All promotional labeling for these products is still under review by the Bureau of Medicine and none of this should be used by the firm until it receives our approval in writing at a later date.

Because preliminary review of the submitted promotional labeling has raised significant questions, Pfizer should be cautioned that no journal advertising should be placed regarding these products unless it is fully in accord with the approved package labeling and otherwise meets the requirements of the regulations under section 502(n).

B. HARVEY MINCHEW, M.D.

DECEMBER 22, 1967.

Mr. JACK POWERS,
Charles Pfizer & Co., Inc.,
235 East 42d Street,
New York, N.Y.

DEAR MR. POWERS: This is to confirm our telephone conversation today concerning the details of Vibramycin at a recent American Academy of Pediatrics meeting. Statements have been received from members of my staff as well as practicing physicians indicating that your firm's representatives stated that the drug was less apt to cause tooth staining because of the lower calcium binding capacity. It also stated that the drug was more effective over a larger spectrum of gram positive and gram negative organisms including certain staphylococcus and pseudomenas species, than were the other tetracyclines. Both of these statements are, of course, inconsistent with your final printed labeling and therefore false and misleading.

You indicated your willingness to clarify any existing misunderstandings by a personal letter from you to your representatives clearly stating that drug detailing will be limited to that which is approved in the final printed labeling. I would appreciate your providing me with a copy of the letter you send to your employees concerning this matter.

Sincerely yours,

JAMES L. GODDARD, M.D.,
Commissioner of Food and Drugs.

APRIL 9, 1968.

Chas. Pfizer & Co., New York, N.Y. (AF 12-118)
NDA 50-006 Vibramycin, 50-007

MEMORANDUM OF TELEPHONE CONVERSATION

Between: Mr. Charles Hagan, Chas. Pfizer & Co. and Dr. R. S. McCleery, Mr. H. W. Chadduck, Division of Medical Advertising/OMS

Subject: Vibramycin Journal Advertisement, example: MD Medical Newsmagazine, April 1968

The subject ad, consisting of a two-page spread of promotional copy plus one column on a third page presenting a "Brief Summary," was brought to the attention of Pfizer representatives at a meeting in the Commissioner's office on April 8, during a discussion of Urobiotic-250 promotion and package labeling.

Defects in the Vibramycin ad were of the same type as those in the Urobiotic-250 advertisement discussed at the 4-8-68 meeting.

This telephone conversation with Mr. Charles Hagan (Pfizer) was by way of follow-up to obtain a record of the firm's agreement to correct the Vibramycin ad defects. The gist of the information and commitments given by Mr. Hagan is as follows:

1. The above-described Vibramycin ad is not scheduled to run after April 1968.

2. Future ads will include corrections of (a) side effect statements that emphasize minimal specific side effects without calling attention to other and more serious side effects listed in the "Brief Summary" of the ad and/or package insert, and (b) broad promotional claims such as ". . . oral broad-spectrum tetracycline antibiotic*" without adding information qualifying the claim so as to bring out limitations of effectiveness and to make the claim more meaningful and informative. The purpose here is to provide some specificity of knowledge of drug without necessarily going into great detail at that point in the ad.