Mich., alleging that it had been shipped in interstate commerce on or about July 14, 1939, by S. B. Penick & Co. from Jersey City, N. J.; and charging that it was adulterated and misbranded. Two drums of oil having been seized, one of which was not in violation of the law, an order was entered on June 14, 1940, releasing the drum which had been erroneously seized.

The article was alleged to be adulterated in that its strength differed from and its purity fell below that which it purported or was represented to possess.

It was alleged to be misbranded in that the statement "35,000 U. S. P. Units of Vitamin D per gram," stenciled on the drum, was false and misleading, since it did not contain 35,000 U. S. P. units of vitamin D per gram.

On July 29, 1940, S. B. Penick & Co., claimant, filed a motion for discovery of the Government's assay and on July 31 an order was entered directing that, upon the claimant's filing its answer, the Government produce and permit the inspection and copying of documents which showed the results of the assay or assays.

On February 28, 1941, the claimant having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond conditioned that it be relabeled under the supervision of the Food and Drug Administration as follows: "Blue Fin Tuna Liver Oil 100,000 U. S. P. Units of Vitamin A Per Gram, 20,000 U. S. P. Units of Vitamin D Per Gram."

774. Adulteration and misbranding of Vi-Penta Drops 'Roche'. U. S. v. 234 Vials of Vi-Penta Drops 'Roche'. Default decree of condemnation and destruction. (F. D. C. No. 4833. Sample No. 69145–E.)

This product was represented to contain 9,000 U. S. P. units of vitamin A per 0.6 cc. but in fact contained not more than 3,500 U. S. P. units of vitamin A per 0.6 cc.

On May 27, 1941, the United States attorney for the Southern District of New York filed a libel (amended September 16, 1941) against the above-named product at New York, N. Y., alleging that it had been shipped in interstate commerce on or about April 22, 1941, by Hoffman-La Roche, Inc., from Nutley, N. J.; and charging that it was adulterated and misbranded.

The article was alleged to be adulterated in that its strength differed from and its quality fell below that which it was represented to possess, namely, 9,000 U. S. P. units of vitamin A per 0.6 cc., since it contained much less than 9,000 U. S. P. units of vitamin A per 0.6 cc.

It was alleged to be misbranded in that the statements, (circular) "Each 10-minim dose of Vi-Penta Drops contains: Vitamin A 9000 U. S. P. Units * * * Indications for Vi-Penta Drops * * * For the normal growth and development of infants or children. In cases of malnutrition, lowered resistance or run-down states. During prolonged illness such as infections, anemias, tuberculosis, typhoid, etc. * * * For gastrointestinal conditions, such as diarrhea, colitis, etc. When restrictions in diet are necessary, as in obesity, diabetes, catarrhal jaundice, etc. Whenever the total food intake must be increased, as in hyperthyroid conditions. For the treatment of certain skin diseases, such as eczema. In certain allergic conditions, such as those due to milk, eggs, wheat, etc. During periods of temporary or persistent vomiting (in infancy, childhood, or pregnancy). In the prophylaxis or treatment of abnormal dentition (or gum and tooth conditions)," were false and misleading since it would not be efficacious for such purposes.

It was also alleged to be adulterated and misbranded under the provisions of the law applicable to food, as reported in notices of judgment on foods.

On March 17, 1942, Hoffman-La Roche, Inc., claimant, having consented to the entry of the decree, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS FOR VETERINARY USE

775. Adulteration and misbranding of sodium cacodylate solution, alkaline compound powder, calcium gluconate compound solution, diuretic powder, canine worm tablets, liquid nux vomica alkaloids, and tonic powder; and misbranding of Aresnol Compound Powder, glucose solution, potassium arsenite compound tablets, santonin-calomel tablets, Guaiadine Tablets, Conjunctivities #1 Tablets, and tetrachlorethylene capsules. U. S. v. Peerless Serum Co. Plea of guilty. Fine, $105 and costs. (F. D. C. No. 555. Sample Nos. 43057–E to 43059–E, incl., 43061–E, 43063–E to 43065–E, incl., 43067–E, 43069–E, 43074–E to 43076–E, incl., 43078–E, 43079–E.)

