

in the United States Pharmacopoeia, an official compendium, but its purity and quality fell below the standard set forth therein.

**DISPOSITION:** December 2, 1946. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

**2020. Adulteration of calcium levulinate. U. S. v. 153 Vials of Calcium Levulinate. Default decree of condemnation and destruction.** (F. D. C. No. 20994. Sample No. 30695-H.)

**LABEL FILED:** September 18, 1946, District of Arizona.

**ALLEGED SHIPMENT:** On or about June 24, 1946, by the Vitamin-Endocrine Co., from Los Angeles, Calif.

**PRODUCT:** 153 vials of *calcium levulinate* at Phoenix, Ariz.

**LABEL, IN PART:** "100 cc Vial Sterile Solution \* \* \* Calcium Levulinate 13½% For Intravenous Use."

**NATURE OF CHARGE:** Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported and was represented to possess, i. e., "Solution \* \* \* Calcium Levulinate \* \* \* For Intravenous Use." The article contained undissolved material, whereas an article which is represented for intravenous use should be free from undissolved material.

**DISPOSITION:** November 13, 1946. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

**2021. Adulteration and misbranding of estrogenic hormones. U. S. v. 262 Vials of Estrogenic Hormones. Default decree of condemnation and destruction.** (F. D. C. No. 20631. Sample No. 52460-H.)

**LABEL FILED:** August 9, 1946, Southern District of Ohio.

**ALLEGED SHIPMENT:** On or about May 29, 1946, by Organics, Inc., from Chicago, Ill.

**PRODUCT:** 262 vials of *estrogenic hormones* at Dayton, Ohio.

**LABEL, IN PART:** "Natural Estrogenic Hormones Isolated From Gravid Equine Urine Consisting Principally of Estrone, Equilin, Equilenin and Beta-Estradiol With Small Quantities of Naturally Occuring Alpha-Estradiol in Corn Oil, 10,000 I. U. Per CC."

**NATURE OF CHARGE:** Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, i. e., 10,000 International Units per cubic centimeter.

Misbranding, Section 502 (a), the label statement "10,000 I. U. per cc." was false and misleading as applied to an article the potency of which was substantially less than 10,000 International Units of estrone per cubic centimeter.

**DISPOSITION:** September 9, 1946. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

**2022. Adulteration and misbranding of estrogenic substance. U. S. v. 1 Glass Jug of Natural Whole Estrogenic Substance. Default decree of condemnation and destruction.** (F. D. C. No. 20425. Sample No. 45060-H.)

**LABEL FILED:** July 23, 1946, Southern District of California.

**ALLEGED SHIPMENT:** On or about April 17, 1946, by the Intramed Co., Inc., from New York, N. Y.

**PRODUCT:** 1 glass jug containing about 2 liters of *estrogenic substance* at Los Angeles, Calif.

**LABEL, IN PART:** "Natural Whole Estrogenic Substance in Sesame Oil."

**NATURE OF CHARGE:** Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, i. e., 20,000 International Units of estrone per cubic centimeter; and, Section 501 (b) (2), a substance, estrogenic material, different from that occurring in gravid mares' urine had been substituted in whole or in part for natural whole estrogenic substance consisting principally of estrone and such other auxiliary hormones as are normally present in gravid mares' urine, which the article was represented to be.

Misbranding, Section 502 (a), the label statements, "Natural Whole Estrogenic Substance \* \* \* Consisting principally of estrone and such other auxiliary hormones as are normally present in gravid mares' urine. Each 1 cc. is equivalent to 20,000 I. U. rated as Estrone," were false and misleading since the estrogenic material present did not consist of estrogens as they occur in and

are extracted from gravid mares' urine, and the potency of the article was greater than 20,000 International Units of estrone per cubic centimeter.

**DISPOSITION:** September 18, 1946. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

**2023. Adulteration and misbranding of Gynestrol Natural Estrogenic Substance. U. S. v. 20 Bottles of Gynestrol Natural Estrogenic Substance (and 3 seizure actions against other lots of the same product). Decrees of condemnation. Portion of product ordered released under bond; remainder ordered destroyed.** (F. D. C. Nos. 18674, 18833, 18896, 19207. Sample Nos. 4380-H, 4381-H, 4394-H to 4398-H, incl., 4400-H, 5401-H to 5403-H, incl., 23365-H, 60020-H.)

**LABELS FILED:** December 17, 1945, and January 11, February 12, and March 25, 1946, Eastern District of Pennsylvania, Eastern District of Missouri, and Western District of New York. The labels filed in the Eastern District of Pennsylvania were amended October 1, 1946.

**ALLEGED SHIPMENT:** Between the approximate dates of September 20, 1943, and November 27, 1945, by S. B. Penick and Co., from New York, N. Y., and Passaic, N. J.

**PRODUCT:** *Gynestrol Natural Estrogenic Substance*. 20 2,000-cc. bottles and 235.128 liters at Philadelphia, Pa.; 9 2,000-cc. bottles at St. Louis, Mo.; and 56 30-cc. vials and 197 10-cc. vials at Buffalo, N. Y., which had been repacked by the consignee from a shipment of 3 2,000-cc. bottles.

**NATURE OF CHARGE:** (Portions) Adulteration, Section 501 (d), a solution of estrogenic substances not composed of estrogens as they occur in and are abstracted from mares' pregnancy urine had been substituted in whole or in part for a solution of estrogenic substances derived from mares' pregnancy urine.

(Portions) Misbranding, Section 502 (a), the statements displayed on the bottles, "Natural Estrogenic Substance \* \* \* Derived from mares' pregnancy urine," were false and misleading since the estrogenic material present in the article did not consist of estrogens as they occur in and are extracted from mares' pregnancy urine.

**DISPOSITION:** March 29, May 23, and October 1, 1946. The Pennsylvania lots having been consolidated on motion of S. B. Penick and Co., claimant, and the Blue Line Chemical Co., St. Louis, Mo., having appeared as claimant for the Missouri lot, judgments of condemnation were entered and the claimed portion of the product was ordered released under bond for relabeling. No claimant having appeared for the New York lot, judgment of condemnation was entered and this lot was ordered destroyed.

**2024. Adulteration of Pluri-B. U. S. v. 34 Vials of Pluri-B. Default decree of condemnation and destruction.** (F. D. C. No. 20995. Sample No. 30694-H.)

**LABEL FILED:** September 18, 1946, District of Arizona.

**ALLEGED SHIPMENT:** On or about June 18, 1946, by Pasadena Research Laboratories, from Pasadena, Calif.

**PRODUCT:** 34 vials of *Pluri-B* at Phoenix, Ariz.

**LABEL, IN PART:** "30 cc. Sterile Solution No. 256 *Pluri-B* (Some factors of the B Complex) For Intramuscular or Intravenous Use."

**NATURE OF CHARGE:** Adulteration, Section 501 (c), the purity and quality of the product fell below that which it purported and was represented to possess, i. e., "Solution *Pluri-B* \* \* \* For Intramuscular or Intravenous Use." The article contained undissolved material, whereas an article which is represented for intramuscular and intravenous use should be free from undissolved material.

**DISPOSITION:** November 7, 1946. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed, with the exception of 12 vials which were ordered delivered to the Food and Drug Administration.

**2025. Adulteration of epinephrine. U. S. v. 77 Tubes of Epinephrine. Default decree of condemnation and destruction.** (F. D. C. No. 20554. Sample No. 63945-H.)

**LABEL FILED:** July 23, 1946, District of New Jersey.

**ALLEGED SHIPMENT:** On or about June 10, 1946, by Wyeth, Inc., from Philadelphia, Pa.