

DRUGS ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

5563. Saccharin tablets and vitamin B₁₂ tablets. (F.D.C. No. 40602. S. Nos. 47-475 M, 59-895 M.)

INFORMATION FILED: 10-15-57, Dist. N.J., against Lit Sales Co., Inc., Newark, N.J., and Stuart W. Lazarus, president.

SHIPPED: Between 6-4-56 and 6-28-56, from the State of New Jersey into the States of Illinois and New York.

LABEL IN PART: (Btl.) "1000 $\frac{1}{4}$ Grain Saccharin Tablets Effervescent Lit Drug Company Newark, N.J. Distributor" and "100 Tablets Vitamin B-12 25 mcg."

CHARGE: 501(a)(1)—contained rodent hairs, fibers, bristles, and nondescript dirt; and 501(a)(2)—prepared under insanitary conditions.

PLEA: Guilty.

DISPOSITION: 5-9-58. Each defendant fined \$1,000.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

5564. Digitoxin tablets. (F.D.C. No. 40546. S. No. 62-191 M.)

QUANTITY: 35 1,000-tablet btls., 178 100-tablet btls., and 1 unlabeled drum containing 102,500 tablets at New York, N.Y.

SHIPPED: Digitoxin powder was shipped on 5-17-56, from Paris, France.

LABEL IN PART: (Btl.) "Bryant * * * Tablets Digitoxin USP 0.2 Mg."

RESULTS OF INVESTIGATION: The digitoxin powder, which was shipped as described above, was used to prepare the *digitoxin tablets*.

Examination showed that the tablets contained not more than 83.1 percent of the declared amount of digitoxin.

LIBELED: 8-23-57, S. Dist. N.Y.

CHARGE: 501(b)—the strength of the article, while held for sale, differed from the standard for digitoxin tablets set forth in the United States Pharmacopeia since the article contained less than 90 percent of the labeled amount of digitoxin.

DISPOSITION: 10-9-57. Default—destruction.

5565. Digitoxin tablets. (F.D.C. No. 40196. S. No. 68-398 M.)

QUANTITY: 1 drum of 99,800 tablets at New York, N.Y.

SHIPPED: Digitoxin powder was shipped on 3-8-56 and 11-16-56 from Paris, France.

LABEL IN PART: "Digitoxin Tablets Pink 0.1 mg."

RESULTS OF INVESTIGATION: The *digitoxin tablets* were prepared from the powder, which had been shipped as described above.

Examination showed that the tablets contained 80.3 percent of the declared amount of digitoxin.

LIBELED: 6-5-57, S. Dist. N.Y.

*See also No. 5562.

CHARGE: 501(b)—the strength of the article, while held for sale, differed from the standard for digitoxin tablets set forth in the United States Pharmacopeia since the article contained less than 90 percent of the labeled amount of digitoxin.

DISPOSITION: 10-11-57. Default—destruction.

5566. Digitoxin tablets. (F.D.C. No. 40642. S. No. 68-991 M.)

QUANTITY: 50,000 tablets in a bulk container at Long Island City, N.Y.

SHIPPED: 1-14-57, from Paris, France.

LABEL IN PART: "Digitoxin 0.2 mgm."

RESULTS OF INVESTIGATION: The shipment described above consisted of digitoxin powder, which was subsequently used in preparing the above-described tablets.

Examination showed that the tablets contained not more than 82 percent of the declared amount of digitoxin.

LIBELED: 10-7-57, E. Dist. N.Y.

CHARGE: 501(b)—the strength of the article, while held for sale, differed from the standard for digitoxin tablets set forth in the United States Pharmacopeia since the article contained less than 90 percent of the declared amount of digitoxin.

DISPOSITION: 11-8-57. Default—destruction.

5567. Soluble saccharin. (F.D.C. No. 40696. S. No. 68-971 M.)

QUANTITY: 1 100-lb. drum at New York, N.Y.

SHIPPED: From Holland.

LIBELED: 10-22-57, S. Dist. N.Y.

CHARGE: 501(b)—when shipped, the quality and purity of the article fell below the standard for soluble saccharin set forth in the United States Pharmacopeia since the article exceeded the heavy metals limit of 20 parts per million prescribed by the standard.

DISPOSITION: 11-22-57. Default—destruction.

5568. Chorionic gonadotropin. (F.D.C. No. 40929. S. No. 57-847 M.)

QUANTITY: 25 boxes, 2 vials each, at Atlanta, Ga.

SHIPPED: 7-25-57, from Los Angeles, Calif.

LABEL IN PART: "Chorionic Gonadotropin 5,000 I.U. For Preparation of Solution in Intramuscular Injection" and "10 cc. Vial Diluent for Chorionic Gonadotropin."

RESULTS OF INVESTIGATION: Analysis showed that the article contained substantially less than 5,000 I.U. of chorionic gonadotropin potency per vial.

LIBELED: 10-31-57, N. Dist. Ga.

CHARGE: 501(c)—the strength of the article, while held for sale, differed from that which it purported or was represented to possess; and 502(a)—the label statement "Chorionic Gonadotropin 5,000 I.U." was false and misleading.

DISPOSITION: 12-9-57. Default—destruction.

5569. Chorionic gonadotropin. (F.D.C. No. 40923. S. No. 67-814 M.)

QUANTITY: 7 boxes, 2 vials each, at Tulsa, Okla.

SHIPPED: 7-15-57, from Los Angeles, Calif.