

4488. Misbranding of whole ovarian substance, suprarenal cortex liquid, and anterior pituitary substance. U. S. v. 14 Vials, etc. (F. D. C. Nos. 37033, 37034. Sample Nos. 15941-L to 15944-L, incl.)

LABEL FILED: August 6, 1954, Northern District of Oklahoma.

ALLEGED SHIPMENT: The *suprarenal cortex liquid* and the 14-vial lot of *whole ovarian substance* were shipped by the Coast Chemical Co., from Los Angeles, Calif., on or about February 9, 1953, and June 21, 1954. The *anterior pituitary substance* and the 15-vial lot of *whole ovarian substance* were shipped by the American Bio-Chemical Corp., from Los Angeles, Calif., on or about April 26 and June 25, 1954.

PRODUCT: 14 vials and 15 vials of *whole ovarian substance*, 25 vials of *suprarenal cortex liquid*, and 21 vials of *anterior pituitary substance* at Tulsa, Okla.

LABEL, IN PART: (Vial) "30 cc Sterile Solution Whole Ovarian Substance Each cc contains the water soluble extractives derived from 80 grains of fresh whole ovarian tissue. Chlorobutanol—0.5% Caution: To be dispensed only by or on the prescription of a physician * * * Note: There is no scientific evidence available that this product has therapeutic or physiological activity," "30 cc Sterile Solution Suprarenal Cortex Liquid Each cc contains the extractives derived from 77½ grains of fresh Suprarenal Cortex tissue. Chlorobutanol—(as preservative)—0.5% Caution: Federal law prohibits dispensing without prescription * * * Intermuscular Injection No claims are made for hormone activity," "Anterior Pituitary Substance Each cc contains the water soluble extractives derived from 40 grains of fresh anterior pituitary lobe. Chlorobutanol—0.5% Caution: Federal law prohibits dispensing without prescription * * * For Intramuscular Use There is no scientific evidence available that this product has therapeutic or physiologic activity," "30 cc Sterile Solution Whole Ovarian Substance Each cc contains the water soluble extractives derived from 40 grains of whole ovarian tissue. Chlorobutanol—0.5% For Intramuscular Use Only Caution: Federal law prohibits dispensing without prescription. Note: There is no scientific evidence available that this product has therapeutic or physiologic activity."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the articles failed to bear adequate directions for use, and the articles were not entitled to any exemption from that requirement.

DISPOSITION: September 2, 1954. Default decree of condemnation and destruction.

DRUGS FOR VETERINARY USE

4489. Misbranding of aqueous extract of anterior pituitary. U. S. v. 335 Boxes * * *. (F. D. C. No. 36876. Sample No. 71002-L.)

LABEL FILED: July 12, 1954, Southern District of Indiana.

ALLEGED SHIPMENT: On or about January 19, 1954, by the Maurry Biologicals Co., from Los Angeles, Calif.

PRODUCT: 335 boxes, each containing 1 vial of *aqueous extract of anterior pituitary* at New Castle, Ind.

LABEL, IN PART: (Box and vial) "Arnold * * * 10 cc Anterior Pituitary Aqueous Sterile Extract Caution: Federal law restricts this drug to sale by or on the order of a licensed veterinarian. Distributed by Arnold Laboratories, New Castle, Ind. * * * Give Intramuscularly Large Animals 5 to 10 cc. Small Animals ½ to 1 cc Each cc contains the water soluble extractive from 18½ grains of fresh anterior pituitary."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use, and the article was not entitled to any exemption from that requirement.

DISPOSITION: September 2, 1954. Default decree of forfeiture and destruction.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

4490. Adulteration and misbranding of chorionic gonadotropin. U. S. v. 200 Packages * * *. (F. D. C. No. 36878. Sample No. 80671-L.)

LIBEL FILED: July 14, 1954, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about December 22, 1953, from Los Angeles, Calif.

PRODUCT: 200 packages, each containing 1 vial, of *chorionic gonadotropin* and 1 vial of diluent at Philadelphia, Pa. Examination showed that the strength of the article was less than 50% of that which it was represented to possess.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess.

Misbranding, Section 502 (a), the statements "Chorionic Gonadotropin * * * 5,000 I. U." appearing on the package label and "Chorionic Gonadotropin—Vials, 5,000 I. U. in dry form" appearing on the package insert were false and misleading as applied to the article, which contained less than 2,500 International Units of chorionic gonadotropin activity per vial.

The article was adulterated and misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: October 6, 1954. Default decree of condemnation and destruction.

4491. Adulteration and misbranding of Poya-Liver Stronger. U. S. v. 11 Vials * * *. (F. D. C. No. 36857. Sample No. 48090-L.)

LIBEL FILED: July 2, 1954, Middle District of Alabama.

ALLEGED SHIPMENT: On or about January 12, 1954, by Testagar & Co., Inc., from Detroit, Mich.

PRODUCT: 11 vials of *Poya-Liver Stronger* at Montgomery, Ala. Analysis showed that the product contained less than 60 percent of the declared amount of vitamin B₁₂.

LABEL, IN PART: (Vial) "10 cc. No. 414A Poya-Liver Stronger Liver-Folic Acid-B₁₂ Combination Intramuscular Use * * * Each cc. contains: * * * Vitamin B₁₂ 60 mcg. * * * For use in the treatment of all types of anemia other than hypochromic."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess, namely, 60 micrograms of vitamin B₁₂ per cubic centimeter.

Misbranding, Section 502 (a), the label statement "Each cc. contains: * * * Vitamin B₁₂ 60 mcg." was false and misleading.

DISPOSITION: July 27, 1954. Default decree of condemnation and destruction.