

(14) 11-3-66—Humorsol, 0.25% and 0.125%—Increased incidence of eye irritations.

In addition to the above, the firm recalled eight drug products which had been distributed to outside clinical investigators whose eligibility to handle investigational drugs was terminated. Investigations are presently continuing on the firm's handling of DMSO and MK-665 with view to ascertaining whether or not there is adequate evidence to sustain criminal action concerning the firm's handling of these investigational drugs. With the exception of the Humorsol recall, all of the recalls are considered "closed" from the standpoint of adequate accounting for the returned merchandise.

RESPONSIBILITY FOR ALLEGED VIOLATIONS

Our investigations of the promotional practices of the larger pharmaceutical firms indicate the planning, drafting and approval of medical journal advertising involve essentially an institutional decision on the part of the firm. In addition, outside advertising agencies are generally involved. In the instant case we do not believe we have evidence to fix any individual responsibility for the placing of this ad beyond the responsibility normally carried by corporate officers. For this reason, we have not recommended the naming of individual defendants.

INTERSTATE RECORDS AND LABELING

The records covering this shipment consist of invoice issued by Merck Sharp & Dolme and identified by both dealer's statement and affidavit of the consignee firm. In addition, we have established distribution of the medical journal and prescribing of the product through affidavit of Mischa F. Grossman, M.D., Cherry Hill Hospital, Cherry Hill, New Jersey, whose affidavit states that he has received the September 26, 1966 issue of *JAMA* which bears an advertisement for Indocin, and that in the regular course of his practice he has prescribed Indocin for some of his patients.

RESPONDENTS' VIEWS PRESENTED AT HEARING

At the hearing held on December 14, 1966, the firm was represented by house counsel Robert L. Banse and retained counsel Hayward H. Coburn of Drinker Biddle & Heath, Philadelphia, Pennsylvania. At the hearing the firm indicated that it would challenge the validity of regulations, disagree with our conclusions and question the wisdom of recommending prosecution for this type of violation. The respondents stressed, however, that the firm's actual response would be in the form of a detailed written response and asked that our evaluation be based on the written record. They did submit a tabulation (Exhibit A) but indicated this would be resubmitted with their written response. During the hearing X asked to be provided with a copy of Dr. England's article in the *Excerpta Medica Foundation* because our medical officers had been unable to locate this publication. They promised to furnish me a copy, but stressed again this would be done apart from their response in that our Charge Sheet had contained no allegations concerning this publication. At the insistence of the respondents for adequate time to prepare their response, they were granted until January 10, 1967 to present this material.

The firm's response to the charges is set forth in considerable detail in Exhibit B and will not be repeated here because the response, itself, should be studied in view of this proposed action. Briefly, the firm challenges our legal position concerning our jurisdiction over false and misleading statements in the body of the advertisement. The firm disagrees with our conclusions concerning use of terms such as "extends the margin of safety in long-term management of arthritic disorders." The firm sets forth its disagreement with each of the interpretations we have alleged in the Charge Sheet. The firm contends that the quotations from the articles cited below the illustrations in the advertisement fairly represent the views of the author. The firm takes issue with our views on listing of contraindications in the brief summary and claims its condensation is both fair and accurate. The firm's views are supported with a tabulation comparing information alleged to be omitted with information actually presented in the advertisement.

The firm also advances the view that even if it were in error the circumstances do not merit institution of criminal action. It recites the history of its dealings with General Counsel William W. Goodrich, Commissioner James L. Goddard