

NATURE OF CHARGE: On or about August 6, 13, 19, 20, 25, and 27, 1953, while a number of *Gantrisin tablets*, *thyroid tablets*, and *Dexedrine Sulfate tablets* were being held for sale, after shipment in interstate commerce, the defendant caused the misbranding, under Section 503 (b) (1), of the drugs by refilling prescriptions for the *Gantrisin tablets* and the *thyroid tablets* without authority from the prescriber and by dispensing the *Dexedrine Sulfate tablets* without a prescription from a practitioner licensed by law to administer such drug.

DISPOSITION: June 30, 1954. The defendant having entered a plea of guilty, the court fined him \$100.

4467. Misbranding of capsules containing a mixture of ergot, apiol, oil pennyroyal, and aloin. U. S. v. Morris J. Heister (Regal Drug Co.). Plea of guilty. Defendant fined \$250 and sentenced to 6 months in jail; jail sentence suspended and defendant placed on probation for 2 years. (F. D. C. No. 35819. Sample Nos. 85091-L, 85121-L.)

INFORMATION FILED: May 10, 1954, Eastern District of Pennsylvania, against Morris J. Heister, trading as the Regal Drug Co., Philadelphia, Pa.

NATURE OF CHARGE: On or about September 11 and October 16, 1953, while a number of *capsules containing a mixture of ergot, apiol, oil pennyroyal, and aloin* were being held for sale at the Regal Drug Co., after shipment in interstate commerce, the defendant caused various quantities of the capsules to be dispensed without a prescription from a practitioner licensed by law to administer such drug. Such act of dispensing was contrary to the provisions of Section 503 (b) (1), and resulted in the dispensed drug being misbranded while held for sale.

DISPOSITION: August 4, 1954. The defendant having entered a plea of guilty, the court fined him \$250 and sentenced him to 6 months in jail, but suspended the jail sentence and placed him on probation for 2 years.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

DRUGS FOR HUMAN USE

4468. Misbranding of extract corpus luteum. U. S. v. 22 Cartoned Vials * * *. (F. D. C. No. 36815. Sample No. 45691-L.)

LABEL FILED: May 26, 1954, District of Massachusetts.

ALLEGED SHIPMENT: On or about April 20, 1954, by Harvey Laboratories, Inc., from Philadelphia, Pa.

PRODUCT: 22 cartoned vials of *extract corpus luteum* at Fitchburg, Mass.

LABEL, IN PART: (Carton and vial) "H 30 cc Size Ampul-Vial Sterilized Soluble Extract Corpus Luteum Each cc. represents 1.0 Gm (15.4 grs.) whole Corpus Luteum, preserved with Chlorobutanol (Chloroform Derivative) 0.5%."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use.

DISPOSITION: July 26, 1954. Default decree of condemnation and destruction.

4469. Misbranding of anterior pituitary solution, Vitopit, suprarenal cortex solution, and Multiglands. U. S. v. 28 Vials, etc. (F. D. C. No. 36809. Sample Nos. 58647-L to 58650-L, incl.)

LIBEL FILED: May 26, 1954, Eastern District of Michigan.

ALLEGED SHIPMENT: On or about July 17, 1953, and February 3, 10, and 18, 1954, by the Vitamix Corp., from Philadelphia, Pa.

PRODUCT: 28 vials of *anterior pituitary solution*, 64 vials of *Vitopit*, 47 vials of *suprarenal cortex solution*, and 468 vials of *Multiglands* at Detroit, Mich. The size of each vial was 30 cc.

Analyses showed that the *suprarenal cortex solution* and the *Multiglands* contained no significant quantity of protein.

LABEL, IN PART: (Vial) "30 cc. Multiple Dose Vial Anterior Pituitary Solution Sterile—Intramuscular Only * * * Each cc. contains the water soluble extraction of dried glands derived from: Anterior Pituitary, fresh gland 18½ grains"; "30 cc. Multiple Dose Vial Vitopit * * * Intramuscular Only * * * Each 2 cc. represents the water soluble extraction of dried glands derived from: Anterior Pituitary fresh gland. . . . 18½ grs. Ovarian Whole Gland fresh gland. . . . 40 grs. Procaine HCl. . . . 1%"; "30 cc. Multiple Dose Vial Suprarenal Cortex Solution Sterile—Intramuscular Only For Professional Use Only * * * Each cc. contains a water soluble extract of 2.5 gram of fresh Suprarenal Cortex Tissue * * * Indications: Foreign Protein Therapy"; and "30 cc. Multiple Dose Vial Multiglands (Plurigland Extract) Intramuscular Only * * * Each 2 cc. represents the water soluble extraction of dried glands derived from: Suprarenal Cortex, fresh gland. . . . 3.0 grs. Thyroid U. S. P. . . . 2.0 grs. Pituitary Anterior, fresh gland. . . . 1.0 grs. Pituitary Posterior, fresh gland. . . . 0.1 grs. Ovarian Substance, fresh gland. . . . 15.0 grs. Thymus, fresh gland. . . . 3.0 grs. Lymphatic, fresh gland. . . . 3.0 grs. * * * Indications: Non-Specific Protein Therapy."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the articles failed to bear adequate directions for use.

Further misbranding, Section 502 (a), the statement "Indications: Foreign Protein Therapy" on the label of the *suprarenal cortex solution* and the statement "Indications: Non-Specific Protein Therapy" on the label of the *Multiglands* were false and misleading since such statements represented and suggested that the articles were effective for providing foreign protein reaction therapy, which was contrary to fact.

DISPOSITION: July 13, 1954. Default decree of condemnation and destruction.

DRUGS FOR VETERINARY USE

4470. Misbranding of anterior pituitary extract. U. S. v. 297 Boxes * * * (F. D. C. No. 36424. Sample No. 81734-L.)

LIBEL FILED: March 18, 1954, District of Nebraska.

ALLEGED SHIPMENT: On or about April 23, 1952, from Chicago, Ill.

PRODUCT: 297 boxes, each containing 1 vial, of *anterior pituitary extract* at Lincoln, Nebr., in possession of Norden Laboratories.

RESULTS OF INVESTIGATION: The product was shipped in bulk from Chicago, Ill., and after its receipt by the consignee, it was repackaged and relabeled.

LABEL, IN PART: (Box) "Norden 10 cc Size Aqueous Extract of Anterior Pituitary"; (vial) "10 cc Size Aqueous Extract of Anterior Pituitary Caution: To be dispensed only by or on the prescription of a veterinarian. Packaged for Norden Laboratories Lincoln, Nebraska Each cc contains water-soluble extractives from 18½ grains fresh tissue. Chlorobutanol (Preserva-