CHARGE: 501(c)—the strength of the article, while held for sale, differed from that which it was represented to possess, namely, 2,500 International Units of chorionic gonadotropin potency per vial; and 502(a)—the label statement "When reconstituted with 10 ml. diluent each vial will contain: Chorionic Gonadotropin 2500 IU" was false and misleading.

DISPOSITION: 2–20–58. Default—destruction.

5590. Chorionic gonadotropin. (F.D.C. No. 41467. S. No. 85–243 M.)

QUANTITY: 261 vials at Chicago, Ill.

SHIPPED: 10–11–57, from Orange, N.J.

RESULTS OF INVESTIGATION: Examination showed that the article contained substantially less than the 2,500 International Units of chorionic gonadotropin potency per vial which it was represented to have.

LIBELED: 3–10–58, N. Dist. Ill.

CHARGE: 501(c)—the strength of the article, while held for sale, differed from that which it was represented to possess, namely, 2,500 International Units of chorionic gonadotropin potency per vial.

DISPOSITION: 4–14–58. Default—destruction.

5591. Reserpine injection. (F.D.C. No. 40420. S. No. 72–560 M.)

QUANTITY: 2,718 ampuls at Milwaukee, Wis.

SHIPPED: 7–5–56, from Detroit, Mich.

RESULTS OF INVESTIGATION: Analysis showed that the article contained 83 percent of the declared amount of reserpine.

LIBELED: 8–14–57, E. Dist. Wis.

CHARGE: 501(c)—the strength of the article, while held for sale, differed from that which it purported or was represented to possess, namely, 2.5 mg. per cubic centimeter; and 502(a)—the label statement "2.5 mg. per cc" was false and misleading as applied to the article, which contained less than the declared amount of reserpine per cubic centimeter.

DISPOSITION: 1–27–58. Consent—destruction.

5592. Cowlserpa tablets. (F.D.C. No. 40994. S. No. 64–348 M.)

QUANTITY: 19 1,000-tablet btls. at Buffalo, N.Y.

SHIPPED: 7–19–57, from Auburn, Mass., by Cowley Pharmaceuticals.

RESULTS OF INVESTIGATION: Examination showed that the article contained 81 percent of the labeled amount of reserpine.

LIBELED: 11–18–57, W. Dist. N.Y.; Amended libel, 12–11–57.

CHARGE: 501(c)—the strength of the article, when shipped, differed from that which it purported and was represented to possess; and 502(a)—the label statement "Each Tablet Contains: Reserpine 0.25 mg." was false and misleading.

DISPOSITION: 1–15–58. Default—destruction.

5593. Phenobarbital capsules. (F.D.C. No. 41203. S. No. 55–960 M.)

QUANTITY: 9,000 capsules in btls. at Muncie, Ind.

SHIPPED: 5–3–57, from Philadelphia, Pa., by Richlyn Laboratories.

LABEL IN PART: "List No. Time-Sule Phenobarbital 1 Gr. * * * 1,000 Capsules Control No. 1586."

RESULTS OF INVESTIGATION: Examination showed that the article contained not more than 77 percent of the declared amount of phenobarbital.

LIBELED: 12–4–57, S. Dist. Ind.

CHARGE: 501(c)—the strength of the article, when shipped, differed from that which it purported and was represented to possess, namely, 1 grain of phenobarbital per capsule; and 502(a)—the label statement "Time-Sule Phenobarbital 1 Gr." was false and misleading.

DISPOSITION: 2–28–58. Default—destruction.

5594. Tran-quil-eez tablets. (2 seizure actions). (F.D.C. Nos. 41374, 41375. S. Nos. 57–528 M, 77–788 M.)

QUANTITY: 23 pkgs., each containing 6 ctns. enclosing a 30-tablet pill box, at St. Petersburg, Fla., and 43 ctns., each containing 1 pill box, at Miami, Fla.

SHIPPED: 9–19–57 and 10–19–57, from Cincinnati, Ohio, by Grandpa Soap Co. and C. S. Dent & Co., Div. Grandpa Soap Co.

LABEL IN PART: (Ctn.) "Dent's Tran-quil-eez 30 Tablets * * * Each enteric-coated tablet contains: Theobromine Sodium Salicylate 100 mg. Acetylsalicylic Acid 3 gr. Acetophenetidin 2 gr. * * * Distributed by C. S. Dent & Co., Cincinnati 2, Ohio."

ACCOMPANYING LABELING: Circulars reading in part "Personal for Women Only Take Free Leaflet" and package insert reading in part "to end those Blue Days * * * Dent's Tran-quil-eez."

LIBELED: 1–23–58 and 1–27–58, S. Dist. Fla.

CHARGE: 501(c)—the strength of the article, when shipped, differed from that which it purported or was represented to possess since it contained a significantly lesser quantity of acetylsalicylic acid (aspirin) than the amount stated on the label; 502(a)—the label statement "Acetylsalicylic Acid 3 Gr." was false and misleading; 502(a)—the labeling of the article contained false and misleading representations that the article was an adequate and effective treatment for overcoming "nerve-racking pre-menstrual symptoms," overcoming effects such as nervous tension and irritability due to extra fluids which alter the water balance in the brain, overcoming pressure exerted by fluids on various parts of the body which result in a heavy, swelling feeling which robs one of looks and vitality and causes the face to become puffy, the hands and fingers to swell up, and causing pain in the back, legs, and breasts, eliminating "those terrible pressures that make you so uncomfortable, nervous and irritable at the onset of your period," and "preparing the body physiologically for the menstrual period"; and 502(e)(2)—the label of the article failed to bear the common or usual name of the active ingredient listed as acetylsalicylic acid, for which the common or usual name is aspirin.

DISPOSITION: 4–9–58 and 4–14–58. Default—destruction.

5595. Del-Caps capsules and Del-Bardex capsules. (F.D.C. No. 41431. S. Nos. 34–042/3 P.)

QUANTITY: 1 9,900-capsule drum, 1 49,900-capsule drum, 8 1,000-capsule btls., 7 500-capsule btls., and 42 100-capsule btls., of *Del-Caps*, and 1 25,000-capsule drum, 3 500-capsule btls., and 7 100-capsule btls. of *Del-Bardex* at Philadelphia, Pa.

SHIPPED: 11–5–57 and 11–27–57, from Rensselaer, N.Y., by Delmar Pharmacal Corp.