Prior to leaving the firm, we returned to the conference room in the Administration Building and conferred with Mr. E. R. Beckwith, Dr. Harold W. Werner, R. H. Woodward, Fred Lamb, and Dr. F. Joseph Murray.

We told these gentlemen that we had not been able to find any notes regarding the food consumption and observations made on the monkeys, and that Dr. King still had not been able to offer any explanation for the discrepancies noted.

Mr. Beckwith reconfirmed his earlier statements of their intention to explore this very thoroughly to try to find answers for their own satisfaction. Mr. Beckwith also stated that he would try to get all of the copies of the records we desired as soon as possible.

DR. JOHN O. NESTOR.
DR. EDWIN GOLDENTHAL.
THOMAS M. RICE,
Supervisory Inspector.

Enclosure [omitted].

U.S. Government Memorandum.

WILLIAM S. MERRELL CO.,
Cincinnati, Ohio, April 11, 1962.

Division of Regulatory Management, Attn: Mr. Goldhammer.
Division of Pharmacology.
MER–29 Investigation (AF 1–942).

Along with Dr. Nestor of Division of New Drugs and Thomas M. Rice of the Cincinnati District, I visited the William S. Merrell Company in Cincinnati, Ohio on April 9 and 10 and copies of our memoranda of these visits have been directed to you. As will be noted in these memoranda, certain discrepancies between the original chronic monkey studies submitted in their new drug application and those found in their data notebooks have been disclosed. These discrepancies are not mistakes on the part of the William S. Merrell Company, but represent the submission of fraudulent and misleading data to FDA. The net effect of this misleading data was to make the drug appear less toxic in monkeys than was actually the case. This is particularly significant since at the time of our consideration of the NDA, representatives of the William S. Merrell Company presented strong arguments against the toxicity observed in rats and dogs in that a higher species, monkeys, which are closer to man than rats or dogs, showed no signs of toxicity upon chronic (16 months) administration of MER–29.

These discrepancies uncovered in our recent visit support the affidavit of Mrs. Jo Jordan in that fraudulent data was submitted to FDA on the monkeys administered MER–29 chronically.

On the basis of the affidavits of Mrs. Jo Jordan and Mr. Bruce Umberger (former employees of the William S. Merrell Company) and of the numerous discrepancies disclosed in Merrell's monkey study on MER–29, we strongly recommend that NDA 12–066 be suspended. In addition, we feel that sufficient evidence has been obtained to support prosecution of the corporation and the individuals involved and would recommend such action.

EDWIN I. GOLDENTHAL, Ph. D.

United States of America
Department of Health, Education, and Welfare

FDC–D–71

In the Matter of MER/29 (triparanol) capsules. New Drug Application No. 12–066

WM. S. MERRELL COMPANY, CINCINNATI, OHIO, APPLICANT

SUSPENSION ORDER

Wm. S. Merrell Company, Cincinnati, Ohio, the applicant for and the holder of effective New Drug Application No. 12–066 applying to MER/29 (triparanol) capsules, having requested the suspension of the effectiveness of said application, on the ground that clinical experience shows the drug is unsafe for use under the conditions of use upon the basis of which the application became effective, and thereby having waived Notice of Hearing as provided by Section 505(e) of the Federal Food, Drug, and Cosmetic Act, prior to such suspension;