DRUG ACTIONABLE BECAUSE OF THE PRESENCE OF A NONCERTIFIED COAL-TAR COLOR

1505. Adulteration and misbranding of Burma Foot Cream. U. S. v. 28 Jars of Burma Foot Cream. Default decree of condemnation and destruction. (F. D. C. No. 12902. Sample No. 68109–F.)

On July 10, 1944, the United States attorney for the Northern District of Ohio filed a libel against 28 jars of Burma Foot Cream at Akron, Ohio, alleging that the article had been shipped on or about April 14, 1944, by the Belmont Co., Springfield, Mass. The article was labeled in part: "Burma Foot Cream * * * Green Food Color."

Examination of a sample disclosed that the article contained a noncertified dye, dimethylaminoazobenzene, more commonly known as Butter Yellow, Colour Index No. 19; and that the label of the article bore no statement of the quantity of the contents.

The article was alleged to be adulterated in that it was a drug that contained, for purposes of coloring only, a green coal-tar color that 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.

The article was alleged to be misbranded (1) in that the label statement "Green Food Color" was misleading as applied to an article containing a color unfit for use in foods; and (2) in that it failed to bear a label containing an accurate statement of the quantity of contents.

On August 8, 1944, 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

1506. Aduleration of isopropyl alcohol compound. U. S. v. 131¼ Dozen Bottles of Isopropyl Alcohol Compound. Default decree of condemnation and destruction. (F. D. C. No. 15617. Sample No. 24323–H.)

On March 10, 1945, the United States attorney for the Eastern District of Louisiana filed a libel against 131¼ dozen bottles of isopropyl alcohol compound at New Orleans, La., alleging that the article had been shipped on or about August 19, 1944, by the Border States Distributing Co., from Houston, Tex. The article was labeled in part: "One Pint St. Francis Rubbing Isopropyl Alcohol Compound 70% By Volume."

Examination of the article disclosed that the isopropyl alcohol content was approximately 46 percent by volume in some bottles and approximately 62 percent by volume in other bottles.

The article was alleged to be adulterated in that its strength differed from that which it was represented to possess, i. e., isopropyl alcohol 70 percent.

On April 19, 1945, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1507. Adulteration of isopropyl alcohol compound. U. S. v. 27¼ Dozen Bottles of Isopropyl Alcohol Compound. Default decree of condemnation and destruction. (F. D. C. No. 15483. Sample No. 24272–H.)

On March 8, 1945, the United States attorney for the Eastern District of Louisiana filed a libel against 27¼ dozen bottles of isopropyl alcohol compound at New Orleans, La., alleging that the article had been shipped on or about January 17, 1945, by the R. & R. Products Co., from Corpus Christi, Tex. The article was labeled in part: "R & R Hospital Brand Isopropyl Alcohol Compound Hospital Grade Isopropyl Alcohol 70% * * * 1 Fl. pint."

Examination showed that the article contained not more than 38.6 percent by volume of isopropyl alcohol.

The article was alleged to be adulterated in that its strength differed from that which it was represented to possess, i. e., isopropyl alcohol 70 percent.

On April 19, 1945, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1508. Adulteration and misbranding of solution of epinephrine hydrochloride. U. S. v. 52 Vials and 168 Bottles of Solution of Epinephrine Hydrochloride. Default decrees of condemnation and destruction. (F. D. C. Nos. 15074, 15152, 15384. Sample Nos. 85403–F, 6266–H, 22313–H, 22314–H.)

On January 19 and February 14 and 15, 1945, the United States attorneys for the Eastern District of Pennsylvania, the District of New Jersey, and the East-

ern District of Missouri filed libels against the following quantities of the above-named product: 52 vials at Philadelphia, Pa., 57 vials at Irvington, N. J., and 168 bottles at St. Louis, Mo., alleging that the article had been shipped between the approximate dates of November 8, 1944, and January 18, 1945, by the Premo Pharmaceutical Laboratories, Inc., from New York, N. Y. The article was labeled in part: "1 Fld. Oz. Premo Vasodrine Solution of Epinephrine Hydrochloride U. S. P. 1–1000."

The United States Pharmacopoeia provides that solution of epinephrine hydrochloride has a potency equivalent to a solution containing 1 gram of U. S. P. Epinephrine Reference Standard in each 1,000 cc. Examination showed that the article had an activity of from 27 to 45 percent of that claimed upon its label and required by the Pharmacopoeia.

The article was alleged to be adulterated in that it was represented as a drug the name of which is recognized in an official compendium, the United States Pharmacopoeia XII, and its strength differed from the standard set forth therein.

It was alleged to be misbranded in that the statement on its label, "Solution of Epinephrine Hydrochloride U. S. P. 1–1000," was false and misleading as applied to the article.

Between February 13 and April 2, 1945, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

1509. Adulteration and misbranding of estrogenic hormones in oil. U. S. v. 3 Bottles of Estrogenic Hormones. Consent decree of condemnation. Product ordered released under bond. (F. D. C. No. 14868. Sample No. 78195–F.)

On December 26, 1944, the United States attorney for the Eastern District of Pennsylvania filed a libel against 3 bottles containing a total of approximately 5,300 cc. of estrogenic hormones at Philadelphia, Pa., alleging that the article had been shipped on or about October 4 and 16, 1944, from Chicago, Ill., by the W. F. Straub and Co..

Examination disclosed that the potency of the article was equivalent to not more than 12,000 International Units of estrone per cubic centimeter.

The article was alleged to be adulterated in that its strength differed from that which it purported and was represented to possess, 20,000 International Units of estrogenic ovarian follicular hormones.

The article was alleged to be misbranded in that the statements on its label, "Whole Natural Estrogenic Hormones From Pregnant Mare's Urine Consisting Mainly of Estrone and Estradiol in Sesame Oil 20,000 IU/CC," were false and misleading since the potency of the article was materially less than was represented.

On March 2, 1945, W. F. Straub and Co., claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond for relabeling under the supervision of the Food and Drug Administration.

1510. Adulteration and misbranding of estrogenic hormone injection. U. S. v. 326 Vials of Estrogenic Hormone Injection. Default decree of condemnation and destruction. (F. D. C. No. 15314. Sample No. 85315–F.)

On February 24, 1945, the United States attorney for the Eastern District of Pennsylvania filed a libel against 326 vials of estrogenic hormone injection at Philadelphia, Pa. It was alleged in the libel that the article had been repackaged by the consignee at Philadelphia, Pa., from bulk material contained in 5 1-liter bottles which had been shipped to it by Halfdan Hebo, from New York, N. Y., on or about May 20, 1944.

The article in the 1-liter bottles was labeled in part: "Biologically tested Estrogenic Substance in Propylene Glycol, 10,000 I. U. per ml." The article in the vials was labeled in part: "Injection Estrogenic Hormone * * * Each cc. contains Estrogenic Hormone 10,000 I. U., obtained from pregnant mares' urine, consisting principally of estrone and estradiol, with Chlorobutanol * * * 1.5% in sterile propylene glycol."

Examination of a sample taken from the repackaged material showed that the article contained estrogenic steroids consisting of compounds including little or no estrone, together with the inert substance cholesterol.

The article was alleged to be adulterated in that a substance containing estrogenic material including little or no estrone and the inert compound cholesterol