The labeling of these veterinary preparations, with the exception of the potassium arsenite compound tablets, and the liquid nux vomica alkaloids, bore

false and misleading curative claims. Some of the products fell below their own declared standards and others failed to comply with certain labeling requirements of the law.

On March 28, 1942, the United States attorney for the District of Kansas filed an information against the Peerless Serum Co., a corporation having a place of business at Kansas City, Kans., alleging shipment within the period from on or about August 16 to on or about October 25, 1940, from the State of Kansas into the State of Oklahoma of quantities of the above-named veterinary preparations which were misbranded and some of which were also adulterated.

Analysis of the sodium cacodylate solution showed that it contained not more than 2.53 grains of sodium cacodylate per cc. It was alleged to be adulterated in that its strength differed from and its quality fell below that which it purported and was represented to possess, since it was represented to contain 4.5 grains of sodium cacodylate per cc.; whereas it contained not more than 2.53 grains of sodium cacodylate per cc. It was alleged to be misbranded (1) in that the statement on the bottle label, "Sodium Cacodylate Solution 4.5 Gr. per cc." was false and misleading; (2) in that the statements on the bottle label, "Useful in the treatment of Anaplasmosis, Swamp Fever, Anemia, Influenza, Shipping Fever, Chronic Skin Diseases and to build up Convalescent Patients," were false and misleading since it would not be efficacious for such purposes; and (3) in that it contained sodium cacodylate, a derivative of arsenic, and its label did not bear a statement showing the substance from which such ingredient was derived.

Analysis of the alkaline compound powder showed that it consisted essentially of sodium hydroxide with small proportions of copper sulfate, sodium thiosulfate, sodium bicarbonate, and phenol, and a minute amount of phenolphthalein flavored with oil of anise. It was alleged to be adulterated in that it contained, for purposes of coloring only, a coal-tar color, namely, phenolphthalein, other than one from a batch that had been certified in accordance with regulations as provided by law. It was alleged to be misbranded in that the statements, "for the treatment of necrotic enteritis * * * Action: Systemic Alkalinizer. Use: To rebuild Alkaline Reserve of bodily tissues and fluids; as an aid in the treatment of Necrotic Enteritis (Swine) and Intestinal Infections of Poultry," borne on the label, were false and misleading since it would not be efficacious for such purposes.

Analysis of a sample of the Aresnol Compound Powder showed that it consisted essentially of arsenic trioxide (1.02 percent), powdered willow bark, linseed meal, and sulfur. It was alleged to be misbranded (1) in that the statements, (box label) "For the internal treatment of chronic supperative processes, such as Fistulour Withers, Poll Evil, Grease Heel, Catarrhal, Respiratory, Uterine Infections, etc., of the Horse," were false and misleading since it would not be efficacious for such purposes; and (2) in that it was fabricated from two or more ingredients and its label did not bear the common or usual name of each active ingredient, including the quantity or proportion of arsenic that it contained.

Analysis of the calcium gluconate compound solution showed that it contained approximately 15.05 percent of calcium gluconate and approximately 4 percent of boric acid. It was alleged to be adulterated in that its strength differed from and its quality fell below that which it purported and was represented to possess in that it was represented to contain 23 percent of calcium gluconate; whereas it contained not more than 15.05 percent of calcium gluconate. It was alleged to be misbranded (1) in that the statement (bottle label and carton) "Calcium Gluconate Comp. Solution * * * 23% Solution," was false and misleading; (2) in that the statement (bottle label) "Indications: * * * azoturia," was false and misleading since it would not be efficacious in the treatment of azoturia; and (3) in that its labeling was misleading since it failed to reveal the fact, material in the light of the representations therein, that it contained boric acid.

Analysis of the Diuretic Powder showed that it contained approximately 2.61 percent of methenamine, also sodium bicarbonate, potassium nitrate, and plant material including uva ursi, a resinous material, and an atropine-bearing drug such as belladonna. It was alleged to be adulterated in that its strength differed from and its quality fell below that which it purported and was represented to possess, since it was represented to contain 3 percent of methenamine; whereas it contained not more than 2.61 percent of methenamine. It was alleged to be misbranded (1) in that the statement, (carton label) "Contains Methenamine, 3%" was false and misleading; (2) in that the statement (carton) "Urinary disorders in horses, such as strangury, urinary retention associated with oedema

and febrile disturbances, acute intestinal inflammations," were false and misleading since it would not be efficacious for such purposes; and (3) in that it was fabricated from two or more ingredients and contained the alkaloids of atropine, hyoscine, and hyoscyamine, constituents of belladonna, but the label did not state the quantity or proportion of atropine, hyoscine, and hyoscyamine present, nor did it state the quantity or proportion of total alkaloids contained as constituents of belladonna.

