

of Merck & Co., Inc. CAUTION: Federal law *** H3088" shipped by you on or about November 7, 1966 to The Drug House Inc., 1880 Princeton Avenue, Trenton, New Jersey.

An informal hearing will be held on Monday, January 15, 1968 at 10:00 (EST) in Room 1204 U.S. Customhouse, 2d and Chestnut Streets, Philadelphia, Pennsylvania, to give you an opportunity to present your views in the matter. The enclosed INFORMATION SHEET explains the purpose and nature of the hearing, and how you may reply. If no response is received on or before the date set, our decision on whether to refer the matter to the Department of Justice for prosecution will be based on the evidence at hand.

By direction of the Secretary of the Department of Health, Education, and Welfare.

IRWIN B. BERCH,
Director, Philadelphia District.

PROHIBITED ACT

Section 301 (a) of the Federal Food, Drug, and Cosmetic Act. The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.

CHARGES

A. The journal advertisement for Indocin appearing in the November 1966 issue of the *American Journal of Medicine* causes the drug to be misbranded under section 502(n) of the Act in that said ad does not fairly show the effectiveness of the drug in the conditions for which it is recommended in the advertisement and fails to achieve fair balance in its presentation as required by regulation 1.105(e) in that:

1. The headline "Extends the margin of safety in the long-term management of arthritic disorders" misleadingly implies that Indocin is safer than all other effective anti-arthritic agents for long-term therapy. Furthermore, the unqualified phrase "arthritic disorders" misleadingly extends by implication the indications for use in the labeling accepted as part of the new drug application.

2. The quotation "... the first non-corticosteroid agent which produced a predictable and measurable reduction in joint-swelling in most cases of active rheumatoid arthritis" from an article by Hart and Boardman (Hart, F. D. and Boardman, P. L.: *British Medical Journal*, 2:965, October 19, 1963) under the ad caption "rheumatoid arthritis" does not represent a true statement of effectiveness for Indocin and presents a distorted view of the drug's effectiveness. In addition, the use of this quotation, along with the reference to the October 19, 1963 article by Hart and Boardman is further misleading in that the quotation and reference is obsolete since it fails to take into account a more recent and more scientific article by the same authors.

3. The quotation "Indomethacin is the drug of choice in acute gout. . ." attributed to Hart and Boardman (Hart, F. D. and Boardman, P. L.: *British Medical Journal*, 2:965, October 19, 1963) appearing under the caption "Gout" misleadingly implies that the author's opinion was based upon a large experience and that it was consistent with the general experience of experts using the drug according to the approved labeling. Furthermore, the claim "the drug of choice" for this new drug, is not supported by the NDA and is contrary to all expert opinion.

4. The quotation "I have had some 500 patients on Indomethacin now for about 3 years. I find it an extremely helpful drug. I think there are certain areas where it will be without question the drug of choice. One of these is osteoarthritis of the hip" attributed to Englund (Englund, D. W. in *Non-Steroidal Anti-Inflammatory Drug Therapy in Rheumatic Disease*, New York Excerpta Medica Foundation, 1965, page 27) appearing under the caption "degenerative joint disease (osteoarthritis) of the hip" is misleading in that the statement "I have had some 500 patients on Indomethacin now for about 3 years . . ." when considered in relation to the headline claim, "extends the margin of safety in the long-term management of arthritic disorders" misleading gives the reader the impression of powerful support through massive research experience of 3-years-long administration to 500 patients on a new drug, when in fact, the statement is an "off the cuff" remark at a symposium supported by a grant from Merck, Sharp & Dohme.