2526. Adulteration and misbranding of phenobarbital sodium tablets and misbranding of atropine sulfate tablets. U. S. v. 95 Bottles, etc. (F. D. C. No. 24838. Sample Nos. 10221–K, 10223–K.)

LIBEL FILED: May 12, 1948, District of New Jersey.

ALLEGED SHIPMENT: On or about December 12, 1947, and January 7, 1948, from Long Island City, N. Y. The *phenobarbital sodium tablets* were shipped by Cole Laboratories, Inc., and the *atropine sulfate tablets* were shipped by the Retort Pharmaceutical Co., Inc., a wholly owned subsidiary of Cole Laboratories, Inc.

PRODUCT: 214 bottles of *phenobarbital sodium tablets* and 1,940 tubes of *atropine sulfate tablets* at Royce, N. J. Examination showed that each bottle of the *phenobarbital sodium tablets* contained less than half the declared number of whole tablets, together with broken and disintegrated tablets; and that each of the whole tablets contained 1.7 grains of phenobarbital sodium. Examination of 30 tubes of *atropine sulfate tablets* showed that they contained from 20 whole tablets to as few as 9 whole tablets per tube, with the entire 30 tubes containing 543 whole tablets, together with broken, chipped, and powdered tablets.

LABEL, IN PART: "1000 Hypodermic Tablets each tablet contains 2 grains (0.12 gm.) Phenobarbital Sodium U. S. P.," and "20 Hypodermic Tablets 1/150 Gr. each Atropine Sulphate U. S. P."

NATURE OF CHARGE: *Phenobarbital sodium tablets.* Adulteration, Section 501 (b), the strength of the article differed from the official standard. The United States Pharmacopoeia requires that sodium phenobarbital tablets contain not less than 90 percent of the labeled amount of sodium phenobarbital, whereas each whole tablet of the article contained less than 90 percent of the declared amount of sodium phenobarbital.

Phenobarbital sodium tablets and *atropine sulfate tablets.* Misbranding, Section 502 (a), the statements "1000 Hypodermic Tablets" on the bottle label of the *phenobarbital sodium tablets* and "20 Hypodermic Tablets" on the tube label of the *atropine sulfate tablets* were false and misleading, since the bottles and tubes contained fewer whole tablets than the declared number.

DISPOSITION: June 21, 1948. Default decree of condemnation and destruction.

2527. Adulteration and misbranding of citrate of magnesia. U. S. v. 4 Cartons * * *. (F. D. C. No. 24593. Sample No. 18045–K.)

LIBEL FILED: April 12, 1948, Southern District of Indiana.

ALLEGED SHIPMENT: On or about February 27, 1948, by Dr. Korony Products, Inc., from Louisville, Ky.

PRODUCT: 4 cartons, each containing 36 bottles, of *citrate of magnesia* at Evansville, Ind. Examination disclosed that the product contained magnesium citrate corresponding to not more than 0.78 gram of magnesium oxide in each 100 cc.

LABEL, IN PART: "Effervescing Solution of Citrate of Magnesia U. S. P. 350 cc. 11¾ Fl. Ozs."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Magnesium Citrate Solution," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its strength differed from the official standard since it contained in each 100 cc. an amount of magnesium citrate corresponding to less than 1.6 grams of magnesium oxide, the minimum permitted by the standard.

Misbranding, Section 502 (a), the label statement "Citrate of Magnesia U. S. P." was false and misleading as applied to an article which was not the U. S. P. product.

DISPOSITION: October 11, 1948. Default decree of forfeiture and destruction.

2528. Adulteration and misbranding of Thi-Cin Cream and Q–2 Cream and misbranding of Bloom Pills. U. S. v. 30 Jars, etc. (F. D. C. No. 24684. Sample Nos. 21160–K to 21162–K, incl.)

LIBEL FILED: On or about April 6, 1948, Western District of Missouri.