Analysis of the Glucose Solution showed that it contained approximately 50 percent of anhydrous glucose. It was alleged to be misbranded in that the statements, "For the treatment of eclampsia, auto-intoxication. Also of value in Milk Fever * * * Adicosis * * * running fits and chronic diseases of a nervous nature," borne on the bottle label and carton, were false and misleading since it would not be efficacious for such purposes.

Analysis of the Potassium Arsenite Compound tablets showed that each tablet contained approximately 1.01 gram of arsenic as As_2O_3 per tablet, and that each tablet would make a solution containing not more than 0.854 gram of arsenic trioxide in 100 cc. It was alleged to be misbranded in that the statement, "Each tablet contains sufficient potassium arsenite to make four ounces of a solution whose arsenic content is the same as that of Fowler's Solution," borne on the bottle label, was false and misleading, since each tablet contained sufficient potassium arsenite to make a solution containing in each 100 cc. not more than 0.854 gram of arsenic trioxide; whereas Fowler's solution is a drug the name of which is recognized in the United States Pharmacopoeia, which provides that Fowler's solution, namely, solution of potassium arsenite, shall contain in each 100 cc. the equivalent of not less than 0.950 gram of As_2O_3, namely, arsenic trioxide.

Examination of the Canine Worm Tablets showed that the product consisted of capsules, each capsule containing a red-coated tablet and gray powder. Analysis showed that the tablets contained approximately 0.073 (1/14) grain of arecoline each and that the powder consisted essentially of sodium bicarbonate, a small proportion of santonin, and plant material including areca nut. The article was alleged to be adulterated in that its strength differed from and its quality fell below that which it purported and was represented to possess since each tablet was represented to contain 1/10 grain of arecoline, whereas each tablet contained not more than 0.073 (1/14) grain of arecoline. It was alleged to be misbranded in that the statement (on the bottle label) "Tablets * * * Contains: Arecoline * * * 1/10 gr.," was false and misleading. It was alleged to be misbranded further in that the statements (bottle label) "For Round * * * Worms in dogs and cats" and "Worm," were false and misleading since it would not be efficacious for such purposes.

Analysis of the Santonin-Calomel tablets showed that they contained santonin and calomel in approximately the quantities declared on the label, namely, "Calomel 1/8 Gr. Santonin 1/2 Gr." The article was alleged to be misbranded (1) in that the statement on the bottle label "Round worms in dogs and cats," was false and misleading since it would not be efficacious for such purposes; (2) in that it was fabricated from two or more ingredients and contained calomel, a derivative of mercury, but the label did not bear a statement showing that said ingredient was derived from mercury; and (3) in that the statement on the bottle label "Each c.c. contains a quarter grain each of strychnine Sulphate and Brucine Sulphate," was false and misleading.

The Tetrachlorethylene Capsules were alleged to be misbranded in that the statement on the bottle label, "For the removal of * * * round worms from all animals," was false and misleading since they would not be efficacious for such purposes.

Analysis of the Tonic Powder showed that it contained not more than 22 percent of phosphate and that it contained arsenic trioxide, sodium sulfate, iron sulfate, a calcium compound, and plant material including nux vomica, gentian, and quassia. It was alleged to be adulterated in that its strength differed from and its quality fell below that which it purported and was represented to possess, since it was represented to contain 28 percent of phosphate, whereas it contained not more than 22 percent of phosphate. It was alleged to be misbranded (1) in that the statements on the cartons, "1 Pound" and "Contains * * * Phosphate, 28%," were false and misleading since each of the cartons contained less than 1 pound of the powder and less than 28 percent of phosphate; (2) in that the statements on the cartons, "restorative. * * * improves digestion and assimilation of food," were false and misleading since it would not be efficacious for such purposes; (3) in that it was fabricated from two or more ingredients and contained strychnine; and (4) in that its container (bottle) was so filled as

to be misleading since the contents occupied not more than 30 percent of its total volume.

