ounce 456 grs. Burdock Root", borne on the label, were false and misleading in that the statements represented that the article was fluidextract of burdock root which conformed to the standard laid down in the National Formulary, and that each mil of the article represented one gram, or each fluid ounce 456 grains, of burdock root, whereas the article did not conform to the tests laid down in the National Formulary, and the article contained little, if any, burdock root.

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 $10 and costs.

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

21591. Adulteration and misbranding of tincture belladonna and ointment of mercuric nitrate. U. S. v. Standard Pharmaceutical Corporation. Plea of guilty. Fine, $20 and costs. (F. & D. no. 29365. Sample nos. 8792–A, 8817–A.)

This case was based on an interstate shipment of tincture of belladonna represented to be of pharmacopoeial standard, which was found to contain alkaloids of belladonna leaves in excess of the maximum prescribed in the United States Pharmacopoeia for tincture belladonna; also of a shipment of ointment of mercuric nitrate, represented to be of National Formulary standard, but which was found to contain less mercuric nitrate than prescribed in the National Formulary for ointment of mercuric nitrate.

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 April 6, 1932, from the State of Maryland into the District of Columbia, of a quantity of tincture of belladonna, and on or about May 27, 1932, from the State of Maryland into the State of Pennsylvania, of a quantity of ointment of mercuric nitrate, which products were adulterated and misbranded. The articles were labeled in part: "Tincture Belladonna (Tinctura Belladonnae) U.S.P. * * * Standard:—0.027 gm. to 0.033 gm. Alkaloids in 100 mils.", "Ointment of Mercuric Nitrate (Ung. Hydrarg. Nit. N.F. (U.S.P. IX) Citrine Ointment * * * Standard Pharmaceutical Corp. Baltimore, Md."

Adulteration of the tincture of belladonna was alleged in the information for the reason that the article was sold under a name recognized in the United States Pharmacopoeia, and differed from the standard of strength, quality, and purity as determined by the test laid down in the said pharmacopoeia official at the time of investigation, since it yielded not less than 0.03657 gram of the alkaloids of belladonna leaves per 100 cubic centimeters, whereas the pharmacopoeia provides that tincture of belladonna shall yield not more than 0.033 gram of the alkaloids of belladonna leaves per 100 cubic centimeters and the standard of strength, quality, and purity of the article was not declared on the container. Adulteration of the ointment of mercuric nitrate was alleged for the reason that it was sold under a name recognized in the National Formulary and differed from the standard of strength, quality, and purity as determined by the tests laid down in the said formulary official at the time of investigation in that it contained less than 7 percent of mercury, namely, not more than 5.13 percent of mercury, whereas the Formulary provides that ointment of mercuric nitrate shall contain not less than 7 percent of mercury, and the standard of strength, quality, and purity of the article was not declared on the container. Adulteration was alleged with respect to both products for the further reason that they fell below the professed standard and quality under which they were sold.

Misbranding was alleged for the reason that the statements, "Tincture Belladonna * * * U.S.P. * * * Standard 0.027 gm. to 0.033 gm. Alkaloids in 100 mils" and "Ointment of Mercuric Nitrate * * * N.F.", borne on the labels of the respective articles, were false and misleading in that the said statements represented that the tincture of belladonna conformed to the standard laid down in the United States Pharmacopoeia and contained not more than 0.033 gram of alkaloids, and that the ointment of mercuric nitrate conformed to the National Formulary, whereas the former was not of pharmacopoeial standard, each 100 mils containing more than 0.033 gram of alkaloids, and the latter did not conform to the tests laid down in the National Formulary.

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)