ALLEGED SHIPMENT: On or about December 2 and 4, 1947, by the Duncan Co., from Oklahoma City, Okla.

PRODUCT: 101 jars of *Thi-Cin Cream*, 91 jars of *Q–2 Cream*, and 42 bottles of *Bloom Pills* at St. Joseph, Mo. Examination showed that the *Thi-Cin Cream* was not a germicide and consisted essentially of oil of cassia and thymol in

a cold cream base; that the *Q–2 Cream* was not an antiseptic and consisted essentially of oil of cassia, thymol, and petrolatum; and that the *Bloom Pills* consisted essentially of calcium sulfide and charcoal.

NATURE OF CHARGE: *Thi-Cin Cream.* Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, i. e., (on label) "germicide," since the article was not a germicide. Misbranding, Section 502 (a), the label statements, "Stops that itching * * * a highly effective germicide in a wide range of skin disorders. Including, Eczema, Seborrheic dermatosis * * * Barber's Itch and externally caused Industrial dermatosis," were false and misleading, since the article was not a germicide and was not effective in the treatment of the conditions and diseases mentioned; and, Section 502 (b) (2), the article failed to bear a label containing an accurate statement of the quantity of the contents.

Q–2 Cream. Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, i. e., (on label) "antiseptic," since the article was not an antiseptic. Misbranding, Section 502 (a), the label statements, "For Itch * * * Kills the Itch Mite on Contact * * * for the relief of Eczema * * * externally caused acne and as an antiseptic for minor cuts and wounds," were false and misleading, since the article was not an antiseptic and was not an adequate treatment for the conditions mentioned.

Bloom Pills. Misbranding, Section 502 (a), certain statements on the label which represented and suggested that the article was effective in the treatment of acne and pimples, were false and misleading, since the article was not effective in the treatment of such conditions.

DISPOSITION: June 21, 1948. Default decree of condemnation and destruction.

2529. Adulteration and misbranding of Anademin tablets. U. S. v. 23 Boxes * * *. (F. D. C. No. 25213. Sample No. 19612–K.)

LIBEL FILED: July 26, 1948, Southern District of Ohio.

ALLEGED SHIPMENT: On or about April 21, 1948, by the Anademin Chemical Co., from Chattanooga, Tenn.

PRODUCT: 23 boxes of *Anademin tablets* at Cincinnati, Ohio. Examination showed that the potency of each tablet was equivalent to less than two-thirds of a U. S. P. digitalis unit.

LABEL, IN PART: (Box) "100 Tablets Anademin Active Ingredients: Strophanthus .0140 mgms. (Containing .0014 mgms. of strophanthin), Squill 99.0090 mgms., Canadian Hemp (apocynum) .3260 mgms. and Elder Flowers (Sambucus) 6510 mgms., with excipients and coating. Each tablet is equivalent in potency to one U. S. P. Digitalis Unit."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, i. e., "one U. S. P. Digitalis Unit."

Misbranding, Section 502 (a), the label statement "Each tablet is equivalent in potency to one U. S. P. Digitalis Unit" was false and misleading.

DISPOSITION: September 10, 1948. Default decree of condemnation and destruction.

2530. Adulteration of Obeto. U. S. v. 5 Boxes * * *. (F. D. C. No. 25239. Sample No. 30595–K.)

LIBEL FILED: August 3, 1948, Southern District of California.

ALLEGED SHIPMENT: On or about March 10, 1948, by the Ziegler Pharmacal Co., from Buffalo, N. Y.

PRODUCT: 5 boxes, each containing 100 ampules, of *Obeto* at Roscoe, Calif. Examination showed that the product was not sterile.

LABEL, IN PART: "2 cc. plus No. 147 Obeto Chlorobutanol 0.5% (Intramuscular)."

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported and was represented to possess, i. e., "Obeto * * * (Intramuscular)," since it was for intramuscular use and was unsterile.

DISPOSITION: August 26, 1948. Default decree of condemnation and destruction.