DRUGS SEIZED BECAUSE OF CONTAMINATION WITH FILTH

458. Adulteration of ampuls of triple distilled water. U. S. v. 4 Boxes of Ampuls of Triple Distilled Water. Default decree of condemnation and destruction. (F. D. C. No. 4399. Sample No. 57061-E.)

Samples of this triple distilled water were found to contain viable mold.

On April 18, 1941, the United States attorney for the Eastern District of Missouri filed a libel against 4 boxes, each containing 25 ampuls of triple distilled water at Kirkwood, Mo., alleging that the article had been shipped in interstate commerce on or about March 6, 1941, by the Zeigler Pharmacal Co. from Buffalo, N. Y.; and charging that it was adulterated.

The article was alleged to be adulterated in that it consisted in part of a filthy substance, namely, mold. It was alleged to be adulterated further in that it purported to be a drug the name of which is recognized in an official compendium, the National Formulary, and its quality and purity fell below the standard set forth in such compendium since it contained micro-organisms; whereas the National Formulary requires that triple distilled water shall be free from micro-organisms.

On May 17, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

Nos. 459 and 460 report the seizure and disposition of Hart's Asthma Medicine which was contaminated with mold growth; and the labeling of which failed to bear adequate warning statements and did bear false and misleading therapeutic claims.

459. Adulteration and misbranding of Hart's Compound Asthma Medicine. U. S. v. 96 2-Ounce, 78 4-Ounce, and 113 6-Ounce Packages of Hart's Compound Asthma Medicine. Default decree of condemnation and destruction. (F. D. C. No. 4376. Sample Nos. 55606-E to 55608-E, incl.)

On April 22, 1941, the United States attorney for the District of Oregon filed a libel against the above-named product at Portland, Oreg., alleging that it had been shipped by Hart's Asthma Medicine Co. from Buffalo, N. Y., within the period from on or about March 15, 1940, to on or about January 13, 1941; and charging that it was adulterated and misbranded.

Analysis of a sample of the article showed that it consisted essentially of potassium iodide (approximately 64 grains per fluid ounce), glycerin, water, and flavoring materials including cinnamon and cardamom.

The article was alleged to be adulterated in that it consisted in part of a filthy substance, namely, mold.

It was alleged to be misbranded: (1) In that the labeling failed to bear such adequate warnings against use in those pathological conditions or by children where its use might be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form as are necessary for the protection of users. (2) In that representations in the labeling that it would be efficacious in the treatment of asthma, including the relief of paroxysms or spasmodic attacks, bronchial trouble including bronchitis and bronchial colds, and hay fever, and that it would preserve health, were false and misleading since it would not be efficacious for such purposes.

On June 4, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

460. Adulteration and misbranding of Hart's Compound Asthma Medicine. U. S. v. 48 2-Ounce, 24 4-Ounce, and 24 6-Ounce Packages of Hart's Compound Asthma Medicine. Default decree of condemnation and destruction. (F. D. C. No. 4377. Sample No. 55437-E.)

On April 28, 1941, the United States attorney for the Western District of Washington filed a libel against the above-named product at Seattle, Wash., alleging that it had been shipped by McKesson & Robbins from Portland, Oreg., on or about February 26, 1941; and charging that it was adulterated and misbranded.

Analysis of a sample of the article showed that it consisted essentially of potassium iodide, glycerin, water, and flavoring materials, including cardamom and cinnamon.

The article was alleged to be adulterated in that it consisted in part of a filthy substance, namely, mold.

It was alleged to be misbranded: (1) In that the labeling failed to bear such adequate warnings against use in those pathological conditions or by children

where its use might be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form as are necessary for the protection of users. (2) In that representations in the labeling that it would be efficacious in the treatment of asthma, including the relief of paroxysms or spasmodic attacks, bronchial trouble including bronchitis and bronchial colds, and hay fever, and that it would preserve health, were false and misleading since it would not be efficacious for such purposes.

On June 30, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS SEIZED BECAUSE OF FAILURE TO COMPLY WITH OFFICIAL OR OWN STANDARDS OR BECAUSE OF SUBSTITUTION[2]

461. Adulteration and misbranding of ampuls of ephedrine sulfate, quinine dihydrochloride, and pituitary solution. U. S. v. American Parentrasol Laboratories, Inc., and George Blank. Corporation fined $400; George Blank fined $400. (F. D. C. No. 2898. Sample Nos. 54573–D, 55419–D, 55461–D, 14938–E.)

These products were all drugs recognized in the National Formulary and their strength or quality differed from that set forth in that compendium. The ampuls of quinine dihydrochloride also fell below the standard declared on their labels.

On February 13, 1941, the United States attorney for the District of Connecticut filed an information against American Parentrasol Laboratories, Inc., Bridgeport, Conn., and George Blank, alleging shipment within the period from on or about July 12, 1939, to on or about May 24, 1940, from the State of Connecticut into the States of Michigan and Pennsylvania of quantities of the above-named drugs which were adulterated and misbranded.

The ephedrine sulfate was alleged to be adulterated in that it purported to be or was represented as ampuls of ephedrine sulfate, a drug the name of which is recognized in the National Formulary, and its strength differed from or its quality fell below the standard set forth in that compendium since it yielded an amount of ephedrine corresponding to less than 72.6 percent, namely, not more than 58.4 percent of the labeled amount of ephedrine sulfate; whereas the National Formulary provides that ampuls of ephedrine sulfate shall yield an amount of ephedrine corresponding to not less than 72.6 percent of the labeled amount of ephedrine sulfate. It was alleged to be misbranded in that the statements, (ampul) "1 c.c.—¾ gr. Ephedrine" and (box) "1 c.c.—¾ gr. Ephedrine Sulphate," were false and misleading, since each cubic centimeter of the article did not contain ¾ grain but did contain a smaller amount, namely, slightly more than ⅔ grain of ephedrine, and each cubic centimeter did not contain ¾ grain of ephedrine sulfate but did contain a smaller amount, namely, approximately 0.6 grain of ephedrine sulfate.

The quinine dihydrochloride was alleged to be adulterated in that it purported to be or was represented as ampuls of quinine dihydrochloride, a drug the name of which is recognized in the National Formulary, and its strength differed from or its quality fell below the standard set forth in that compendium in that it yielded less than 95 percent, namely, approximately 55.3 percent of the labeled amount of quinine dihydrochloride; whereas the National Formulary provides that ampuls of quinine dihydrochloride shall yield not less than 95 percent of the labeled amount of quinine dihydrochloride, and its difference in strength or quality from such standard was not plainly stated on its label. It was alleged to be misbranded in that the statements, (ampul) "1 c. c. Quinine Dihydrochloride 7½ grs." and (box) "1 c. c. Quinine Di HCL * * * 7½ grs.," were false and misleading, since each cubic centimeter of the article contained less than 7½ grains, namely, 4.15 grains of quinine dihydrochloride.

The pituitary solution was alleged to be adulterated in that it purported to be or was represented as ampuls of posterior pituitary, a drug the name of which is recognized in the National Formulary, and its strength differed from or its quality fell below the standard set forth in that compendium, since 1 cubic centimeter produced an activity upon the isolated uterus of a virgin guinea pig corresponding to less than 80 percent, namely, not more than 62½ percent of that produced by 0.005 gram of the standard powdered posterior pituitary; whereas the National Formulary provides that unless otherwise stated on the label, ampuls of posterior pituitary contain measured quantities of sterile

[2] See also Nos. 426, 429, 436, 446, 449, 458.