

that the article was adequate and effective in the treatment of periodontal disease, Vincent's infection, pyorrhea, oral surgery, trench mouth, throat irritations, burns, skin irritations, boils, cuts, abrasions, scratches, prophylaxis for men, rectal irritations, hemorrhoids, colon therapy, athlete's foot, eye irritations, infections, scalds, dermatitis, x-ray lesions, conjunctivitis, iritis, corneal ulcers, chemical burns, coryza, otitis media, sinusitis, tonsillitis, laryngitis, thrush, pruritis anus, fissures, fistula, colitis, amoeba infections, malignancy, gonorrhea, venereal prophylaxis, prostate inflammation, cystitis, hydrocele, leucorrhea, Trichomonas, endometritis, cervicitis, influenza, intestinal and focal toxemia, arthritis, gastric ulcer, duodenal ulcer, thyroid deficiency, cystic goiter, erysipelas, gangrene, carbuncles, furunculosis, abscesses, ulcerations, abrasions, bedsores, and incisions.

PLEA: Guilty.

DISPOSITION: 10-27-58. The defendant was fined \$300 and sentenced to jail for 1 year. The court suspended 11 months of the jail sentence and placed the defendant on probation for 5 years on condition that he serve 30 days in jail.

**5752. Digitalis powder, digitalis tablets, and digitalis capsules.** (F.D.C. No. 42207. S. Nos. 8-567/9 P.)

QUANTITY: 3 10-lb. tins of *digitalis powder*, 64,000 *digitalis tablets* in bottles, and 17,300 *digitalis capsules* in bottles, at Pittsburgh, Pa.

SHIPPED: The *digitalis powder* was shipped on 11-18-58, from New York, N.Y., after having been imported from England.

RESULTS OF INVESTIGATION: The *digitalis tablets* and *digitalis capsules* were manufactured at Pittsburgh, Pa., from *digitalis powder* which had been shipped in bulk as described above.

LIBELED: 9-24-58, W. Dist. Pa.

CHARGE: 501(b)—the strength of the *digitalis powder*, tablets, and capsules, while held for sale, differed from the standards for such drugs set forth in the United States Pharmacopeia; 502(a)—the following label statements: (powdered *digitalis*) "10 International Units of activity in 1.0 gramme" (The U.S.P. Digitalis Unit was set by the U.S.P. to conform as closely as possible to the International Unit.), (tablets) "60 mg. (1 Gr.)" and (capsules) "1½ gr. (0.1 Gm.)" were false and misleading as applied to the articles which contained substantially less than their declared potency, namely, (powdered *digitalis*) 10 International Units per gram, (tablets) 1 grain per tablet, and (capsules) 1½ grains per capsule.

DISPOSITION: 10-14-58. Default—destruction.

**5753. Digitalis tablets.** (F.D.C. No. 42170. S. No. 35-125 P.)

QUANTITY: 3 2,000-tablet btl. at Woodbury, N.J.

SHIPPED: 7-22-58, from Philadelphia, Pa., by Raymer Pharmacal Co.

LABEL IN PART: (Btl.) "2000 Tablets Allen's English Digitalis 1½ Grains  
\* \* \* Standardized to U.S.P. Requirements for Powdered Digitalis."

RESULTS OF INVESTIGATION: Examination showed that the *digitalis* potency of the article was significantly less than its professed potency of 1½ grains of United States Pharmacopeia *digitalis* per tablet.

LIBELED: 9-4-58, Dist. N.J.

CHARGE: 501(b)—the strength and quality of the article, when shipped, differed from the standard for *digitalis tablets* set forth in the United States Pharmacopeia; and 502(a)—the label statement "Digitalis 1½ grains" was false and misleading.

DISPOSITION: 10-9-58. Default—destruction.

**5754. Digitalis tablets.** (F.D.C. No. 42045. S. No. 8-972 P.)

QUANTITY: 1 drum containing 50,000 tablets at Rochester, N.Y.

SHIPPED: Prior to 3-25-58, a quantity of powdered digitalis leaves was shipped from Jersey City, N.J., to Syracuse, N.Y., where it was manufactured into tablets by Mutual Pharmacals Div. of Domfield Co., Inc. On 3-25-58, the tablets were shipped to Rochester, N.Y.

LIBELED: 7-18-58, W. Dist. N.Y.

CHARGE: 501(b)—the strength and quality of the article, while held for sale, differed from the standard for *digitalis tablets* set forth in the United States Pharmacopeia; and 502(a)—the label statement "Each Tablet Contains: Digitalis 1-½ GR." was false and misleading as applied to the article which contained less than 1½ grains of digitalis per tablet.

DISPOSITION: 9-25-58. Default—destruction.

**5755. Ergonovine maleate tablets.** (F.D.C. No. 41885. S. No. 15-402 P.)

QUANTITY: 1 4,800-tablet btl. at Toledo, Ohio.

SHIPPED: 2-14-58, from New York, N.Y.

LIBELED: 6-25-58, N. Dist. Ohio; amended libel, 9-2-58.

CHARGE: 501(b)—the quality and purity of the article, when shipped, fell below the standard for *ergonovine maleate tablets* set forth in the United States Pharmacopeia since the tablets failed to comply with the tests laid down in the Pharmacopeia for absence of "Foreign alkaloids and ergotamine."

DISPOSITION: 10-31-58. Default—destruction.

**5756. Liver-folic acid B<sub>12</sub>.** (F.D.C. No. 42090. S. No. 16-715 P.)

QUANTITY: 149 cartoned vials at Knoxville, Tenn.

SHIPPED: 7-10-57, from Chicago, Ill.

LABEL IN PART: (Vial) "10 cc — Liver-Folic Acid-B<sub>12</sub>. Each cc Contains Vitamin B-12 Activity (From Liver Injection U.S.P. BEEF) Equivalent To: Cyanocobalamin 5 Mcgm. Fortified With Folic Acid 5 Mg. Vit. B-12 Cryst. 25 Mcgm."

RESULTS OF INVESTIGATION: Examination showed that the article contained not more than 34 percent of the declared amount of vitamin B<sub>12</sub>.

LIBELED: 8-15-58, E. Dist. Tenn.

CHARGE: 501(c)—the strength of the article, while held for sale, differed from that which it purported and was represented to possess, namely, an activity equivalent to 30 micrograms of vitamin B<sub>12</sub> per cubic centimeter; and 502(a)—the label statement "Each cc Contains—Vitamin B-12 Activity (From Liver Injection U.S.P. BEEF) Equivalent to: Cyanocobalamin 5 Mcgm. Fortified With Folic Acid 5 Mg. Vit. B-12 Cryst. 25 Mcgm." was false and misleading as applied to the article which contained less than the declared amount of vitamin B<sub>12</sub>.

DISPOSITION: 9-19-58. Default—destruction.