

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

4455. Adulteration of ammonium chloride tablets. U. S. v. 1 Drum * * *.
(F. D. C. No. 36365. Sample No. 58343-L.)

LIBEL FILED: February 2, 1954, Northern District of Illinois.

ALLEGED SHIPMENT: On or about December 4, 1953, by the Shaw Pharmacal Co., from St. Louis, Mo.

PRODUCT: 1 drum containing 9,800 *ammonium chloride tablets* at Chicago, Ill.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Ammonium Chloride Tablets," a drug the name of which is recognized in the National Formulary, an official compendium, and its quality fell below the official standard. The standard specifies that a coating may be applied to ammonium chloride tablets, provided that such coating will disintegrate in the alimentary tract. The tablets of the article were so coated that they did not disintegrate in the alimentary tract.

DISPOSITION: May 12, 1954. Default decree of condemnation and destruction.

4456. Adulteration and misbranding of vitamin B complex. U. S. v. 25 Cartoned Vials * * *. (F. D. C. No. 36352. Sample No. 57938-L.)

LIBEL FILED: On or about January 21, 1954, Eastern District of Virginia.

ALLEGED SHIPMENT: On or about May 25, 1951, from Decatur, Ill.

PRODUCT: 25 cartoned vials, 10-cc. size, of *vitamin B complex* at Richmond, Va. Analysis showed that the article contained 73 percent of the declared amount of vitamin B₁.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess, namely, 50 milligrams of thiamine HCl per cubic centimeter.

Misbranding, Section 502 (a), the label statement "Each cc. contains: * * * Thiamine HCl . . . 50 mg." was false and misleading.

The article was adulterated and misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: July 21, 1954. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

4457. Misbranding of liver injection. U. S. v. 119 Cartoned Vials * * *.
(F. D. C. No. 36370. Sample No. 65384-L.)

LIBEL FILED: February 6, 1954, District of Minnesota.

ALLEGED SHIPMENT: On or about July 31, 1952, from New Brunswick, N. J.

PRODUCT: 119 cartoned vials, 10-cc, size, of *liver injection* at Minneapolis, Minn. Microbiological examination of the product indicated the presence of 8 micrograms of vitamin B₁₂ per cubic centimeter.

NATURE OF CHARGE: Misbranding Section 502 (a), the label statement "Each cc. contains: 15 Units U. S. P. Injectable" was false and misleading as applied to the article, which contained 8 micrograms of vitamin B₁₂ per cubic centimeter; and, Section 502 (g), the article purported to be "Liver Injection,"

*See also Nos. 4452, 4453, 4456.

a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and the article was not labeled as prescribed in such compendium since its label failed to state the potency in terms of vitamin B₁₂ activity, as the compendium requires. The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: June 23, 1954. Default decree of destruction.

4458. Misbranding of Chilton's throat tablets. U. S. v. 39 Cartons * * *.
(F. D. C. No. 36396. Sample No. 40042-L.)

LIBEL FILED: February 18, 1954, Southern District of California.

ALLEGED SHIPMENT: On or about January 12, 1954, by the Chilton Laboratories, from Montclair, N. J.

PRODUCT: 39 cartons, each containing 12 retail packages, of *Chilton's throat tablets* at North Hollywood, Calif.

LABEL, IN PART: (Carton) "Chilton's Throat Tablets * * * Sore Throat New Antibiotic * * * Tyrothricin * * * Recently authorized for sale to public by U. S. Government Agency (F. D. A)"; (retail package) "Chilton's * * * Throat Tablets. Each tablet contains 2 mg. of tyrothricin and 5 mg. benzocaine * * * For relief of Sore Throat due to minor irritations."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the carton and package labels of the article were false and misleading since the statements represented and suggested that the article was an adequate and effective treatment for sore throat, whereas the article was not an adequate and effective treatment for sore throat.

Further misbranding, Section 502 (a), the statement on the carton label of the article, namely, "Recently authorized for sale to public by U. S. Government Agency (F. D. A.)," was misleading since it represented and suggested that the article designated "Chilton's Throat Tablets" had been authorized for sale by the Food and Drug Administration under the labeling employed therefor, whereas such was contrary to fact.

DISPOSITION: April 21, 1954. Default decree of condemnation and destruction.

4459. Misbranding of electrotherapy device. U. S. v. 1 Device * * *.
(F. D. C. No. 34928. Sample No. 42434-L.)

LIBEL FILED: April 6, 1953, Northern District of California.

ALLEGED SHIPMENT: On or about August 1, 1952, by Rittenhouse & Revere, Inc., from Albuquerque, N. Mex.

PRODUCT: 1 *electrotherapy device* at Salinas, Calif. The device was designed for vaporizing liquids and for producing galvanic, surge galvanic, sine wave, and faradic voltages.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in an accompanying circular entitled "Physics" were false and misleading. The statements represented and suggested that use of the device constituted an adequate and effective treatment for adhesions, amenorrhea, anemia, aphonia, emphysema, bronchiectasis, bronchitis, cataracts, cerebral congestion, cervical laceration, cervicitis, stenosis of the cervix, cirrhosis of the liver, colitis, constipation, deafness, dysmenorrhea, endometritis, erosion of the cervix, stricture of the esophagus, granulated eyelids, fibroids, adolescent goiter, colloid goiter, herpes zoster, hypertension, hyperovarianism, intestinal stasis and ptosis, iritis, chronic nephritis, kraurosis vulvae, labyrinthitis, leukorrhoea, mastitis,