DRUG ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

3609. Adulteration of crude drug mixture. U. S. v. 6 Barrels * * *. (F. D. C. No. 31950. Sample No. 1719–L.)

LIBEL FILED: On or about October 30, 1951, Northern District of Georgia.

ALLEGED SHIPMENT: On or about April 2, 1945, from New York, N. Y.

PRODUCT: 6 110-pound barrels of *crude drug mixture* at Atlanta, Ga.

LABEL, IN PART: (Barrel) "Special Formula 643 Alex Senna Pumpkin Seed American Wormseed Anise Seed."

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy substance by reason of the presence of insects. The article was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: December 3, 1951. Default decree of condemnation and destruction.

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

3610. Adulteration of phenobarbital tablets. U. S. v. 36 Bottles, etc. (F. D. C. No. 31750. Sample Nos. 25629–L, 25630–L, 25731–L.)

LIBEL FILED: October 3, 1951, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about February 21 and August 9, 1951, by the Robin Pharmacal Corp., from New York, N. Y.

PRODUCT: *Phenobarbital tablets.* 36 bottles of ¼-grain tablets and 32 bottles and 36 bottles of ½-grain tablets at Philadelphia, Pa.

NATURE OF CHARGE: Adulteration, Section 501 (b), the tablets purported to be and were represented as "Phenobarbital Tablets," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and their strength differed from, and their quality fell below, that which they purported and were represented to possess. The tablets which were represented to contain ¼ grain of phenobarbital contained less than 94 percent of the labeled amount of phenobarbital and failed to meet the weight variation test laid down in the United States Pharmacopeia for individual tablets; the tablets in the 32-bottle lot which were represented to contain ½ grain failed to meet the weight variation test and the disintegration test laid down in the Pharmacopeia; and the tablets in the 36-bottle lot which were represented to contain ½ grain failed to meet the disintegration test.

DISPOSITION: December 3, 1951. Default decree of condemnation and destruction.

3611. Adulteration and misbranding of Estrotron. U. S. v. 15 Dozen Bottles, etc. (F. D. C. No. 31207. Sample No. 21027–L.)

LIBEL FILED: June 27, 1951, Northern District of Texas; amended libel filed on or about August 13, 1951.

ALLEGED SHIPMENT: On or about April 13, 1951, by the Pitman-Moore Co., Div. of Allied Laboratories, Inc., from Indianapolis, Ind.

*See also No. 3605.

PRODUCT: 15 dozen bottles of *Estrotron* at Dallas, Tex., together with accompanying leaflets entitled "Estrotron." A sample of this product was found to contain not more than 1.52 milligrams of estrogenic ketosteroids per cubic centimeter.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, 2 milligrams of estrogenic ketosteroids per cubic centimeter.

Misbranding, Section 502 (a), the following statements in the labeling of the article were false and misleading as applied to an article which contained less than the declared amount of estrogenic ketosteroids per cubic centimeter: (Bottle label) "* * * Estrotron, 2 mg. (20,000 I. U.) per cc * * * consisting primarily of estrone with smaller amounts of naturally occurring estrogens * * * standardized to 20,000 I. U. of activity per cc. * * *" and (leaflet) "* * * containg 2 mg. of estrogenic substance per cc. equal in estrogenic activity to 20,000 I. U. per cc."

DISPOSITION: September 5, 1951. The Pitman-Moore Co., Div. of Allied Laboratories, Inc., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond to be brought into compliance with the law, under the supervision of the Food and Drug Administration.

3612. Adulteration and misbranding of conjugated estrogens. U. S. v. 18 Bottles * * *. (F. D. C. No. 31308. Sample No. 10358–L.)

LIBEL FILED: July 2, 1951, Eastern District of Michigan.

ALLEGED SHIPMENT: On or about January 30, 1951, by the Keith-Victor Pharmacal Co., from St. Louis, Mo.

PRODUCT: 18 bottles of *conjugated estrogens* at Detroit, Mich. Analysis showed that the product contained a total amount of estrogenic steroids calculated to 0.83 mg. of sodium estrone sulfate per tablet.

RESULTS OF INVESTIGATION: The tablets were shipped from St. Louis, Mo., in a drum and repacked into bottles by the consignee at Detroit, Mich.

LABEL, IN PART: (Bottle) "100 Code No. 190 Sodestrin Tablets"; (drum) "Estrogen 1.25 Mg. Tablets."

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

Misbranding, Section 502 (a), the label statement "Each * * * Tablet contains: Naturally-occurring water soluble Conjugated Estrogens equivalent in biological activity to 1.25 mg. of Sodium Estrone Sulfate" was false and misleading as applied to a product whose equivalent in biological activity was less than that declared.

DISPOSITION: August 30, 1951. Default decree of condemnation and destruction.

3613. Adulteration and misbranding of uterine capsules. U. S. v. 15 Boxes * * *. (F. D. C. No. 31604. Sample No. 21724–L.)

LIBEL FILED: August 6, 1951, Eastern District of Louisiana.

ALLEGED SHIPMENT: On or about March 14 and April 4, 1951, by the Globe Laboratories, from Fort Worth, Tex.

PRODUCT: 15 boxes each containing 1 dozen *uterine capsules* at New Orleans, La. Examination of the product showed that it contained no sodium perborate.