

Federal law restricts this drug to sale by or on the order of a licensed veterinarian."

DISPOSITION: 11-18-57. Default—destruction.

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

**5471. Digitoxin powder (2 seizure actions).** (F.D.C. Nos. 40514, 40515. S. Nos. 62-014 M, 62-019 M.)

QUANTITY: 5 aluminum btls., 2 containing 5 grams and 3 containing 10 grams, at New York, N.Y., and 1 aluminum btl. containing 41.37 grams, at Long Island City, N.Y.

SHIPPED: 11-16-56, from Paris, France, by Labomial L. M.

LABEL IN PART: "Labomial Digitoxin U.S.P."

RESULTS OF INVESTIGATION: Examination showed that the 5-btl. lot of the article contained not more than 84.6 percent digitoxin and that the 1-btl. lot contained not more than 82.8 percent digitoxin.

LIBELED: 7-17-57 and 7-23-57, E. Dist. N.Y.; and S. Dist. N.Y.

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

DISPOSITION: 10-17-57 and 10-18-57. Default—destruction.

**5472. Digitoxin tablets.** (F.D.C. No. 40659. S. No. 68-969 M.)

QUANTITY: 1 drum containing 57,200 tablets at Hempstead, N.Y.

SHIPPED: Between 3-24-53 and 3-7-56, from France.

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

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

Examination showed that the tablets contained not more than 83 percent of the declared amount of digitoxin.

LIBELED: 10-2-57, E. Dist. N.Y.

CHARGE: 501(b)—while held for sale, the strength of the article 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: 10-25-57. Default—destruction.

**5473. Dextro-amphetamine sulfate timed disintegration capsules.** (F.D.C. No. 40568. S. No. 62-813 M.)

QUANTITY: 54 100-capsule btls. at Jersey City, N.J.

SHIPPED: 10-30-56, from Long Island City, N.Y., by Nysco Laboratories, Inc.

RESULTS OF INVESTIGATION: Examination showed that the article contained 142 percent of the labeled amount of dextro-amphetamine sulfate and released 64 percent of its dextro-amphetamine sulfate ingredient during the first hour.

LIBELED: 8-15-57, Dist. N.J.

CHARGE: 501(c)—the strength and quality of the article, when shipped, differed from that which it purported to possess since it contained more than

\*See also No. 5464.

the labeled amount of dextro-amphetamine sulfate and failed to disintegrate in the manner declared on the label; and 502(a)—the label statements "Dextro-Amphetamine Sulfate 15 Mgm. Timed Disintegration Capsule Each Capsule contains 15 mgm. of Dextro-amphetamine sulfate in a special base that provides for time disintegration of the contents throughout a period of about 6-10 hours. This capsule is equivalent to one tablet of 5 mgm. potency taken three times a day" were false and misleading for a product that contained more than 15 mg. of dextro-amphetamine sulfate per capsule and which did not consist of capsules equivalent to those of 5 mg. potency taken three times a day.

DISPOSITION: 11-29-57. Default—destruction.

**5474. Soluble saccharin.** (F.D.C. No. 40636. S. No. 68-624 M.)

QUANTITY: 1 45-lb. drum at Brooklyn, N.Y.

SHIPPED: From Holland.

LABEL IN PART: "FHT Saccharine Soluble Granular Made in Holland."

LIBELED: 9-12-57, E. 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.

DISPOSITION: 10-18-57. Default—destruction.

**5475. Prophylactics.** (F.D.C. No. 40576. S. Nos. 44-343/4 M, 44-356/7 M.)

QUANTITY: 27 ctns., each containing 48 pkgs. and each pkg. containing 3 units, at Little Rock, Ark.

SHIPPED: 5-7-57 and 5-27-57, from Atlanta, Ga., by W. H. Reed & Co.

LABEL IN PART: (Pkg.) "Golden Pheasant \* \* \* Prophylactics \* \* \* One Fourth Dozen"; (individual foil wrapped unit) "One Lubricated Golden Pheasant Prophylactic Insist on the Genuine Mfgd. in W. Germany Packed by W. H. Reed & Co., Atlanta, Ga."

RESULTS OF INVESTIGATION: Examination showed that the article was defective in that it contained holes.

LIBELED: 8-22-57, E. Dist. Ark.

CHARGE: 501(c)—the quality of the article fell below that which it purported to possess when shipped; and 502(a)—the label statement "Prophylactics" was false and misleading as applied to a product containing holes.

DISPOSITION: 10-1-57. Default—destruction.

#### DRUGS ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS\*

**5476. Invertose.** (F.D.C. No. 40937, S. No. 78-645 M.)

QUANTITY: 3 ctns., 12 btls. each, at Wichita, Kans.

SHIPPED: Between 3-18-57 and 9-28-57, from Lincoln, Nebr., by Norden Laboratories.

LABEL IN PART: (Btl.) "Norden 500 cc Invertose A source of readily assimilable carbohydrate for parenteral use."

RESULTS OF INVESTIGATION: Examination showed that the article was invert sugar.

\*See also Nos. 5464, 5469, 5470, 5473, 5475.