

Liver Solution U. S. P. Adulteration, Section 501 (b), the article purported to be and was represented as liver injection, a name recognized in the United States Pharmacopoeia, but its quality and purity fell below the official standard. The Pharmacopoeia provides that liver injection shall conform to the requirements of the test for sterility of liquids set forth therein, whereas the article did not conform to such requirements but was contaminated with living micro-organisms.

DISPOSITION: May 8, 1946. Pleas of guilty having been entered, the corporation was fined \$750; Joseph H. Moss was fined \$450; and George E. Hickey was fined \$750 and was sentenced to 30 days in jail.

1911. Adulteration of anterior pituitary and ovarian extract. U. S. v. 5 Vials of Anterior Pituitary and 7 Vials of Ovarian Extract. Default decree of condemnation and destruction. (F. D. C. No. 15364. Sample Nos. 16512-H, 16514-H.)

LABEL FILED: March 19, 1945, Northern District of Illinois.

ALLEGED SHIPMENT: On or about August 30 and December 12, 1944, by the Torigian Laboratories, from New York, N. Y.

PRODUCT: 5 30-cc. vials of *anterior pituitary* and 7 30-cc. vials of *ovarian extract* at Chicago, Ill.

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity and quality of the articles fell below that which they purported to possess, in that they were offered for intramuscular injection and were not sterile but were contaminated with living, spore-forming bacteria which rendered them unsuitable and unsafe for intramuscular injection.

DISPOSITION: June 14, 1945. No claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

1912. Adulteration of Pyoamide and Coll-Thiol. U. S. v. 47 Ampuls of Pyoamide and 19 Vials of Coll-Thiol. Default decree of condemnation and destruction. (F. D. C. No. 20059. Sample Nos. 45044-H, 45046-H.)

LABEL FILED: June 10, 1946, Southern District of California.

ALLEGED SHIPMENT: On or about May 18, 1945, and January 28, 1946, by the Intra Products Co., from Denver, Colo.

PRODUCT: 47 ampuls of *Pyoamide* and 19 vials of *Coll-Thiol* at Los Angeles, Calif.

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

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

1913. Adulteration of Novisyn and epinephrine hydrochloride solution. U. S. v. 28 Boxes of Novisyn and 84 Vials of Epinephrine Hydrochloride Solution. Default decree of condemnation and destruction. (F. D. C. No. 19834. Sample Nos. 45735-H, 45736-H.)

LABEL FILED: May 6, 1946, Northern District of California.

ALLEGED SHIPMENT: On or about May 1, 1945, and January 19, 1946, by the S. E. Massengill Co., from Bristol, Va.

PRODUCT: 28 boxes, each containing 50 ampuls, of *Novisyn* and 84 vials of *epinephrine hydrochloride solution* at San Francisco, Calif.

LABEL, IN PART: "Novisyn * * * For Intramuscular or Intravenous Administration," and "Solution Epinephrine Hydrochloride * * * For Subcutaneous, Intramuscular or Intracardial administration."

NATURE OF CHARGE: *Novisyn*. Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess since it contained undissolved material, whereas an article which is represented for intramuscular or intravenous administration should be free from undissolved material.

Epinephrine Hydrochloride Solution. Adulteration, Section 501 (b), the article purported to be and was represented as epinephrine hydrochloride injection, a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the official standard since it was contaminated with undissolved material.

DISPOSITION: June 19, 1946. No claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

1914. Adulteration of B-Parplex Solution and sodium thiosulfate solution. U. S. v. 28 Vials of B-Parplex Solution and 49 Ampuls of Sodium Thiosulfate Solution. Default decree of condemnation and destruction. (F. D. C. No. 19569. Sample Nos. 46404-H, 46405-H.)

LIBEL FILED: April 5, 1946, Northern District of California.

ALLEGED SHIPMENT: On or about December 9, 1940, and January 13 and 20, 1945, by the Intra Products Co., from Denver, Colo.

PRODUCT: 28 vials of *B-Parplex Solution* and 49 ampuls of *sodium thiosulfate solution* at San Francisco, Calif. Examination showed that the *B-Parplex Solution* contained mold; and that the *sodium thiosulfate solution* contained undissolved material.

LABEL, IN PART: "30 cc Sterile Solution B-Parplex No. 5," or "Intravenous Solution Sodium Thiosulphate 10 cc."

NATURE OF CHARGE: *B-Parplex Solution*. 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 mold, whereas an article purporting to be for intravenous use should be free from mold.

Sodium thiosulfate solution, Section 501 (b), the article purported to be and was represented as ampuls of sodium thiosulfate, a drug the name of which is recognized in the National Formulary, an official compendium, but its quality and purity fell below the official standard since it was contaminated with undissolved material.

DISPOSITION: May 15, 1946. No claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

1915. Adulteration of estrogens and Betaplex. U. S. v. 26 Vials of Estrogens and 4 Vials of Betaplex. Default decree of condemnation and destruction. (F. D. C. No. 19399. Sample Nos. 60039-H, 60040-H.)

LIBEL FILED: March 27, 1946, Western District of New York.

ALLEGED SHIPMENT: Between the approximate dates of April 28 and October 22, 1945, by Lincoln Laboratories, Inc., from Decatur, Ill.

PRODUCT: 26 vials of *estrogens* and 4 vials of *Betaplex* at Buffalo, N. Y. Examination showed that the *estrogens* contained agglomerated material unsuitable for intramuscular injection; and that the *Betaplex* was contaminated with undissolved material.

LABEL, IN PART: "15 cc. Size Aqueous Suspension of Estrogens * * * For intramuscular use," or "30 cc. Vial Betaplex * * * Intramuscular or Intravenous."

NATURE OF CHARGE: Adulteration, Section 501 (c), (*estrogens*) the quality of the article fell below that which it purported and was represented to possess in that it was represented to be for intramuscular use, whereas it contained agglomerated material unsuitable for intramuscular injection; (*Betaplex*) the purity and quality of the article fell below that which it purported and was represented to possess, since it was represented to be appropriate for intramuscular or intravenous use and should have been free from undissolved material.

DISPOSITION: April 22, 1946. No claimant having appeared, judgment of condemnation was entered and the products were ordered destroyed.

1916. Adulteration of estrogenic hormones. U. S. v. 165 Boxes of Estrogenic Hormones. Default decree of condemnation and destruction. (F. D. C. No. 19398. Sample No. 14483-H.)

LIBEL FILED: March 28, 1946, Northern District of Ohio.

ALLEGED SHIPMENT: On or about January 21, 1946, by the Barry Allergy Laboratories, Inc., from Detroit, Mich.

PRODUCT: 165 boxes, each containing 1 vial, of *estrogenic hormones* at Canton, Ohio.

LABEL, IN PART: "Estrogenic Hormones (Natural) A Standardized preparation containing estrogenic hormones isolated from gravid mare's urine consisting principally of estrone, equilin, equilenin, beta-estradiol in sesame oil."

NATURE OF CHARGE: Adulteration, Section 501 (d) (2), estrogenic material different from that occurring in gravid mares' urine had been substituted in whole