OCTOBER 25, 1967.

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 in response to your letter of September 28, 1967, in which you answered certain questions which we raised in our letter to you dated April 24, 1967. The views you express concerning the subject's advertisement of the drug Oby-Rex in *Modern Medicine* for September, 1965, have been carefully considered. However, we have observed that, although the statute and the regulations pertaining to advertising refer only to "side effects" and "contraindications", other regulations pertaining to the labeling of prescription drugs refer to "relevant hazards, contraindications, side effects, and precautions" (for example, see: 21 C.F.R. Section 1.106(b)(3)(i); 1.106(b)(4)(i); 130.4(c); 130.9(d)(1); 130.11(a)(1) and (3)). Thus, where the agency has desired to require inclusion of information in the labeling of a prescription drug of "hazards" or "precautions", it has done so by using those specific words even though in the same sentence it has required the inclusion of "side effects" and "contraindications." Accordingly, it appears that the agency has recognized that each of these words has a separate definite meaning and we could not sustain a contention that "precautions" are included by implication in the statutory language, particularly in an instance in which the labeling of the drug as approved by the agency distinguished between what constitutes "side effects and contraindications" and "precautions."

Therefore, prosecution on the basis of the failure of the subjects to include in the advertisement a statement of the "precautions" is declined.

Insofar as the counts pertaining to the shipment, on April 18, 1964, and March 1, 1965, to Doctors McSpirit and Reider, according to their request, of 30 mg strength tablets of Oby-Rex and Oby-Rex M tablets are concerned, we are not persuaded that such drastic action as criminal prosecution is required, or that if it were instituted a successful result could be obtained.

The offenses took place between two and one half and three and one half years ago but were not reported until January of this year. Despite your statement that compliance has not been achieved, no additional violations have been reported and the subjects have filed a supplemental new drug application requesting approval for the 30 mg dosage form. Although this application has been characterized as "incomplete" it has not been withdrawn nor has the agency taken any steps looking toward a refusal to approve it. Apparently the subjects are attempting to complete the application. Thus, despite your statement as to the consensus of medical opinion, the record before the agency is such as to leave open the question as to whether such dosage form is proper.

In addition, the facts that under the approved labeling a dosage totaling 60 mg per day may eventually be reached in the administration of this drug and that the dosage form of the shipment was specifically ordered by licensed physicians who are legally entitled, and ethically required, to prescribe for their patients the dosage dictated by their own judgment based upon a knowledge of their patients' requirements will tend to weaken any criminal prosecution.

Accordingly, it is our view that the time which has elapsed since the commission of the violation and the factual situation make this an unattractive case for criminal action. Moreover, since the subjects have not sold this dosage indiscriminately in interstate commerce and have filed a supplemental application covering its use, it would seem prosecution is not necessary to enforce compliance with the requirement of the law.

Thus, prosecution is declined.

Sincerely,

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