Analysis of the Guaiadine Tablets showed that they contained small proportions of potassium dichromate, iodine, guiacol, and creosote. The article was alleged to be misbranded in that the statements on the bottle label, "Indications: In the treatment of the so-called Fowl Cholera, Typhoid, Roup, Coccidosis and various troubles originating in the intestinal tract of fowls," were false and misleading since it would not be efficacious for such purposes.

Analysis of the Conjunctivitis #1 Tablets showed that they contained boric acid, zinc sulfate, salicylic acid, and methylene blue. They were alleged to be misbranded in that the statement "Conjunctivitis," borne on the bottle label, was false and misleading since they would not be efficacious in the treatment of conjunctivitis.

Analysis of the Liquid Nux Vomica Alkaloids showed that the article contained not more than 0.1503 (slightly less than 1/6) grain of strychnine sulfate and 0.0441 (1/23) grain of brucine sulfate, per cc. It was alleged to be adulterated in that its strength differed from and its quality fell below that which it purported and was represented to possess, since it was represented to contain 1/4 grain of strychnine sulfate and 1/4 grain of brucine sulfate per cc.; whereas it contained not more than 0.1503 (slightly less than 1/6) grain of strychnine sulfate and not more than 0.0441 (1/23) grain of brucine sulfate per cc. It was alleged to be constituent of the drug nux vomica, but its label failed to declare the quantity of strychnine that it contained.

On April 13, 1942, a plea of guilty was entered on behalf of the defendant and the court imposed a fine of $105 and costs.

776. Adulteration and misbranding of cod-liver oil. U. S. v. 5 Barrels and 1 Drum of Cod-Liver Oil. Default decrees of condemnation. Portion of product ordered disposed of for stock and poultry feed; remainder ordered destroyed. (F. D. C. Nos. 7567, 7586. Sample Nos. 71520-E, 80695-E.

This product differed from the pharmacopoeial standard since it was not partially destearinated, and it was off in color and odor and high in free fatty acids. The oil in the drum contained smaller amounts of vitamin D and vitamin A than those declared on the label.

On May 26 and 29, 1942, the United States attorneys for the Southern District of Ohio and Eastern District of Missouri filed libels against 5 30-gallon barrels of cod-liver oil at Mt. Orab, Ohio, and 1 30-gallon drum of cod-liver oil at St. Louis, Mo., which had been consigned on or about February 17 and April 4, 1942, alleging that the article had been shipped in interstate commerce by the Swiftide Co., from Portland, Maine; and charging that it was adulterated and misbranded. The article was labeled in part: "Swiftide Brand Cod Liver Oil."

It was alleged to be adultered in that it was represented as a drug the name of which is recognized in an official compendium but its quality fell below the standard set forth in that compendium and the manner in which it differed from such standard was not stated on the label.

It was alleged to be misbranded in that the name "Cod Liver Oil" was false and misleading since it was not cod-liver oil. A portion was alleged to be misbranded further in that the statements (drum) "Guaranteed to Contain Not Less Than 200 A. O. A. C. Units Vitamin D" and "Not less than 1,000 Units Vitamin A Per Gramme," were false and misleading since it contained not more than 100 A. O. A. C. units of vitamin D and not more than 700 U. S. P. units of vitamin A per gram. The oil in the drum was also alleged to be misbranded under the provisions of the law applicable to foods, as reported in Notices of Judgment on Foods.

On June 30, 1942, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS[5]

DRUGS FOR HUMAN USE

777. Alleged misbranding of Armi Mineral Water. U. S. v. Ralph R. Markwood (Armi Mineral Water Co.). Demurrer to the information sustained. Case ordered dismissed. (F. D. C. No. 4114. Sample Nos. 5790-E, 27566-E.)

On June 24, 1941, the United States attorney for the Northern District of Ohio filed an information against Ralph R. Markwood, trading as the Armi

[5] See also Nos. 754, 757, 759, 765, 766, 772, 774.