

On January 7, 1941, a plea of guilty having been entered, the court sentenced the defendant to 10 months' imprisonment on the 10 counts covering violations of the Federal Food, Drug, and Cosmetic Act, but suspended sentence and placed the defendant on probation for 1 year. (On each of the 8 counts charging violation of the Federal Food and Drugs Act of 1906 the court imposed a fine of \$1.)

348. Adulteration and misbranding of elixir iron, quinine, and strychnine phosphates; and of ammoniated mercury ointment. U. S. v. Standard Pharmaceutical Corporation. Plea of guilty. Fine, \$50 and costs. (F. D. C. No. 2889. Sample Nos. 1457-E, 1463-E.)

These products were represented to be drugs the names of which are recognized in official compendiums and their strength differed from and their quality fell below the standard set forth therein.

On January 31, 1941, the United States attorney for the District of Maryland filed an information against the Standard Pharmaceutical Corporation, Baltimore, Md., alleging shipment on or about April 18, 1940, from the State of Maryland into the District of Columbia of quantities of elixir of iron, quinine, and strychnine phosphates and of ammoniated mercury ointment which were adulterated and misbranded.

The elixir of iron, quinine, and strychnine phosphates was alleged to be adulterated 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 strength differed from or its quality or purity fell below the standard set forth therein, since it yielded less than 3.875 grams, namely, not more than 1.17 grams of the anhydrous alkaloids of quinine and strychnine per 1,000 cubic centimeters; whereas the National Formulary provides that elixir of iron, quinine, and strychnine phosphates shall contain 5 grams of quinine phosphate and 250 milligrams of strychnine phosphate per 1,000 cubic centimeters, and a drug so prepared should yield not less than 3.875 grams of the anhydrous alkaloids of quinine and strychnine per 1,000 cubic centimeters; and its difference in strength, quality, or purity from the standard set forth in said compendium was not stated plainly on the label. The article was alleged to be misbranded in that the statement "Elixir Iron, Quinine and Strychnine Phosphates N. F. VI.," borne on the label, was false and misleading since it did not comply with the specifications for elixir of iron, quinine, and strychnine phosphates set forth in the National Formulary, sixth edition.

The ammoniated mercury ointment was alleged to be adulterated in that it purported to be and was represented as a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its strength differed from or its quality or purity fell below the standard set forth in that compendium, since it contained not more than 4.22 percent of ammoniated mercury; whereas the pharmacopoeia provides that ammoniated mercury ointment shall contain 10 percent of ammoniated mercury. It was alleged to be misbranded in that the statement, "Ammoniated Mercury Ointment * * * U. S. P. This ointment contains 10% Ammoniated Mercury U. S. P.," borne on the label, was false and misleading, since it did not comply with the specifications for ammoniated mercury set forth in the pharmacopoeia and it contained less than 10 percent of ammoniated mercury.

On February 10, 1941, a plea of guilty was entered on behalf of the defendant and the court imposed a fine of \$50 and costs.

349. Adulteration and misbranding of aromatic spirits of ammonia and larkspur lotion. U. S. v. Royal Manufacturing Co. of Duquesne, Koloman Kovacs, Samuel S. Kovacs, and Martin Kovacs. Pleas of nolo contendere. Judgment of guilty. Total fines, \$400. Individual defendants placed on probation for 3 years. (F. D. C. No. 2078. Sample Nos. 77148-D, 77149-D.)

This case involved a shipment of a drug purporting to be aromatic spirits of ammonia but part of which was found to consist of larkspur lotion, and of a drug purporting to be larkspur lotion but a part of which was found to be spirits of ammonia.

On September 5, 1940, the United States attorney for the Western District of Pennsylvania filed an information against the Royal Manufacturing Co. of Duquesne, a corporation, Duquesne, Pa., and Koloman Kovacs, Samuel S. Kovacs, and Martin Kovacs, alleging shipment on or about October 11, 1939, from the State of Pennsylvania into the State of Virginia of quantities of spirits of ammonia and larkspur lotion which were adulterated and misbranded. The articles were labeled in part: "Powertay Spirits of Ammonia Aromatic [or

"Larkspur Lotion"] * * * Distributed by Powers-Taylor Drug Company, Richmond, Virginia."

