

suspension which, upon being shaken a reasonable length of time, would insure a uniform distribution of solid in vehicle and, therefore, uniform and proper dosage.

DISPOSITION: 9-20-60. Default—destruction.

6489. Sodium para-aminosalicylic acid tablets. (F.D.C. No. 43394. S. No. 61-104 P.)

QUANTITY: 74 24-btl. cartons and 25 btls. at Detroit, Mich.

SHIPPED: Between 5-22-59 and 6-4-59, from Auburn, Mass., by Cowley Pharmaceuticals, Inc.

LABEL IN PART: "1,000 Tablets Salamin Sodium Each Tablet Contains: Sodium Para-Aminosalicylic Acid 0.5 grams (7.72 grains)."

RESULTS OF INVESTIGATION: Examination showed that the article contained 87.6 percent of the labeled amount of sodium para-aminosalicylic acid; that the average weight of tablets in two subdivisions was below declared weight of active ingredient; and that a substantial number of broken tablets were found in the sample. United States Pharmacopeia requires *sodium para-aminosalicylic acid tablets* to contain from 95 to 105 percent of labeled amount of the drug.

LIBELED: 7-22-59, E. Dist. Mich.

CHARGE: 501(b)—when shipped, the article purported to be a drug recognized in the United States Pharmacopeia, an official compendium, and its strength differed from, and its quality fell below the standard set forth in the compendium; 502(a)—the label statement "Each tablet contains: Sodium Para-Aminosalicylic Acid 0.5 grams (7.72 grains)" was false and misleading.

DISPOSITION: 12-28-60. Consent—claimed by shipper and reconditioned to be brought into compliance with the law.

6490. Posterior pituitary injection. (F.D.C. No. 45135. S. No. 41-134 R.)

QUANTITY: 12 vials at St. Louis, Mo.

SHIPPED: 8-22-60, from Chicago, Ill., by Medical Chemicals Corp.

LABEL IN PART: (Vial) "10 cc Sterile Multiple Dose Vial Posterior Pituitary Injection 10 U. S. P. Units/cc (Obstetrical) 0.5 Chlorobutanol * * * Medical Chem. Corp. Chicago 51, Ill. 6132."

RESULTS OF INVESTIGATION: Analysis showed that the potency of the article was not more than 4.6. U. S. P. posterior pituitary units per cubic centimeter.

LIBELED: 11-7-60, E. Dist. Mo.

CHARGE: 501(b)—when shipped, the strength of the article fell below the standard set forth in the United States Pharmacopeia; and 502(a)—the label statement "Posterior Pituitary Injection 10 U. S. P. Units/cc" was false and misleading.

DISPOSITION: 12-14-60. Default—destruction.

6491. Rubber prophylactics. (F.D.C. No. 44536. S. No. 32-793/5 R.)

QUANTITY: 56 ctns., each containing 48 3-unit paper sleeves; 138 ctns., each containing 48 3-unit plastic cans; 198 ctns., each containing 12 paper sleeves of 4 3-unit paper packs, at Brooklyn, N.Y.

SHIPPED: 2-16-60 and 3-18-60, from Akron, Ohio, by March Rubber & Plastic Co.