1305. Misbranding of Rudy's Pile Suppository. U. S. v. 36 Packages of Rudy's Pile Suppository. Default decree of condemnation and destruction. (F. D. C. No. 12361. Sample No. 79374-F.)

On May 11, 1944, the United States attorney for the Eastern District of Virginia filed a libel against 36 packages of the above-mentioned product at Norfolk, Va., alleging that the article had been shipped on or about February 14, 1944, by the Martin Rudy Estate, from Lancaster, Pa.

Examination of samples showed that the article consisted essentially of lead carbonate 0.25 grain, tannic acid, creosote, and iodoform in a suppository base.

The article was alleged to be misbranded (1) in that the statement in the labeling, "Tends to relieve the discomforts of Piles (Bleeding * * * Protruding)," was false and misleading since the article would not constitute a safe and effective treatment for the discomfort of bleeding and protruding piles; (2) in that its labeling failed to bear adequate warnings against its use in the case of bleeding piles; and (3) in that it was dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the label.

On July 14, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

1306. Adulteration and misbranding of Dr. Hubbels Formula for Dental Hygiene. U. S. v. Hubbel Products Corporation. Plea of guilty. Fine, $50. (F. D. C. No. 12597. Sample No. 52281-F.)

On November 6, 1944, the United States attorney for the District of Massachusetts filed an information against the Hubbel Products Corporation, Boston, Mass., alleging shipment of a quantity of the above-named product from the State of Massachusetts into the State of Maine, on or about March 11, 1944.

The article was alleged to be adulterated in that its strength differed from that which it purported and was represented to possess, since it was represented as containing 8 grains of chloral hydrate to the fluid ounce, whereas it contained approximately 14 grains of chloral hydrate to the fluid ounce.

It was alleged to be misbranded (1) in that the statement on its label, "Chloral Hydrate 8 grs. to Fluid Oz.," was false and misleading; (2) in that its label bore no statement of the quantity of the contents; (3) in that its labeling bore no directions for use; and (4) in that it was a drug for use by man, and it contained chloral hydrate, a derivative of chloral, which derivative, by regulations, has been designated as habit-forming, but the label of the article did not bear the name and quantity or proportion of the derivative and, in juxtaposition therewith, the statement "Warning—May be habit-forming."

On December 27, 1944, a plea of guilty having been entered on behalf of the corporation, the court imposed a fine of $25 on each of 2 counts, a total fine of $50.

1307. Misbranding of Fentone Compound. U. S. v. 31 Packages of Fentone Compound. Default decree of condemnation and destruction. (F. D. C. No. 12297. Sample No. 41524-F.)

On May 19, 1944, the United States attorney for the Southern District of Mississippi filed a libel against 31 packages of Fentone Compound at Jackson, Miss., alleging that the article had been shipped on or about August 5 and September 25, 1943, from Paris, Tenn., by the Fentone Medicine Co.

Examination showed that the article consisted essentially of water; Epsom salt; small proportions of sodium salicylate; iron, ammonium, and potassium compounds, including carbonates and phosphates; saccharin; oil of cinnamon; and a red coloring matter.

The article was alleged to be misbranded because of false and misleading statements on its label and in an accompanying circular entitled, "Is Intestinal Stasis Spreading Poisons Throughout Your System Contaminating the Blood-Stream, Liver and Kidneys?", regarding the efficacy of the article in the treatment of liver and kidney disorders, high blood pressure, rheumatism,

*See also Nos. 1304, 1305.

arthritis, nervousness, sleeplessness, backache, belching and bloating, stiff joints, heartburn, heart palpitation, swollen stomach, constipation, upset stomach, clogged liver, acid in the kidneys, packed colon, headache, dizziness, hyperacidity of the stomach and kidneys, indigestion, vomiting, nausea, a tired, worn-out feeling, frequent getting up at night, loss of vigor, neuritis, swollen joints, leg pains, coated tongue, bad breath, and toxemia.

The article was alleged to be misbranded further (1) in that its label failed to bear the common or usual name of each active ingredient; (2) in that its labeling failed to bear adequate directions for use; and (3) in that it was a laxative and its labeling failed to bear such warnings as are necessary for the protection of users.

On November 6, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1308. Misbranding of Garfield's Seidlitz Powders. U. S. v. 1,440 Packages of Garfield's Seidlitz Powders. Consent decree of condemnation. Product ordered released under bond to be relabeled. (F. D. C. No. 12175. Sample No. 77913-F.)

On April 12, 1944, the United States attorney for the Eastern District of Pennsylvania filed a libel against 1,440 packages of the above-named product at Philadelphia, Pa., alleging that the article had been shipped on or about December 24, 1943, by Garfield and Co., from New York, N. Y.; and charging that it was misbranded.

The article was alleged to be misbranded in that the labeling of 90 percent of the packages failed to bear warnings that the article should not be used when abdominal pain, nausea, vomiting, or other symptoms of appendicitis are present, and that frequent use of the preparation may result in dependence on laxatives to move the bowels.

On May 23, 1944, Garfield and Co., 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.

1309. Misbranding of Dependon Intrauterine Paste. U. S. v. 16 Packages of Dependon Intrauterine Paste. Default decree of condemnation and destruction. (F. D. C. No. 10437. Sample No. 10634-F.)

On August 19, 1943, the United States attorney for the Northern District of California filed a libel against 16 packages of the above-named product at Roseville, Calif., alleging that the article had been shipped on or about February 25, 1943, from White Bear Lake, Minn., by A. M. Jenks; and charging that it was misbranded. The article was unlabeled.

Examination of a sample disclosed that the article consisted essentially of soap, potassium iodide (1 percent), and water.

The article was alleged to be misbranded in that it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor; (2) an accurate statement of the quantity of contents; (3) the common or usual name of each active ingredient; and (4) adequate directions for its use.

On October 16, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

1310. Adulteration of crude drugs. U. S. v. 1 Bag of Elder Berries, 1 Bag of Peach Tree Leaves, and 8 Bags of White Pine Bark. Default decree of condemnation and destruction. (F. D. C. No. 11996. Sample Nos. 66225-F, 66228-F, 66229-F.)

On or about March 25, 1944, the United States attorney for the District of New Jersey filed a libel against 1 bag containing approximately 117 pounds of elderberries, 1 bag containing approximately 75 pounds of peach tree leaves, and 8 bags containing approximately 1,628 pounds of white pine bark at Jersey City, N. J., alleging that the articles had been shipped on or about January 24 and 26, 1944, from Boone, N. C., by the Wilcox Drug Co.; and charging that they were adulterated.

The white pine bark was alleged to be adulterated (1) in that it consisted in whole or in part of a filthy and decomposed substance by reason of the presence of worm-bored and moldy bark; and (2) in that it purported to be and was represented as a drug the name of which is recognized in the National Formulary, an official compendium, but its quality and purity fell