This hearing was held to afford the respondent an opportunity to present his views on additional advertisement appearing in *American Journal of Medicine*, November 1966.

The position of the firm with respect to the charges remains essentially the same. Our review of the written summation does not change any of our views as set forth in the January 26, 1967 Summary and Recommendation. Accordingly, we renew our recommendation for prosecution of Merck Sharp and Dohme, Division of Merck & Co., Inc., on this number.

IRWIN B. BERCH,
Director, Philadelphia District.

FOOD AND DRUG ADMINISTRATION,
Philadelphia District, February 6, 1968.

RECORD OF HEARING

Sample number and product: 126–350 B, Indocin Capsules, 25 Mg.
Firm cited [additional citation]: Merck Sharp & Dohme, Division of Merck & Co., Inc., West Point, Pennsylvania 19486.
Date of Hearing: February 6, 1968.
Where Held: Philadelphia District—FDA.
Present: Mr. Hayward H. Coburn, Attorney-at-Law, Drinker Biddle & Reath, Philadelphia, Pennsylvania 19107. Mr. Irwin B. Berch, Director, Philadelphia District.

This hearing was originally scheduled for January 15, 1968 and was rescheduled at the request of the respondent. Mr. Coburn presented an up-to-date Legal Status Sheet and acknowledged that the shipment was made as alleged and that the advertisement in question did appear as set forth in the Charge Sheet.

Mr. Coburn stated that the firm's response would be the written response presented to me at the hearing. This is an 18-page statement to which are attached Exhibits A–1, A–2, B, C, D, E, and F. I asked Mr. Coburn whether or not the firm had made any changes in its promotional or advertising practices since the receipt of the current citation. He stated the firm's revisions are reflected in the mailing to physicians (Exhibit E) and the revised advertisement (Exhibit F) which appeared following the earlier citation. He added that, in common with other newly-introduced drugs, additional data accumulated from human experience serve to identify other possible human reactions. He assured me these were being regularly incorporated in the revised labeling which the firm submits in accordance with the new drug regulations.

The respondent did not remain for the dictation of this hearing record.

IRWIN B. BERCH,
Director, Philadelphia District.

MERCK SHARP & DOHME,
West Point, Pa., March 8, 1968.

DIRECTOR
Bureau of Medicine
ACTING DIRECTOR
Division of Medical Advertising/OMS

We concur in the prosecution recommendation of Philadelphia District in its S & R dated February 6, 1968, and we recommend that the subject number not be placed in permanent abeyance unless such action is advocated in an opinion from General Counsel. We think that there is a valid basis for prosecution on the issues. Further, the attitude of the firm, as reflected in the letter response to the Notice of Hearing dated January 3, 1968, is poor to the extent of inviting prosecution notwithstanding its *pro forma* conclusion that prosecution should no follow.

Our comments will be directed to the written response dated February 6, 1968 and prepared by H. H. Coburn, attorney for Merck on the staff of Drinker, Biddle and Reath. Our purpose will be to show: (a) the poor attitude of the firm, (b) the inadequacy of the response, and (c) to point up tryable issues that we believe exist on the basis of the clear language of the statute, and apart from the regulations. Our comments are not intended to be all-inclusive.