LABEL IN PART: (Ctn. and ampul) "Infundin Posterior Pituitary Injection * * * 1 cc. (10 U.S.P. Units)."

LIBELED: 3–14–58, W. Dist. Pa.

CHARGE: 501(b)—the strength of the article, when shipped, fell below the standard for the article set forth in the United States Pharmacopeia; and 502(a)—the label statement "Posterior Pituitary Injection * * * 1 cc. (10 U.S.P. Units)" was false and misleading as applied to the article, the potency of which was substantially less than 10 U.S.P. posterior pituitary units per cubic centimeter.

DISPOSITION: 6–18–58. Default—destruction.

5627. Pituitary posterior injection. (F.D.C. No. 41612. S. No. 83–304 M.)

QUANTITY: 3 cases, containing a total of 621 vials, at New Castle, Ind.

SHIPPED: 9–10–57 and 9–19–57, from Berkeley, Calif., by Borden Laboratories, Inc.

RESULTS OF INVESTIGATION: Individual vial labels to be affixed by the dealer read in part "10CC Posterior Pituitary Injection * * * 20 U.S.P. Units per CC." Also accompanying the article was a loose label which read in part "Borden Laboratories, Inc. * * * 500 Vials Posterior Pituitary Extract 20 Units U.S.P. ML."

LIBELED: 3–20–58, S. Dist. Ind.

CHARGE: 501(b)—the strength of the article, when shipped, fell below the standard for posterior pituitary extract set forth in the United States Pharmacopeia; and 502(a)—the label statements "Posterior Pituitary Extract 20 Units U.S.P. ML." and "10 CC Posterior Pituitary Injection * * * 20 U.S.P. Units Per CC" were false and misleading as applied to the article, the potency of which was substantially less than 20 U.S.P. posterior pituitary units per milliliter or per cubic centimeter.

DISPOSITION: 6–27–58. Default—destruction.

5628. Amphetidisin-10 capsules. (F.D.C. No. 41577. S. No. 37–724 P.)

QUANTITY: 35 1,000-capsule btls. at St. Louis, Mo.

SHIPPED: 10–17–57, from Rensselaer, N.Y., by Delmar Pharmacal Corp.

LABEL IN PART: "1000 Capsules Amphetidisin-10 Timed Disintegration Capsules Dextro-Amphetamine Sulfate 10 Mg. Each Capsule Contains 10 Mg. of Dextro-Amphetamine Sulfate in a Special Base that Provides for Timed Disintegration of the Contents throughout a Period of about 6–10 Hours."

RESULTS OF INVESTIGATION: Analysis showed that the article contained the labeled amount of dextro-amphetamine sulfate of which 88 percent was released within 2 hours.

LIBELED: 2–13–58, E. Dist. Mo.

CHARGE: 501(c)—the quality of the article, when shipped, differed from that which it purported or was represented to possess in that it failed to disintegrate at a uniform rate over a 6- to 10-hour period; and 502(a)—the labeled statement "Timed Disintegration Capsules * * * Each Capsule Contains 10 Mg. of Dextro-Amphetamine Sulfate in a Special Base that Provides for Timed Disintegration of the Contents throughout a Period of about 6–10 Hours" was false and misleading.

DISPOSITION: 3–12–58. Default—destruction.