

material, including aloes and ergot, and essential oils such as oil of pennyroyal; that the capsules consisted essentially of ergot alkaloids, aloin, oil of savin, and apiol; and that the ampuls contained solution of posterior pituitary.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since it failed to state why the article was to be used; and, Section 502 (f) (2), the labeling failed to bear adequate warnings against use of the article in those pathological conditions wherein its use may be dangerous to health since the statement appearing in a circular, "Ampuls should not be used in cases of nephritis, myocarditis, arteriosclerosis, and threatened rupture of the uterus," was not a warning that would adequately inform the user that the contents of the ampul should not be used in cases of kidney disease, heart disease, high blood pressure, or hardening of the arteries.

DISPOSITION: June 26, 1946. The Hassenstein Co. having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered destroyed.

1909. Misbranding of estrogenic hormone. U. S. v. 48 Vials of Estrogenic Hormone. Default decree of forfeiture and destruction. (F. D. C. No. 19363. Sample No. 52625-H.)

LIBEL FILED: March 20, 1946, Southern District of Indiana.

ALLEGED SHIPMENT: On or about November 28, 1945, by International Hormones, Inc., from Brooklyn, N. Y.

PRODUCT: 48 unlabeled vials of *estrogenic hormone* at Indianapolis, Ind. The vials were packed in a labeled carton. No written agreement existed between the shipper and the consignee as to the labeling of the product.

LABEL, IN PART: (Carton) "Estrogenic Hormone 10,000 I. U./cc Corn Oil 50-30 cc vials ½% Chlorbutanol."

NATURE OF CHARGE: Misbranding, Section 502 (e) (2), the article was fabricated from two or more ingredients and its label failed to bear the common or usual name of each active ingredient, since the designation "Estrogenic Hormone," borne on the carton, is not the specific name of any particular substance but is a generic name for a class of substances.

Further misbranding, Section 502 (b) (1), the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; Section 502 (b) (2), it failed to bear an accurate statement of the quantity of the contents; and, Section 502 (f) (1), its labeling failed to bear adequate directions for use.

DISPOSITION: May 13, 1946. No claimant having appeared, judgment of forfeiture was entered and the product was ordered destroyed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

1910. Adulteration of Hyposols Liv-Vi-B, Hyposols Liver Solution U. S. P., and Hyposols Sulisocol. U. S. v. The Drug Products Co., Inc., Joseph H. Moss, and George E. Hickey. Pleas of guilty. Corporation fined \$750; Joseph H. Moss fined \$450; and George E. Hickey fined \$750 and sentenced to 30 days' imprisonment. (F. D. C. No. 17787. Sample Nos. 82095-F, 82972-F, 6201-H.)

INFORMATION FILED: March 6, 1946, Eastern District of New York, against the Drug Products Co., Inc., a corporation, Long Island City, N. Y., Joseph H. Moss, president, and George E. Hickey, vice president, of the corporation.

ALLEGED SHIPMENT: On or about August 25 and October 12 and 13, 1944, from the State of New York into the State of New Jersey.

LABEL, IN PART: "Hyposols * * * Liv-Vi-B * * * Inject Intramuscularly," "Hyposols Liver Solution U. S. P. * * * (injectable)," or "Hyposols Sulisocol * * * Intravenous—Intramuscular."

NATURE OF CHARGE: *Liv-Vi-B* and *Sulisocol*. Adulteration, Section 501 (c), the purity and quality of the articles fell below that which they purported and were represented to possess. The *Liv-Vi-B* purported and was represented to be suitable and appropriate for intramuscular injection, and the *Sulisocol* purported and was represented to be suitable for intramuscular and intravenous injection, which uses require sterile products. The articles were not suitable and appropriate for the purposes claimed since they were not sterile but were contaminated with living micro-organisms.

*See also No. 1904.

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.)

LIBEL 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.)

LIBEL 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.)

LIBEL 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.