

454. Misbranding of Rux compounds and Williams formulas. U. S. v. Certain Quantities of Rux Compound Regular, Rux Compound Strengthened, Williams Formula Regular, and Williams Formula Strengthened. Default decree of condemnation and destruction. (F. D. C. No. 3390. Sample Nos. 24139-E to 24143-E, incl.)

The label of the Williams formulas failed to bear adequate directions and warning statements, and that of all four products bore false and misleading therapeutic claims.

On November 18, 1940, the United States attorney for the Middle District of Pennsylvania filed a libel against 29 bottles of Rux Compound Regular; 191 8-fluid-ounce bottles, 16 3-fluid-ounce bottles, and 2 quart bottles of Rux Compound Strengthened; 27 bottles of Williams Formula Regular; and 195 8-fluid-ounce bottles, 20 3-fluid-ounce bottles, and 2 quart bottles of Williams Formula Strengthened at Sayre, Pa., alleging that the articles had been shipped on or about July 26, 1940 by the Williams S. L. K. Laboratories from Milwaukee, Wis.; and charging that they were misbranded.

Analyses of samples showed that Rux Compound Regular consisted essentially of sodium, potassium, and strontium salts of salicylic, benzoic, and acetic acids, extracts of plant drugs including quassia, saccharin, and water, the total amount of salicylic acid represented being 21.1 grains per fluid ounce; Rux Compound Strengthened consisted essentially of the same ingredients, the total amount of salicylic acid represented being 32.8 grains per fluid ounce; Williams Formula Regular consisted essentially of Rochelle salt (21.5 grains per fluid ounce), methenamine (5.2 grains per fluid ounce), iron and ammonium citrate (2.4 grains per fluid ounce), extracts of plant drugs including a laxative drug, nux vomica, and Cayenne pepper, alcohol (3 percent), and water; and Williams Formula Strengthened consisted essentially of Rochelle salt (40.2 grains per fluid ounce), methenamine (9.3 grains per fluid ounce), iron and ammonium citrate (3.8 grains per fluid ounce), extracts of plant drugs including a laxative drug, nux vomica, and Cayenne pepper, alcohol (2.3 percent), and water.

Williams Formula Regular and Williams Formula Strengthened were alleged to be misbranded in that the labeling did not bear adequate directions for use since the following directions were not suitable and appropriate for articles of their composition and therefore were not adequate: (Bottle and carton containing Williams Formula Regular and 8-fluid-ounce bottle and carton containing Williams Formula Strengthened) "Adults—Tablespoonful before meals and at bedtime with a glass of water with each dose. Reduce dose if too active"; (circular accompanying 8-fluid-ounce bottle of Williams Formula Strengthened) "Important Directions Williams Formula is generally taken right before meals and at bedtime, making four doses a day to start. * * * Follow carefully directions for dosage on label. If desired, 2 teaspoonsful may be taken each dose for a few days. Reduce dose if too active. * * * After taking a course of Williams Formula many people prefer to keep a bottle on hand to be taken as needed. Some find it advisable to take the medicine a week or ten days, then skip a week or two, resuming the dosage when they feel the need of it. Your own experience should soon guide as to how to take Williams Formula to obtain the most good from it. * * * Directions For Combination Use When using Rux and Williams Formula together, in indicated conditions, follow these directions: Take 2 teaspoonsful of Rux every 3 hours for the first 3 days, and Williams Formula before meals and at bedtime. After 3 days, take 1 teaspoonful of Rux after meals and at bedtime, using Williams Formula morning and night only. In this way one bottle of Williams Formula lasts as long as two bottles of Rux." Williams formulas were alleged to be misbranded further in that the labeling failed to bear adequate warnings against unsafe dosage or methods or duration of administration in such manner and form as are necessary for the protection of users, since it did not inform the purchaser that frequent or continued use of the article might result in dependence upon laxatives to move the bowels. They were alleged to be misbranded still further in that representations in the labeling that Williams Formula Regular would provide iron for the blood and an alkalizer for excess stomach acid; that it would be efficacious in the treatment of constipation, sick headaches, dizzy attacks, nausea, poor appetite, gas pains, bloat, tired-out, run-down, "half-alive" feeling; that it had helped bring users to a greater enjoyment of living; that it would relieve suffering and make life happier; that it would give gentle laxing action; that it would serve as a tonic to help whip the user out of depressing mental laziness and give him increased pep and vitality; that it would

alkalize urine flow to relieve acid kidney pains, and that it would serve as a diuretic for kidneys; that it would cure pimples, relieve choking spells, and tone up the intestinal muscles; and that Williams Formula Strengthened was an iron source, were false and misleading since the drugs were not efficacious for such purposes.

Rux Compound Regular and Rux Compound Strengthened were alleged to be misbranded in that representations in the labeling that they were efficacious for pronounced pain and for relief of muscular pain and congestion, were false and misleading since they would not be efficacious for such purposes.

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

Nos. 455 to 457 report the seizure and disposition of intra-cervical or intra-uterine types of metal or rubber-covered stem pessaries which were potentially dangerous.

455. Misbranding of pessaries. U. S. v. 8 Gold Pessaries. Default decree of condemnation and destruction. (F. D. C. No. 3004. Sample No. 34352-E.)

On September 19, 1940, the United States attorney for the Eastern District of New York filed a libel against 8 gold pessaries at Brooklyn, N. Y., alleging that the article had been shipped on or about November 19, 1938, March 14, 1939, and July 23, 1940, by American Platinum Works from Newark, N. J.; and charging that its was misbranded in that its labeling failed to bear adequate directions for use.

On November 14, 1940, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

456. Misbranding of pessaries. U. S. v. 1 Large, 2 Small, and 6 Medium Gold Pessaries. Default decree of condemnation. Product ordered delivered to United States Mint. (F. D. C. No. 3309. Sample No. 35296-E.)

On or about November 2, 1940, the United States attorney for the Northern District of Texas filed a libel against 9 gold pessaries at Fort Worth, Tex., alleging that the article had been shipped on or about September 10, 1940, by the Kny-Scheerer Corporation from Long Island City, N. Y.; and charging that it was misbranded. It was labeled in part: "Perfection 1/10 14 Kt. Gold Pessary."

The article was alleged to be misbranded (1) in that its labeling did not bear adequate directions for use; and (2) in that its labeling did not bear adequate warnings against use in those pathological conditions 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 protection of users.

On February 26, 1941, no claimant having appeared, judgment of condemnation was entered and the product was ordered delivered to the Director of the Mint for reclamation, for the use of the United States, of its gold content.

457. Misbranding of pessaries. U. S. v. 125 Gold Pessaries. Consent decree of condemnation. Product ordered released under bond to be relabeled. (F. D. C. No. 3095. Sample Nos. 30915-E to 30920-E, incl.)

On October 15, 1940, the United States attorney for the Northern District of Illinois filed a libel against 125 pessaries at Chicago, Ill., alleging that the article had been shipped by Nicholas Mandula from New York, N. Y., on or about August 28, 1940; and charging that it was misbranded. It was labeled in part: "Illinois Special Gold Medium [or "Small" or "Large"] Pessary 10 Karat"; or "Illinois Special Gold-Filled Pessary Medium [or "Small" or "Large"] Tubular X-Cel."

The article was alleged to be misbranded (1) in that the labeling failed to bear adequate warnings against its use in those pathological conditions where its use might be dangerous to health or against unsafe methods or duration of administration or application; and (2) in that the labeling failed to bear adequate directions for use.

On December 27, 1940, the Illinois Surgical Supply Co., Chicago, Ill., claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond to be relabeled under the supervision of the Food and Drug Administration.