6178. Conjugated estrogen powder and conjugated estrogen granules. (F.D.C. No. 43915. S. Nos. 65–949/50 P, 65–960 P.)

QUANTITY: 2 cans, 500 grams each, and 3 cans, 2 kilograms each, of estrogen powder, and 7 cans of estrogen granules, at Buffalo, N.Y.

SHIPPED: Between July 1954 and 8–5–59, from Montreal, Canada, by Steroid Laboratories, Ltd.

LABEL IN PART: (Can) "Product of Steroid Laboratories Limited * * * Montreal, Canada, 500 Grams [or "2 Kilograms"] Conjugated Estrogens (Equine) Powder * * * Control No. 71302 [or "73730"]" or "1546 Grams Conjugated Estrogens (Equine) Granules. 5.67 mg/gram * * * Control No. 87243."

RESULTS OF INVESTIGATION: Analysis showed that the total estrogen content corresponded to not more than (2 cans) 12.6 mgs., (3 cans) 11.2 mgs., and (7 cans) 4.7 mgs. of estrone per gram.

LIBELED: 11–17–59, W. Dist. N.Y.

CHARGE: 501(c)—when shipped and while held for sale, the strength of the article differed from that which it purported and was represented to possess; and 502(a)—the label statements of the articles (2 cans) "15.45 mgm/gm," (3 cans) "13.29 mgm/gm," and (7 cans) "5.67 mg/gram" were false and misleading.

DISPOSITION: 2–8–60. Consent—claimed by Steroid Laboratories, Ltd., Montreal, Canada; one can was destroyed and the remainder were relabeled.

6179. Vernalin (ophthalmic solution). (F.D.C. No. 43970. S. No. 69–722 P.)

QUANTITY: 70 8-oz. cartoned btls. at Trenton, N.J.

SHIPPED: 10–27–59, from Philadelphia, Pa., by Wall & Ochs, Inc.

LABEL IN PART: (Btl. & ctn.) "Vernalin (Improved) Contains: Sodium Carbonate Monohydrated (Active Ingredient) Camphor Water, Rose Water, Fluorescein Sodium (Diagnostic Agent) Chlorbutanol 0.5% as preservative * * * Wall & Ochs * * * Chestnut Street, Phila."

ACCOMPANYING LABELING: Circular entitled "Vernalin."

RESULTS OF INVESTIGATION: Examination showed that the article was contaminated with viable microorganisms.

LIBELED: 12–17–59, Dist. N.J.

CHARGE: 501(c)—when shipped, the quality and purity of the article fell below that which it purported to possess; and 502(a)—the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for all types of conjunctivitis.

DISPOSITION: 1–18–60. Default—destruction.

6180. Digitalis tablets. (F.D.C. No. 43926. S. Nos. 85–337/8 P.)

QUANTITY: 160,000 tablets in bulk drums and 48 1,000-tablet btls. at Edgewater, N.J.

SHIPPED: During May 1959, from New York, N.Y., by Excel Pharmacal Co.

LABEL IN PART: (Drum) "Tablets Digitalis Grains 1½ gr." and (btl.) "Excel 1,000 Tablets Digitalis 1½ Grains * * * USP * * * Manufactured by Excel Pharmacal Company, New York, N.Y."

RESULTS OF INVESTIGATION: Analysis showed that the digitalis potency of the article was less than the declared potency of 1½ grains per tablet. The tablets in the bottles had been repackaged by the dealer from the bulk drums shipped as described above.