On point 2(b) above Mr. Hagan said that he would discuss with Mr. George Strong (Pfizer) the language to be used in qualifying such a claim and would telephone us on Friday, April 12, and propose language for an opinion.

3. Mr. Hagan indicated that he would send the FDA a letter in regard to Vibramycin ad and it was left that such a decision was to be that of the firm. Unless such a letter of commitment is received, however, additional attention to the ad should be considered by FDA.

H. W. CHADDUCK.

U.S. GOVERNMENT MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
FOOD AND DRUG ADMINISTRATION,
April 18, 1968.

To: Max B. McQueen, M.D., Office of Marketed Drugs (MD–330)
From: William E. Dye, Ph. D., Office of New Drugs (MD–140)
Subject: Proposed labeling change for package insert for Vibramycin Capsules, Charles Pfizer dated March 1, 1968

1. This is a request to add the following sentences to the insert: "The spectrum of Vibramycin is essentially that of the other tetracycline analogues. Certain strains of organisms, including Staph. aureus, may exhibit greater susceptibility *in vitro* to Vibramycin than to the other analogues. *In vitro* susceptibility testing should be conducted.

2. There is no objection to the first sentence.

3. Although the references quoted do show some increase in *in vitro* susceptibility to Vibramycin when compared to other tetracycline analogues, I recommend that the second sentence be deleted. The effect seen could easily be a laboratory artifact based upon a difference in the stability of the analogues or to a difference in the pH at which they display maximal antibacterial effectiveness. This sentence implies that Vibramycin might be effective in clinical infections caused by tetracycline-analogue resistant Staphylococcus aureus. There is no evidence for this. If the sentence is permitted to remain, it can be expected to be the basis for advertising claims for this drug with the above implication.

4. There is no objection to the third sentence.

WILLIAM E. DYE, Ph. D.,
Clinical Microbiologist, DAD.

MEMORANDUM OF CONFERENCE

April 23, 1968.

NDA No. 50–006, 50–007

Between: Mr. Avergun, Dr. McDermott, Dr. Sikowski, Pfizer; and Dr. Ortiz, Dr. McQueen, Dr. Hurwitz, Dr. Dye, Dr. Borowsky, FDA

Dr. Hurwitz discussed the proposed labeling for Sterane. He stated that the changes were satisfactory, but a pregnancy warning was necessary. The company disagreed about the wording of the warning but agreed to consider it.

Discussion of the labeling of the proposed 20 million unit vial of Penicillin G centered on the labeling.

A supplement to revise labeling on Vibramycin was considered next. The supplement, dated March 1, 1968, inserted in the labeling words to the effect that the drug was particularly indicated for use in infections caused by staph. aureus. Dr. Dye contended that the results in the article on which this claim was based were invalid because they could well be due to laboratory artifact. He also cited an article in the American Journal of Medicine stating tetracyclines should not be used in staphylococcal infections at any time. These facts coupled with the fact that this new wording might well be used for misleading advertising claims led to FDA position that the supplement should be denied. The company disagreed, but stated they would withhold action until they received our letter.

STEPHEN A. BOROWSKY, M.D.,
Division, Meta/Endo Drug Surveillance.