alone. Since your letter leaves the impression (p. 9) that the subjects have filed a supplemental new drug application covering the 30 mg dosage form for "Obetrol" and you do not indicate whether or not the application has been rejected, it would appear that in this respect compliance with the Act may be deemed to have been achieved.

Therefore, we are withholding further action with regard to the violations of April 18, 1964, and March 1, 1965, in order that you may inform us as to whether you believe prosecution for these violations should be instituted. In view of the factual situations outlined in your letter we are particularly interested in being informed as to the status of any supplemental application for the 30 mg dosage form. You will undoubtedly appreciate the force of an argument to a jury that physicians could have prescribed two 30 mg doses per day which would have been within the allowable lifitation of the approved labeling and which would have been available to patients by taking one 20 mg and one 10 mg tablet.

If there is any sound medical reason why such dosage should not be prescribed and thus why 30 mg tablets should not be available to physicians, we would be able to counteract any such defense with some force. Whether or not such reason exists is therefore a factor to which we would attach considerable importance in the event prosecution is requested as to the foregoing violations.

We also believe that it would be helpful to know whether the subjects in any way solicited the sale of the 30 mg tablets on April 18, 1964, and March 1, 1965, to Doctors McSpirit and Reider respectively, or whether such sales were solely as a result of unsolicited orders by the purchasers.

Sincerely,

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

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
September 26, 1967.

Attention Harold P. Shapiro, Chief, Administrative Regulations Section.
Re Rexar Pharmacal Corp., Armin Rosner, and Martin Benjamin. Your ref: FMV:JWK:mlh, 21-52-246. F.D.C. No. 53053.

Hon. FRED M. VINSON, Jr.,
Assistant Attorney General, Criminal Division, Department of Justice, Washington, D.C.

DEAR MR. VINSON: We have considered with the Food and Drug Administration the questions that you raised concerning this case.

The four counts which allege violations of 21 U.S.C. 331(d) are strong counts involving the distribution of unapproved new drugs, and would by themselves, support criminal action.

The firm did submit a supplemental new drug application for Oby-Rex 30 mg., but it was incomplete and the firm has been advised of this. Therefore, compliance has not been achieved. Moreover, the firm was advised in 1964 both to discontinue their violative advertising and that a 30 mg. tablet would require a new drug application.

It is irrelevant that a physician could have prescribed a 20 mg. and a 10 mg. tablet, thereby giving his patient a total of 30 mg. at each dose. This does not make it legal for the firm to market a 30 mg. dose without complying with the new drug requirements. Had a doctor so prescribed, he would have exceeded the limits of the safety approval in the new drug application. While he may, in his discretion, prescribe an excessive dose for his own patient, he does so at the risk of civil liability for exceeding the dosage that has been proved safe, as required by law. The fact is that the consensus of medical opinion holds that the dosage of 30 mg. per tablet is not generally recognized as safe. To say that a person can take 20 5-grain aspirins at one time is not to say that it is permissible to make a 100-grain aspirin tablet.

The Administration's file does not reflect that the firm has detail men or uses other means for the direct solicitation of orders from physicians.