and representatives of the Bureau of Medicine. The firm takes the position that since it has made forthright correction of the alleged violations prosecution should not ensue. Attached to the firm's response is a copy of the advertisement for the November 14, 1966 issue of *JAMA* which it contends fully meets the requirements of Section 502(n).

DISTRICT'S CONCLUSIONS

In reviewing the firm's position in response to the hearing we find we cannot agree with most of the firm's contentions. With regard to the jurisdictional question concerning false and misleading claims in the body of the advertisement, we understand this was one of the issues presented by the industry during its initial request for a hearing on the proposed regulations. Thereafter, in the ensuing dialogue the industry withdrew its objections in light of the exchange of memoranda of understanding. Although we do not have a record of these events at the District, we understand that Merck Sharp & Dohme was a party to these proceedings and its attack upon the validity of the regulation is somewhat belated.

We believe the misrepresentations concerning the comparative safety of Indocin are serious in nature, particularly in light of the continued receipt of medical data indicating this product must be prescribed with caution. The manner in which the clinical studies were quoted is also of serious consequence, particularly when viewed from the standpoint that few physicians have available to them the original articles to compare for a more complete evaluation of the product. In this connection, we wish to point out that one of the articles (the *Excerpta Medica Foundation* booklet) could not be located in our rather extensive medical library.

The firm's comment concerning references in the brief summary to ulceration of the stomach, duodenum, or small intestine, may have some merit. If this recommendation is approved, I believe it would be well to delete reference to them lest we become involved in unnecessarily complex semantics in presentation of our case.

Although the firm presents persuasive arguments for mitigating circumstances tending to establish that need for prosecution no longer exists, we do not agree with the firm's position. As one of the leaders of the pharmaceutical industry, the firm had available to it the best brains and talent in the medical advertising field, yet it chose to utilize advertising tactics that should have been abandoned upon passage of the Kefauver-Harris Amendment of 1962. The contention that mitigating circumstances can exist appears to be of little consequence when we consider there exists no adequate method to correct the improper advertising once it has been printed and disseminated to prescribing physicians.

SPECIAL REVIEW REQUESTED

In separate communication of January 10, 1967 (Exhibit C), Mr. Coburn transmitted a copy of the *Excerpta Medica Foundation* publication entitled "NON-STEROIDAL ANTI-INFLAMMATORY DRUG THERAPY IN RHEUMATIC DISEASE" (Exhibit D). Attached with the Summary and Recommendation is the single copy of this publication which the Bureau of Medicine requested for review. Upon review of this material they may consider inclusion of additional charges. If they do, we recommend no additional citation issue because the charges would be included within the general scope of the first portion of our Charge Sheet enclosed with the Notice of Hearing.

IRWIN B. BERCH,
Director, Philadelphia District.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
FOOD AND DRUG ADMINISTRATION,
Philadelphia Pa., January 3, 1968.

MERCK SHARP & DOHME,
Division of Merck & Co., Inc.,
West Point, Pa:

Investigation by this Administration indicates your responsibility for violation of the Federal Food, Drug, and Cosmetic Act, as described in the attached Charge Sheet, with respect to the following:

Consignment of an article labeled in part: (btl) "100 *** CAPSULES INDOCIN (INDOMETHACIN) *** 25 mg. Merck Sharp & Dohme West Point, Pa. Division