6752. Barium sulfate. (F.D.C. No. 46418. S. No. 96–443 R.)

QUANTITY: 2,843 10-lb. cans, at Vineland, N.J., in possession of Eastern Laboratories, Inc.

SHIPPED: 5–17–61, from New York, N.Y.

LABEL IN PART: (Can) "Barium Sulfate U.S.P. * * * Eastern Laboratories, Inc. * * * Whittaker, Clark & Daniels, Inc. New York, New York."

RESULTS OF INVESTIGATION: Analysis showed that the article failed to conform to the United States Pharmacopeia requirements for *barium sulfate*, in that it did not meet the limits for acid-soluble substances, soluble barium salts, and sulfide, when tested in accordance with U.S.P. XVI.

The article had been repacked and labeled as described by the dealer from bulk stock shipped as "Lot #333 Blanc Fixe."

LIBELED: 8–29–61, Dist. N.J.

CHARGE: 501(b)—while held for sale, the article purported to be and was represented as a drug, barium sulfate, the name of which is recognized in the United States Pharmacopeia, an official compendium, and its quality fell below the standard set forth in such compendium; and 502(a)—the article's label statement "Barium Sulfate U.S.P." was false and misleading as applied to a product which did not conform to the standards for *barium sulfate*, U.S.P.

DISPOSITION: 10–23–61. Consent—claimed by the dealer and released under bond for relabeling.

6753. Pas-C tablets. (F.D.C. No. 46526. S. No. 13–747 T.)

QUANTITY: 33 1,000-tablet btls. at Milwaukee, Wis.

SHIPPED: 10–2–61, from Chicago, Ill., by Hellwig, Inc.

LABEL IN PART: "Hellwig Pas-C Pascorbic 0.5 Grams Conjugated Para-Amino Salicylic Ascorbate Hellwig, Inc."

RESULTS OF INVESTIGATION: Analysis showed that the article was para-aminosalicylic acid. No ascorbic acid was found.

LIBELED: 11–7–61, E. Dist. Wis.

CHARGE: 501(d)(2)—when shipped, para-aminosalicylic acid had been substituted in whole or in part for conjugated para-aminosalicylic ascorbate; and 502(a)—the label statement "Conjugated Para-Amino Salicylic Ascorbate" was false and misleading when applied to an article which contained no ascorbate but was entirely para-aminosalicylic acid.

DISPOSITION: 12–4–61. Consent—claimed by Hellwig, Inc., without admitting the allegations of adulteration and misbranding, and released under bond for relabeling.

6754. Isoproterenol hydrochloride sublingual tablets. (F.D.C. No. 46342. S. No. 30–801 T.)

QUANTITY: 190 50-tablet btls. at Los Angeles, Calif.

SHIPPED: 6–25–61, from Philadelphia, Pa., by Physicians' Drug & Supply Co.

LABEL IN PART: "50 Sublingual Tablets Isoproternol Hydrochloride U.S.P. Each tablet contains: Isopropylarterenol HCl U.S.P. 15 mg. * * * Physicians' Drug & Supply Co. Philadelphia 6, Pa."

RESULTS OF INVESTIGATION: Analysis showed that the article failed to conform to the United States Pharmacopeia requirement for sublingual tablets in that it failed to disintegrate within three minutes as specified in U.S.P. XVI.