to use prescription drugs. The incomplete application was rejected by the incomplete letter. Our regulations, upheld on this point by the Sixth Circuit in the Turkel case, call for filing over protest if the Company wishes to pursue its application. This Company has not done so and its application is a closed one.

Exceeding approved dosage of drugs is one of the surest ways to patient injury. Physicians have neither the legal nor the ethical right to experiment with their patients with excessive dosages without the patients informed consent, and when drugs of interstate origin are used, without compliance with the IWD regulations.

Very truly yours,

WILLIAM W. GOODRICH,
Assistant General Counsel,
Food and Drug Division.

MAY *29, 1968.*

Re Rexar Pharmacal Corp., FDC No. 53053.
Mr. WILLIAM W. GOODRICH,
Assistant General Counsel,
Department of Health, Education, and Welfare,
Washington, D.C.

DEAR MR. GOODRICH: This is to acknowledge receipt of your letter of April 18, 1968, requesting us to reconsider our decision to decline prosecution in this matter.

Your comments relative to the alleged violation of the advertising provisions of the Federal Food, Drug, and Cosmetic Act appear to be the same as those made in at least one other similar matter. (See Syntex Laboratories, Inc., FDC No. 53222.) Our views regarding the narrow issue presented by similar facts were fully set forth in our letters to you pertaining to that matter and in our letter of October 25, 1967, concerning the present submission. We adhere to them and to our decision not to prosecute this matter insofar as the advertisement is concerned.

Neither does the information contained in your letter warrant any change in our decision not to prosecute on the basis of the shipments to Dr. McSpirit in April 1964, and Dr. Reider in March of 1965. Despite the statement that there were four additional shipments in June 1965, no evidence has been submitted proving that the sales were to persons other than duly qualified physicians who ordered the larger dosage form for the purpose of dispensing them to bona fide patients being treated by them. The sales of the drug in New York State do not constitute violations of the Federal law and cannot be construed as exhibiting an intent to violate the Federal Food, Drug, and Cosmetic Act.

Accordingly, we are still of the opinion that the age of the alleged violations and the factual situation present a very poor basis for criminal prosecution. The facts are such as to raise grave doubts as to whether they constitute a violation in the legal sense. Moreover, it is our belief that the circumstances upon which the Government would be compelled to rely are so unappealing to a judge and a jury as to render a conviction highly unlikely.

We desire to correct the statement attributed to us in your letter that, "a physician is ethically and legally bound to treat patients wih drug dosages beyond the limits of safety proven through new drug procedures." That is *not* our position. The correct statement of our position, to which we adhere, appears in the next to the last paragraph of our letter of October 25, 1967.

For the reasons indicated above, we continue to be of the view that prosecution of this case is not feasible. We are therefore closing our file.

Sincerely,

FRED M. VINSON, Jr.,
Assistant Attorney General,
Criminal Division.
By HAROLD P. SHAPIRO,
Chief, Administrative Regulations Section.

MARCH 16, 1967.

In reply refer to F.D.C. No. 53222.
The Honorable ATTORNEY GENERAL,
Department of Justice, Washington, D.C.

DEAR MR. ATTORNEY GENERAL: We request the institution of criminal proceedings in the District of New Jersey, under the Federal Food, Drug, and