On February 6, 1963, the firm was again inspected and the Food and Drug Administration learned that the firm was distributing Obetrol tablets in violation of its New Drug Application. A seizure was made of this drug in Los Angeles, California.

EVIDENCE OF VIOLATIVE SHIPMENT

Counts I and II

This sample was collected on August 8, 1964, from J. Raymond McSpirit D.O., 703 Cedar Lane, Teaneck, New Jersey, by Inspector Frederick T. Merola. The sample was identified by Dr. McSpirit, who furnished the Inspector with an invoice showing that the drugs were shipped by Rexar Pharmacal Corp. from Brooklyn, New York on or about April 18, 1964.

Counts III and IV

This sample was collected on October 5, 1965, from Daniel Reider, D.O., 2361 Lemoine Avenue, Fort Lee, New Jersey, by Inspector Paul T. Wiener. The sample was identified by Dr. Reider, who furnished the Inspector with an invoice showing that the drugs were shipped by Rexar Pharmacal Corp. from Brooklyn, New York, on or about March 1, 1965.

Count V

This sample was collected on December 15, 1965, from D. Katzman & Co., 670 Winters Avenue, Paramus, New Jersey, by Inspector Alfred M. Levy. The sample was identified by Mr. Stanley Szewczyck, a buyer for the firm, who furnished the Inspector with an invoice showing that the drug had been shipped by Rexar Pharmacal Corp. from Brooklyn, New York, on or about October 1, 1965. On December 29, 1965, Inspector Levy obtained from Richard P. Keating, M.D., 130 Prospect Street, Ridgewood, New Jersey, the September 13, 1965, issue of *Modern Medicine*, together with an appropriate affidavit signed by Dr. Keating.

RESPONSIBILITY OF INDIVIDUALS

Both Mr. Armin Rosner, President, and Mr. Martin Benjamin, Vice President, share equally the responsibility for the conduct of the firm. During the inspection of February 6, 1963, the Inspector observed that both men were familiar with the manufacturing and control procedures. They told the inspector they shared equally in the responsibility for making major decisions in the firm's operations. During the inspection of August 3, 4 and 5, 1964, the Inspectors obtained information and specimens of the advertisements of Obetrol tablets from Mr. Martin Benjamin. At that time, Mr. Armin Rosner told the inspectors that he considered the responsibility for operations of the firm, including labeling, shipping and sanitation, to be a joint one between himself and Mr. Benjamin. Both men, the Inspector noted, knew exactly what was going on in the operation of this business.

During the inspection of September 29, 1965, Mr. Benjamin told the Inspector that Mr. Rosner was in charge of plant sanitation, shipping and manufacturing operations and that Mr. Benjamin was active in sales and promotion.

In the last three to four years, both Mr. Rosner and Mr. Benjamin have dealt with the Inspectors either singly or together during each of the inspections made by the Food and Drug Administration. The firm is small enough so that each of the two men was aware of what was going on in the firm. In addition, they jointly set company policy and were equally responsible for the labeling and the advertising for the drugs which were shipped in interstate commerce.

HEARING HELD PURSUANT TO 21 U.S.C. 335

A Notice of Hearing was issued to Rexar Pharmacal Corp., Mr. Arwin Rosner and Mr. Martin Benjamin on January 10, 1966, charging the shipment in interstate commerce of a New Drug, the 30 mg. dosage form of Obetrol, without an approved New Drug Application. It was also alleged that the firm had misbranded its Obetrol 10 mg. tablets because of medical journal advertising which did not state in brief summary, or at all, certain side effects and contraindications as set forth in its approved New Drug Application labeling for the drug. Mr. Rosner and Mr. Benjamin, together with their attorney and consultants, appeared at the Hearing.

The respondents first addressed themselves to the charge concerning the omission of a precautionary statement in the advertising for the drug, Obetrol. They claimed that they were guided by a press release issued by the Food and Drug