On September 22, 1933, a plea of guilty to the information was entered on behalf of the defendant company, and the court imposed a fine of $20 and costs.

M. L. WILSON, *Acting Secretary of Agriculture.*

21592. Adulteration and misbranding of tincture of aconite root, fluidextract of ergot, and fluidextract of belladonna leaves. U. S. v. Standard Pharmaceutical Corporation. Plea of guilty. Fine, $40 and costs. (F. & D. no. 28167. I.S. nos. 39503, 46101. 46102, 46104.)

This case was based on interstate shipments of tincture of aconite root, fluidextract of ergot, and fluidextract of belladonna leaves, which were represented to be pharmacopoeial products but which fell below the standard laid down in the United States Pharmacopoeia for such products.

On September 20, 1933, the United States attorney for the District of Maryland, acting upon a report by the Secretary of Agriculture, filed in the district court an information against the Standard Pharmaceutical Corporation, Baltimore, Md., alleging shipment by said company in violation of the Food and Drugs Act, on or about October 28, November 20, and November 30, 1931, from the State of Maryland into the State of Georgia, of quantities of fluidextract of belladonna leaves, tincture of aconite root, and fluidextract of ergot, and on or about February 9, 1932, from the State of Maryland into the District of Columbia, of a quantity of tincture of aconite root, which products were adulterated and misbranded. The articles were labeled in part: "Tincture Aconite Root (Tinctura Aconiti) U.S.P."; Fluidextract Ergot (Fluidextractum Ergotae) U.S.P. Physiologically Tested"; "Fluidextract Belladonna Leaves (Atropi Belladonna) * * * One hundred mils contains 0.3 gm. Alkaloids. * * * Standard Pharmaceutical Corp. Baltimore, Md."

Analyses of samples of the articles by this Department showed that the tincture of aconite root possessed approximately one-third the potency required by the United States Pharmacopoeia, that the fluidextract of ergot was less than one-third as potent as required by the pharmacopoeia; and that the fluidextract of belladonna leaves contained 8 percent more alkaloid than the maximum permitted by the pharmacopoeia.

It was alleged in the information that the articles were adulterated in that they were sold under names recognized in the United States Pharmacopoeia and differed from the standard of strength, quality, and purity as determined by the tests laid down in the said pharmacopoeia in the following respects, and their own standard of strength, quality, and purity were not declared on the container:

The tincture of aconite root, when administered subcutaneously to guinea pigs, had a minimum lethal dose of more than 0.00045 cubic centimeter for each gram of body weight of guinea pig (the two lots requiring 0.0017 cubic centimeter and 0.0013 cubic centimeter, respectively, per gram of guinea pig for a lethal dose), whereas the pharmacopoeia required that tincture of aconite root, when administered subcutaneously to guinea pigs, shall have a minimum lethal dose of not more than 0.00045 cubic centimeter for each gram of body weight of guinea pig;

The fluidextract of ergot, when administered by intramuscular injection to single-comb white Leghorn cocks required more than 0.5 cubic centimeter for each kilogram of body weight of cock to produce a darkening of the comb corresponding in intensity to that caused by the same dose of the standard fluidextract of ergot, whereas the pharmacopoeia provides that fluidextract of ergot, when administered by intramuscular injection to a single-comb white Leghorn cock in doses not exceeding 0.5 cubic centimeter for each kilogram of body weight of cock, shall produce a darkening of the comb corresponding in intensity to that caused by the same dose of the standard fluidextract of ergot;

The fluidextract of belladonna leaves yielded not less than 0.356 gram of the total alkaloids of belladonna leaves per 100 cubic centimeters, whereas the pharmacopoeia provides that fluidextract of belladonna leaves shall yield not more than 0.33 gram of the total alkaloids of belladonna leaves per 100 cubic centimeters. Adulteration was alleged for the further reason that the strength and purity of the articles fell below the professed standard and quality under which they were sold.