The product purporting to be spirits of ammonia was alleged to be adulterated in that its strength differed from and its quality and purity fell below that which it purported or was represented to possess in that each of the bottles was represented to contain spirits of ammonia aromatic U. S. P.; whereas each of said bottles did not contain spirits of ammonia aromatic U. S. P. but a number of them did contain larkspur lotion. It was alleged to be adulterated further in that another substance, namely, larkspur lotion, had been substituted in part for spirits of ammonia aromatic U. S. P.

The product purporting to be spirits of ammonia was alleged to be misbranded in that the statements, "Spirit of Ammonia Aromatic U. S. P. Alcohol 65% By Vol. * * * An Agreeable stimulant and carminative preparation," borne on the label, were false and misleading in that they represented that the article consisted of aromatic spirits of ammonia which conformed to the requirements of the United States Pharmacopoeia, that it contained 65 percent of alcohol by volume and was an agreeable stimulant and carminative preparation; whereas it was not as represented in that the article in a number of bottles consisted of larkspur lotion, the larkspur lotion in the said bottles contained not more than 22.1 percent of alcohol by volume, and larkspur lotion is not an agreeable stimulant and carminative preparation. It was alleged to be misbranded further in that it consisted in part of larkspur lotion and was offered for sale under the name of another article, namely, "Spirits of Ammonia Aromatic U. S. P."

The product purporting to be larkspur lotion was alleged to be adulterated in that its strength differed from and its quality and purity fell below that which it purported and was represented to possess in that each bottle was represented to contain larkspur lotion; whereas a number of said bottles contained spirits of ammonia aromatic. It was alleged to be adulterated further in that another substance, namely, spirits of ammonia aromatic U. S. P. had been substituted in part for larkspur lotion.

The product purporting to be larkspur lotion was alleged to be misbranded in that the statement "Larkspur Lotion * * * Alcohol 20% by Vol.," borne on the bottle label, was false and misleading since it represented that the article consisted of larkspur lotion and contained 20 percent of alcohol by volume; whereas the article in a number of the bottles consisted of aromatic spirits of ammonia and the aromatic spirits of ammonia in the said bottles contained not less than 68.1 percent of alcohol. It was alleged to be misbranded further in that it consisted in part of aromatic spirits of ammonia and was offered for sale under the name of another article, namely, larkspur lotion.

On October 24, 1940, pleas of nolo contendere having been entered on behalf of each of the defendants, they were found guilty by the court. The corporation and each of the individual defendants were fined \$100 and one-fourth of the costs on count I, and the individual defendants were placed on probation for 3 years on the remaining three counts.

350. Adulteration of tincture of digitalis. U. S. v. Yates Drug & Chemical Co. Tried to the court. Judgment for the Government. Fine, \$500. (F. D. C. No. 940. Sample No. 68344-D.)

This product differed from the strength, quality, and purity set forth in the United States Pharmacopoeia for tincture of digitalis.

On July 30, 1940, the United States attorney for the Southern District of New York filed an information against the Yates Drug & Chemical Co., a corporation, New York, N. Y., alleging delivery for introduction in interstate commerce, namely, a delivery on or about September 18, 1939, for shipment from the State of New York into the State of New Jersey, of a quantity of tincture of digitalis that was adulterated.

The article was alleged to be adulterated in that its label bore the words "Tincture Digitalis U. S. P. XI," which purported and represented that it was a drug the name of which is recognized in an official compendium, namely, the United States Pharmacopoeia, eleventh edition, and that it was of the strength, quality, and purity of tincture of digitalis as set forth in said compendium; whereas its strength fell below the standard for strength of tincture of digitalis so set forth in this, that whereas the eleventh edition of the United States Pharmacopoeia states that the potency of tincture of digitalis shall be such that 1 cubic centimeter thereof shall possess an activity equivalent to not less than 1 and not more than 1.1 U. S. P. digitalis units, the potency of the article was such that 1 cubic centimeter possessed an activity equivalent to not more than 0.58 U. S. P.