

**DRUGS ACTIONABLE BECAUSE OF THE PRESENCE OF NONCERTIFIED
COAL-TAR COLORS**

1764. Action to enjoin and restrain the interstate shipment of adulterated and misbranded coal-tar colors. U. S. v. Interstate Color Co., Inc., and Samuel H. Ebert. Consent decree granting injunction. (Inj. No. 68.)

COMPLAINT FILED: July 1, 1944, Southern District of New York, against the Interstate Color Co., Inc., New York, N. Y., and Samuel H. Ebert, president and treasurer of the corporation.

NATURE OF CHARGE: That since on or before May 11, 1943, the defendants had been introducing and delivering for introduction into interstate commerce quantities of *coal-tar colors* which were adulterated and misbranded in the following manner:

Adulteration, Section 501 (a) (4), the articles bore and contained, for purposes of coloring only, coal-tar colors from a batch other than one certified in accordance with the regulations.

Misbranding, Section 502 (a), the labels of the articles bore false and misleading statements.

It was also charged that the defendants had been introducing and delivering for introduction into interstate commerce quantities of coal-tar colors which were adulterated and misbranded under the provisions of the law applicable to cosmetics, as reported in notices of judgment on cosmetics.

PRAYER OF COMPLAINT: That the defendants be permanently enjoined and restrained from commission of the acts complained of.

DISPOSITION: January 4, 1945. The defendants having consented to the entry of a decree, the court issued an order enjoining them from introducing or delivering for introduction into interstate commerce any adulterated and misbranded drugs or cosmetics including colors consisting in whole or in part of Oil Yellow F. N., Colour Index No. 19, or Oil Yellow C., Colour Index No. 17, and all mixtures or combinations purporting to be certified mixtures which contain Croceine Orange, Colour Index No. 26. It was provided, however, that the order should not apply to the shipment of those colors for use other than as drugs or cosmetics.

1765. Adulteration of color. U. S. v. 1 Can of Color. Default decree of condemnation and destruction. (F. D. C. No. 16319. Sample No. 106-H.)

LABEL FILED: June 5, 1945, Southern District of Florida.

ALLEGED SHIPMENT: On or about November 14, 1941, from Charlotte, N. C., by the National Aniline Division, Allied Chemical and Dye Corporation.

PRODUCT: 1 can containing approximately 2½ pounds of *color* at Tampa, Fla.

Examination showed that the product contained D&C Green No. 6 and Butter Yellow, Colour Index No. 17, the latter being a dye which cannot be certified for use in foods, drugs, or cosmetics, and which possesses carcinogenic properties.

LABEL, IN PART: "Natl Oil Green M-255."

NATURE OF CHARGE: Adulteration, Section 501 (a) (4), the product bore and contained, for purposes of coloring only, a coal-tar color, Butter Yellow, Colour Index No. 17, which had not been listed for use in drugs in accordance with the regulations and was other than one from a batch that had been certified.

DISPOSITION: July 14, 1945. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

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

1766. Adulteration and misbranding of Tossebeone. U. S. v. E. Tosse & Co., Inc. Plea of guilty. Fine, \$100. (F. D. C. No. 14302. Sample No. 35056-F.)

INFORMATION FILED: June 11, 1945, Eastern District of New York, against E. Tosse & Co., Inc., Brooklyn, N. Y.

ALLEGED SHIPMENT: On or about March 28, 1944, from the State of New York into the State of Georgia.

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

*See also No. 1751.

since it was represented to contain 100 milligrams of thiamine hydrochloride per cubic centimeter, whereas it contained not more than 77.5 milligrams of thiamine hydrochloride per cubic centimeter.

Misbranding, Section 502 (a), the label statement, "Each cc. containing 100 mgm. Thiamine Hydrochloride," was false and misleading.

DISPOSITION: September 13, 1945. A plea of guilty having been entered on behalf of the defendant, the court imposed a fine of \$50 on each of the 2 counts of the information, a total fine of \$100.

1767. Adulteration and misbranding of Folestrin Suppositories and pituitary liquid. U. S. v. Armour and Co. (The Armour Laboratories). Plea of guilty. Fine, \$1,000 and costs. (F. D. C. No. 14215. Sample Nos. 39168-F, 54610-F.)

INFORMATION FILED: June 13, 1945, Northern District of Illinois, against Armour and Co., a corporation, trading as the Armour Laboratories, Chicago, Ill.

ALLEGED SHIPMENT: November 1 and 26, 1943, from the State of Illinois into The State of Indiana.

LABEL, IN PART: "Armour * * * Folestrin," and "Armour * * * Pituitary Liquid."

NATURE OF CHARGE: *Folestrin*. Adulteration, Section 501 (c), the strength of the article fell below that which it purported and was represented to possess, since each suppository was represented to contain 2,000 International Units of estrone, whereas each suppository contained not more than 500 International Units of estrone. Misbranding, Section 502 (a), the label statement, "Each Suppository Contains 2,000 International Estrogenic Units," was false and misleading since it represented and suggested that each suppository contained 2,000 International Units of estrone, whereas each suppository contained not more than 500 International Units of estrone.

Pituitary Liquid. Adulteration, Section 501 (d), a preparation of posterior pituitary having a potency per cubic centimeter of materially less than 20 U. S. P. posterior pituitary units had been substituted for pituitary liquid having a potency of 20 U. S. P. posterior pituitary units per cubic centimeter, which the article was represented to be. Misbranding, Section 502 (a), the label statements, "Pituitary Liquid Double Strength Solution of Posterior Pituitary Injection U. S. P. XII 20 U. S. P. Units Per cc," and "The Strength of This Solution is Double That of the Official U. S. P. Preparation 20 U. S. P. Units Per cc," were false and misleading since the article did not possess a potency of double that possessed by posterior pituitary injection of the official standard, but possessed a potency of not more than two-thirds of that claimed; and each cubic centimeter of the article did not contain 20 U. S. P. posterior pituitary units but contained not more than $13\frac{1}{3}$ posterior pituitary units.

DISPOSITION: September 24, 1945. A plea of guilty having been entered on behalf of the defendant, the court imposed a fine of \$1,000 and costs.

1768. Adulteration and misbranding of estrogenic substance in oil and estrogenic hormones. U. S. v. 70 Vials of Estrogenic Hormones (and 2 other seizure actions against estrogenic hormones and estrogenic substance). Decree of condemnation. Products ordered released under bond. (F. D. C. Nos. 15881, 15882, 15897. Sample Nos. 3826-H, 3828-H, 3905-H.)

LABELS FILED: April 6 and 12, 1945, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: Between the approximate dates of December 8, 1944, and February 23, 1945, by the Pro-Medico Laboratories, Inc., from Brooklyn, N. Y.

PRODUCT: 70 vials and 5,895 ampuls of *estrogenic hormones* and 4 bottles of *estrogenic substance* at Philadelphia, Pa. Examination showed that the estrogenic material present in the product consisted essentially of estradiol with no significant proportion of estrone.

LABEL, IN PART: (Vials) "20 cc. Estrogenic Hormones Multiple Dose Vial A sterile solution in ampul oil of estrogenic substances derived from equine urine"; (ampuls) "1 cc. Estrogenic Hormones * * * Professional Prod. Co., Phila., Pa. Dist.;" and (bottles) "Estrogenic Substance in Oil. Each cc contains Estrogenic Substance derived from equine urine."

NATURE OF CHARGE: Adulteration, Section 501 (d), 70-vial lot and 4-bottle lot, a preparation containing estrogenic material including little or no estrone had been substituted in whole or in part for a preparation containing estrogenic substances as they occur in equine urine.