Misbranding was alleged for the reason that the statements appearing on the labels of the respective products, "Tincture Aconite Root (Tinctura Aconiti)

U.S.P.", "Fluidextract Ergot * * * U.S.P. Physiologically Tested", "Fluidextract Belladonna leaves * * * One hundred mils. contains 0.3 gm. alkaloids", were false and misleading, since the said statements represented that the tincture of aconite root and the fluidextract of ergot conformed to the standard prescribed in the United States Pharmacopoeia, and that the fluidextract of belladonna leaves contained 0.3 gram of alkaloids in each 100 mils, whereas the said tincture of aconite root and the fluidextract of ergot did not conform to the standard prescribed in the United States Pharmacopoeia, and the fluidextract of belladonna leaves contained more than 0.3 gram of the alkaloids, namely, not less than 0.356 gram of alkaloids per 100 mils.

On September 22, 1933, a plea of guilty to the information was entered on behalf of the defendant company, and the court imposed a fine of $40 and costs.

M. L. WILSON, *Acting Secretary of Agriculture.*

21593. Misbranding of Minwater Crystals. U. S. v. 40 Boxes, et al., of Minwater Crystals. Default decrees of condemnation, forfeiture, and destruction. (F. & D. nos. 30426, 30459, 30460, S. nos. 35814–A, 35815–A, 35851–A, 35853–A, 35882–A, 36687–A, 36688–A, 36689–A.)

Examination of the drug product, Minwater Crystals, disclosed that it contained no ingredient or combination of ingredients capable of producing certain curative and therapeutic effects claimed on the carton label and in the circulars shipped with the article.

On May 17, 1933, the United States attorney for the Western District of Missouri, acting upon a report by the Secretary of Agriculture, filed in the district court a libel praying seizure and condemnation of 215 packages of Minwater Crystals at Kansas City, Mo. On June 3, 1933, the United States attorney for the Western District of Oklahoma filed libels against 184 boxes of Minwater Crystals at Oklahoma City, Okla. It was alleged in the libels that the article had been shipped in interstate commerce by the Minwater Crystal Co. in various shipments on or about October 17, 1932, and April 11, 1933, from Dallas, Tex., and on or about December 7, 1932, and February 10, 1933, from Mineral Wells, Tex., and that it was misbranded in violation of the Food and Drugs Act as amended.

Analysis of a sample of the article by this Department showed that it consisted essentially of anhydrous sodium sulphate, with small proportions of sodium carbonate and sodium chloride.

The libels charged that the article was misbranded in that the following statements appearing in the labeling, regarding the curative and therapeutic effects of the article, were false and fraudulent: (Carton) "* * * Keeps You Healthy * * *", (circular) "Nature's Way To Health—Course of Treatment—Obtain quick relief by thoroughly flushing the system. Gradually reduce the dosage until about the tenth day, after which normal strength of the natural mineral water is usually sufficient to maintain a normal, healthy condition of the system. Detailed treatment follows: * * * Specific Treatment For Common Ills, * * * and auto-Intoxication—Take one level teaspoonful of Minwater Mineral Wells Crystals in a large glass of warm water thirty minutes before breakfast. Repeat daily until elimination is regulated * * * High Blood Pressure, Nervous Ailments, or Excess Acidity—Dissolve eight level teaspoonfuls of Minwater Mineral Wells Crystals in a gallon of water and drink eight to twelve glasses daily, between meals. Do not drink with, or immediately after meals. Rheumatism (including Neuritis, Arthritis, and other forms)—Take one level teaspoonful of Minwater Mineral Wells Crystals in a large glass of warm water thirty minutes before each meal and again at retiring. Three or four free evacuations daily should result. Observe a proper diet, with very little meat, and drink water freely. Diabetes, Stomach, Bladder and Kidney Ailments—Dissolve eight level teaspoonfuls of Minwater Mineral Wells Crystals in a gallon of water and drink from eight to twelve glasses daily, according to the effect on the bowels and kidneys. Observe proper diet. The Morning After—Avoid that quivering stomach, headache and heavy heart the morning after indiscretions. Take two level teaspoonfuls of Minwater Mineral Wells Crystals in a large glass of hot water immediately upon arising. Notice the difference: Over-weight—Regain and keep that youthful figure. Minwater Mineral Wells Crystals Are recommended for removing excess weight and maintaining a youthful figure. Use regularly in the form of drinking water at the rate of one ounce to one gallon, drinking eight to twelve glasses daily."