

**NATURE OF CHARGE:** Adulteration, Section 501 (c), the strength of the products differed from that which they purported and were represented to possess, since each drug contained considerably less than  $\frac{1}{4}$  grain of morphine sulfate in each fluid ounce.

Misbranding, Section 502 (a), the label statement, "Each Fluidounce Contains: Morphine Sulfate, 1-4 Gr.," was false and misleading.

**DISPOSITION:** October 9, 1946. A plea of nolo contendere having been entered on behalf of the defendant, a fine of \$200 was imposed.

**2017. Adulteration of sweet oil and misbranding of isopropyl alcohol compound. U. S. v. Pennex Products Co., Inc., and Martin Sachnoff. Pleas of nolo contendere. Fine of \$100 and costs against corporate defendant; fine of \$10 against individual defendant. (F. D. C. No. 20949. Sample Nos. 10061-H, 10385-H.)**

**INFORMATION FILED:** October 16, 1946, Western District of Pennsylvania, against the Pennex Products Co., Inc., Pittsburgh, Pa., and Martin Sachnoff, secretary of the corporation.

**ALLEGED SHIPMENT:** On or about April 3 and October 11, 1945, from the State of Pennsylvania into the States of West Virginia and Ohio.

**LABEL, IN PART:** "Hospital Isopropyl Alcohol Compound," or "Pennex Brand Sweet Oil."

**NATURE OF CHARGE:** *Sweet Oil*, adulteration, Section 501 (b), the article purported to be and was represented as *sweet oil*, a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its strength differed from, and its quality and purity fell below, the official standard since it did not consist of the fixed oil obtained from the ripe fruit of *Olea europaea* Linné, as prescribed by the Pharmacopoeia, but did consist of cottonseed oil.

*Isopropyl Alcohol Compound*, misbranding, Section 502 (a), the label statement "Isopropyl Alcohol 70% by volume" was false and misleading since the article contained less than 70 percent of isopropyl alcohol by volume.

**DISPOSITION:** November 4, 1946. Pleas of nolo contendere having been entered, the court imposed a fine of \$100 and costs against the corporate defendant and a fine of \$10 against the individual defendant.

**2018. Adulteration of Aciform II. U. S. v. 4 Vials and 6 Boxes of Aciform II. Default decree of condemnation and destruction. (F. D. C. No. 20103. Sample Nos. 45066-H, 45067-H.)**

**LABEL FILED:** June 12, 1946, Southern District of California.

**ALLEGED SHIPMENT:** On or about March 18, 1946, by the Aciform Sales Corporation, from Chicago, Ill.

**PRODUCT:** 4 30-cc. vials, 4 boxes, each containing 12 1-cc. ampuls, and 2 boxes, each containing 12 2-cc. ampuls, of *Aciform II* at Los Angeles, Calif.

**NATURE OF CHARGE:** Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported to possess, since it purported to be for intravenous use and contained undissolved material, whereas an article intended for intravenous use should be free from undissolved material.

**DISPOSITION:** July 12, 1946. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

**2019. Adulteration of dextrose and sodium chloride injection. U. S. v. 177 Flasks of Dextrose and Sodium Chloride Injection. Default decree of condemnation and destruction. (F. D. C. No. 21162. Sample No. 59927-H.)**

**LABEL FILED:** October 7, 1946, Western District of Pennsylvania.

**ALLEGED SHIPMENT:** On or about July 25, 1946, by Readyflask, Inc., from Cleveland, Ohio.

**PRODUCT:** 177 1-liter flasks of *dextrose and sodium chloride injection* at McKees Rocks, Pa. The United States Pharmacopoeia specifies that Injection Dextrose and Sodium Chloride, which the product purported to be, must conform to the official pyrogen test. Examination showed that the article failed to comply with this test since it contained pyrogens.

**LABEL, IN PART:** "Dextrose 5% w/v in Isotonic Solution of Sodium Chloride, U. S. P."

**NATURE OF CHARGE:** Adulteration, Section 501 (b), the article purported to be *dextrose and sodium chloride injection*, a drug the name of which is recognized

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