In the United States District Court for the Eastern District of Pennsylvania

No. ——

UNITED STATES OF AMERICA, PLAINTIFF

v.

An article of drug consisting of 45 individually cartoned bottles, more or less, labeled in part:

(bottle and ctn.)

"Lasix 40 Mg. Furosemide 100 Tablets Caution: Federal law prohibits * * * Directions: * * * 1 or 2 tabs. see insert * * * Hoechst Pharmaceuticals, Inc. Formerly Lloyd Bros., Inc. Cincinnati, Ohio 45229 * * * Control 600376B"

(insert)

"Lasix Brand of furosemide * * * Original Printing June 3, 1966"

DEFENDANT

COMPLAINT FOR FORFEITURE

To The Honorable Judge of the United States District Court For The Eastern District of Pennsylvania.

Now comes the United States of America, by Drew J. T. O'Keefe, United States Attorney for the Eastern District of Pennsylvania and shows to the court:

1. That this complaint is filed by the United States of America and prays seizure and condemnation of a certain article of drug, as hereinafter set forth, in accordance with the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

2. That there is at Philadelphia, Pennsylvania, in possession of Drug House, Inc., 1011 West Butler Street, or elsewhere within the jurisdiction of this Court, an article of drug consisting of 45 individually cartoned bottles, more or less, labeled in part: (bottle and carton) "Lasix 40 Mg. Furosemide 100 Tablets Caution: Federal law prohibits * * * Directions: * * * 1 or 2 tabs. See insert * * * Hoechst Pharmaceuticals, Inc. Formerly Lloyd Bros., Inc. Cincinnati, Ohio 45229 * * * Control 600376B" (Insert) "Lasix Brand of furosemide * * * Original Printing June 3, 1966" which were shipped, on or about November 3, 1966, by Hoechst Pharmaceuticals, Inc., Cincinnati, Ohio, via unknown carrier.

3. That the aforesaid article was misbranded when introduced into and while in interstate commerce, within the meaning of 21 U.S.C. 352(n) in that it is a prescription drug distributed and offered for sale in the State of Pennsylvania, and the advertisements for the drug appearing in the Journal of the American Medical Association for October 10, 1966, Medical World News of October 21, 1966, Medical Economics of October 31, 1966, and MD Medical News Magazine of November 1966, caused to be issued by the manufacturer, packer, or distributor of the drug, fail to include a true statement of information in brief summary relating to the effectiveness and contraindictions of said drug as required by regulations 21 CFR 105 as follows:

(A) the advertisements lack fair balance in their presentations on effectiveness and contraindications, and do not fairly show the effectiveness of the drug in the conditions for which it is recommended or suggested in the advertisements, as required by regulations 21 CFR 105(e) since the advertisements represent,

(1) That when the drug was compared with hydrochlorothiazide substantial increases in water and sodium excretion were shown in the case of furosemide (by reference to a paper by Dr. H. Kleinfolder, published in German M. Month. (8:459, 1963) but fail to reveal that the studies were conducted with only eight patients, and that the overlap of the standard errors of the means derived from the data is so great that the data do not permit their unspecified repetition in the advertisements and the implied extrapolation to experience to be expected in the general population;

(2) That a paper by R. J. Timmerman, M.D. published in *Curr. Therap. Rea.* 6:88, 1964, pertains to the time of onset and length of action of the drug in edematous patients but misleadingly fail to reveal that the studies reported by the paper were not conducted on edematous patients;