JANUARY 17, 1967.

In reply refer to F.D.C. No. 53053.
The Honorable ATTORNEY GENERAL,
Department of Justice,
Washington, D.C.

DEAR MR. ATTORNEY GENERAL: We request the institution of criminal proceedings under the Federal Food, Drug, and Cosmetic Act, against Rexar Pharmacal Corporation, Brooklyn, New York, Mr. Armin Rosner and Mr. Martin Benjamin.

The offenses complained of occurred during the period from about April 18, 1964, to about October 1, 1965, and involve the introduction into interstate commerce at Brooklyn, New York, for delivery to Teaneck, Fort Lee and Paramus, New Jersey, of Oby-Rex tablets and time disintegration capsules and Obetrol tablets.

There are transmitted herewith a suggested form of criminal information and the following exhibits:

(1) Copies of Notice of Hearing.

(2) Copies of bottle labels for Oby-Rex and Obetrol tablets.

(3) Copies of package insert labeling (the approved New Drug Application labeling) for Obetrol tablets.

(4) Copy of the advertisement for Obetrol tablets which appeared in *Modern Medicine* for September 13, 1965.

SECTIONS OF THE ACT INVOLVED

The Information charges four violations of 21 U.S.C. 331(d) in that the defendants caused the introduction into interstate commerce of new drugs, the Oby-Rex capsules and tablets, which was in violation of 21 U.S.C. 355(a), since no approval of an application filed pursuant to 21 U.S.C. 355(b) was effective with respect to the drugs.

The Information also alleges in one count that the Obetrol tablets were misbranded within the meaning of 21 U.S.C. 352(n) in that the defendants failed to include in the advertisement caused to be issued by them with respect to the drug in the September 13, 1965, issue of the *Modern Medicine*, a true statement of information in brief summary relating to side effects and contraindications and effectiveness of such drug as required by regulations 21 CFR 1.105(e) and (f)(2).

REASONS FOR INVESTIGATIONS

On July 24, 1959, the firm received an approved New Drug Application for a product known as Obetrol tablets in 10 and 20 milligram strengths. Obetrol consisted of a combination of four different amphetamine salts in equal strengths as follows: Methamphetamine Saccharate, Methamphetamine Hydrochloride, Amphetamine Sulfate, Dextro Amphetamine Sulfate.

"Obetrol" was the trade name used when the drug was sold to wholesalers, while "Oby-Rex" was the trade name used when the same drug was sold to doctors. The drug will be referred to as "Obetrol" in the letter in the interest of clarity.

In 1962, the Food and Drug Administration learned that the firm was distributing a 30 milligram tablet and capsule under the name of "Obetrol" without a supplemental New Drug Application. However, there was no evidence that the firm was shipping this drug in interstate commerce at that time. On February 6, 1963, Food and Drug Administration Inspector Ernest Schmalz inspected this firm and learned that it was still manufacturing the 30 milligram Obetrol capsules and tablets, but apparently not shipping the drug in interstate commerce. Mr. Armin Rosner, the President of the firm, was asked by the inspector about the 30 milligram dosage form and his reasons for not filing a New Drug Application or a supplemental New Drug Application for these products. Mr. Rosner replied that he was of the opinion that the New Drug Application for Obetrol allowed dosages up to 60 milligrams per day. He pointed out that the directions for use for the 30 milligram tablets provided that the daily dosage fell within this range. He, therefore, questioned the need for submitting a supplemental New Drug Application or a second New Drug Application for the 30 milligram dosage form. He was advised by Inspector Schmalz to discuss this matter with the Food and Drug Administration's New Drug Branch in Washington, D.C.