

a list of where the ad(s) appeared. He requested copies of telegrams to detail men concerning the present incident.

The discussion turned to remedial considerations. Dr. Goddard said that the first obligation is to correct the bad impressions caused by the promotion.

Mr. Weeden commented about the lack of certified material to market and urged rapid action.

Drs. Goddard and Ley and Mr. Goodrich joined in requesting the following actions. The "remedial" letter should be sent air-mail. A draft will be prepared and sent to Dr. Ley for review. A corrective advertisement will be prepared and run in journals where the defective ad(s) have appeared. Accurate copy of the ads [there are two] will be sent in for detailed review. Corrective information for detailing will be prepared for review.

As to timing, Mr. Weeden said that some material had cleared to the retail level. Mr. Goodrich noted that such material could be subject to seizure. Dr. Goddard requested that Mr. Weeden sponsor the collection of information as to material shipped from wholesalers to retailers. After some discussion, Mr. Weeden said that efforts could be made to have the Bristol field force contact wholesalers. Also, a copy of the telegram will be sent to FDA regarding the embargo of stocks in the hands of wholesalers.

Before leaving the meeting at this point, Dr. Goddard indicated that there was no intention to prolong the embargo unduly but that full corrective action must be taken and that will take time, perhaps 30-60 days.

Dr. Ley continued the meeting and said, in view of the urgency, that a copy of the current ad and of the detail men's brochures should be sent to him for Dr. McCleery's review, which will require time. It was left to the visitors to propose copy for the "remedial" letter, and corrective ad copy if they wished. Dr. Ley said alternatives would be considered if proposed. One possibility suggested by Mr. Goodrich was to convert the remedial ad into a mailing piece.

At this point, Dr. McCleery said that Bristol's competitors had proceeded in an orderly manner and that his group is engaged in assisting them in their promotion; therefore, it would not be fair to postpone existing commitments to handle Bristol's problem exclusively. He said, however, that his review would proceed as rapidly as possible after receipt of the Bristol input.

There was a brief exchange regarding preclearance of promotional labeling of antibiotic drugs. Mr. Simonton seemed unclear as to this but it was emphasized that the regulation revised in February 1968 makes it certain that preclearance is not normally required.

At conclusion of the meeting after Dr. Peltier had summarized the required information to be submitted (copy of current ad, remedial letter draft, and detailing instructions), Dr. McCleery said that if Bristol could get the material to us by Wednesday May 29, we could probably meet Friday to discuss it. He said that, among other things, the material should include a straightforward scientific statement of the place of Dynapen in therapy.

After the meeting, it was arranged that Bristol would meet in Dr. Ley's office at 3:00 p.m., Friday, May 31 to discuss the remedial pieces.

[Note: In lieu of a critique, which because of lack of time could not be prepared in advance of this meeting, there are attached a xerox copy of a marked up copy of the Bristol promotional letter showing areas of error and a copy of a rough draft of comments on the letter dated May 23, 1968].

H. W. CHADDUCK.

BRISTOL LABORATORIES,
DIVISION OF BRISTOL-MYERS CO.,
Syracuse, N.Y., May 27, 1968.

Dr. HERBERT L. LEY, Jr.,
Director, Bureau of Medicine,
Food and Drug Administration,
Arlington, Va.

DEAR DR. LEY: Enclosed is the Dynapen promotional literature as well as the other material you requested from Mr. Weeden:

(1) *Exhibit A*.—Three copies of the enclosed manila index folder and its contents were given to our salesmen to be used as a "keeper." That means the folder was not left with the doctor but rather used as a visual aid by the salesman to help him acquaint the doctor with the new drug. The salesman's instructions were to use the quotation sheet (headed: Antibiotic Resistance