I reminded Mr. Beckwith that they had promised to secure copies of these charts for us as soon as possible, and I again emphasized that we were anxious to get these copies as they were needed in the evaluation.

Mr. Beckwith stated that they were trying to get a complete picture of the whole situation, and that they would collect and duplicate the charts as soon as possible. He said because of the change in personnel about the time these charts were prepared, the data was scattered, and it was taking some time to get all of the pieces of information together.

I suggested that if the firm was unable to get the originals of the pages we wanted, that we would be happy to attempt to photograph the carbon copies in the bound notebook. Mr. Beckwith assured me that they would make every effort to get the material together as soon as possible and would notify me when it was ready. During the conversation, it was also verified that the information they were getting for Dr. Nestor relative to the clinical studies would be sent directly to him in Washington.

THOMAS M. RICE

U.S. Government Memorandum.

WILLIAM S. MERRELL Co.,
Cincinnati, Ohio, April 17, 1962.

To: Administration.

From: Cincinnati District.

Subject: Mer 29 investigation, and recall; refusal to supply data.

During a visit to the firm today by Supervisory Inspector Thomas M. Rice and Inspector Charles W. Gressle, inquiry was made as to the copies of the raw data bound notebooks and copies of the original pages from these notebooks sent to the library, which had been promised to us at the time of our visits to the firm on April 9th and 10th. This was first discussed in the presence of Dr. George O. Sharp, Mr. Fred Lamb, and Mr. Ed R. Beckwith, Executive Vice-President. The point was not resolved at the time of the discussion with these three gentlemen, but the point was again raised with Mr. Lamb and Mr. Sharp later on during the same visit.

Mr. Lamb was advised that our record showed that we had made this request in detail at the time of our visit of April 9th and 10th and that both numbers and page numbers were set forth in detail. Mr. Lamb claimed that he did not recollect that the pages were written down in detail, and he produced a confidential memorandum of the visits which did not show that the pages were given. I pointed out that this was at variance with my recollection, and pointed out that Mr. Lamb personally was in the group of individuals during the final conferences when these pages were enumerated specifically. I also pointed out that at the time we were in Dr. King's office, Mr. Lamb had been called by Mr. Murray to seek permission at our request when we had requested that the notebooks be loaned to us so that we could make copies of the pages ourselves. I pointed out that at this time Mr. Lamb refused to deliver the books to us on the grounds that it was against company policy, but that he promised to have the pages we desired duplicated for us. Mr. Lamb made a point that this request was not made in writing, and that he did not consider it was a promise, but rather that he had said he would try to get them for us. I pointed out that we had given a Notice of Inspection at the time of our visit on April 9th, and that we had given another Notice of Inspection at the time of our visit today. Mr. Lamb made a point of the fact that the notices we had given related to Section 704 of the Act, and no where in this section did it state that it was mandatory that records of this type be given during an inspection. I pointed out that I considered such records an integral part of an inspection of a new drug product.

I also pointed out that Mr. Beckwith had been called again about April 12th to ask why the copies had not been supplied us.

Mr. Lamb made a point of stating that he was not refusing to provide this information as an individual, but he did not "run the company". He said that he did not want the record to show that he or the firm were refusing our request, but that inasmuch as discussions were being held at the Washington level in regard to the whole matter, and the fact that the firm had already instituted a recall, he did not see why it was necessary to produce these records for us. He said he felt it was a decision that he personally could not make, and it would be up to the attorneys at the Washington level to make this decision.