

The article was alleged to be misbranded in that the statement appearing in the circular, "These powders contain no Antipyrine, Phenacetine, Chloral Hydrate, Cocaine, Morphia, or other narcotics", was false and misleading since it created the impression that the article contained no ingredient closely related to and having the physiological effects similar to phenacetin; whereas it contained acetanilid, which chemically is closely related to and has the physiological effects of phenacetin. It was alleged to be misbranded further in that the following statements appearing in the circular were false and misleading in that they would mislead the purchaser into the belief that the article was a safe and appropriate medicine for the treatment of neuralgia, toothache, colds, grippe, etc.; whereas it was not a safe and appropriate treatment, but was dangerous when used as directed: "Put a powder on the tongue and take a swallow of water. A second dose, if required, may be taken in fifteen, twenty or thirty minutes after the first; then at intervals of 4 to 6 hours if necessary to allay fever. * * * Children 5 to 10 years of age may be given one-fourth powder; 10 to 15 years, one-half powder; a second dose in 30 minutes if necessary, then every 6 hours. Neuralgia, Tooth-Ache, Colds, Grippe &c., Headache from malaria, (fever and ague) and neuralgia or tooth ache, should have medium doses of quinine with a Headache powder every four to six hours." The article was alleged to be misbranded further in that certain statements on the carton and in the accompanying circular falsely and fraudulently represented that it was effective in the treatment of sick and nervous headache, toothache, grippe, neuralgia, colds, etc., and headache from malaria (fever and ague).

On December 21, 1936, no claimant having appeared, judgment of condemnation was entered and it was ordered that the product be destroyed.

HARRY L. BROWN, *Acting Secretary of Agriculture.*

26980. Adulteration and misbranding of Supreme Gauze Bandage. U. S. v. 5 Gross Packages of Supreme Gauze Bandage. Default decree of condemnation and destruction. (F. & D. no. 88486. Sample no. 8968-C.)

This product was represented on the label to be sterile when it was not sterile, but contained viable micro-organisms.

On November 5, 1936, the United States attorney for the District of New Jersey, acting upon a report by the Secretary of Agriculture, filed in the district court a libel praying seizure and condemnation of 5 gross packages of Supreme Gauze Bandage at Newark, N. J., alleging that the article had been shipped in interstate commerce on or about August 11, 1936, by Supreme First Aid Co., from New York, N. Y., and that it was adulterated and misbranded in violation of the Food and Drugs Act.

It was alleged to be adulterated in that its purity fell below the professed standard or quality under which it was sold, namely, "Sterilized", when it was not sterile, but did contain viable micro-organisms.

The article was alleged to be misbranded in that the statement, appearing on the label, "Supreme Sterilized Gauze Bandages * * * Is Scientifically Prepared for Surgical Use", was false and misleading when applied to a bandage that was not sterile.

On December 21, 1936, no claimant having appeared, judgment of condemnation was entered and it was ordered that the product be destroyed.

HARRY L. BROWN, *Acting Secretary of Agriculture.*

26981. Adulteration and misbranding of Pituitary Extract, Lederle. U. S. v. Lederle Laboratories, Inc. Plea of guilty. Fine, \$100. (F. & D. no. 88049. Sample no. 72408-B.)

The potency of this product was only two-thirds of that required by the United States Pharmacopoeia, and only one-third of that claimed on the label.

On December 10, 1936, the United States attorney for the Southern District of New York, acting upon a report by the Secretary of Agriculture, filed in the district court an information against Lederle Laboratories, Inc., New York, N. Y., charging shipment by said corporation in violation of the Food and Drugs Act, on or about May 6, 1936, from the State of New York into the State of New Jersey of a quantity of an article contained in ampoules and labeled "Pituitary Extract, Lederle twice the strength of Liquor Pituitarii U. S. P. X 20 International Units per cc", which was adulterated and misbranded.

The article was alleged to be adulterated in that it was sold under and by a name recognized in the United States Pharmacopoeia, and differed from

its standard of strength, quality, and purity as determined by the test laid down in said pharmacopoeia in that 1 cubic centimeter of the solution had an activity upon the isolated uterus of the virgin guinea pig corresponding to less than 80 percent of that produced by 0.005 gram of standard powdered pituitary; whereas said pharmacopoeia provided that 1 cubic centimeter of solution of pituitary should have an activity upon the isolated uterus of the virgin guinea pig corresponding to not less than 80 percent of that produced by 0.005 gram of standard powdered pituitary; and the standard of strength, quality, and purity of the article was not declared on the container thereof. Said article was alleged to be adulterated further in that its strength and purity fell below the professed standard and quality under which it was sold in that it was represented to be pituitary extract that conformed to the standard laid down in the United States Pharmacopoeia, it was represented to have twice the strength of liquor pituitarii prescribed by the United States Pharmacopoeia, it was represented to contain 20 international units per cubic centimeter, it was represented to be a double strength solution; 1 cubic centimeter of the article was represented to contain 20 units, it was represented to be pituitary extract that contained quantitatively all the known physiologically active constituents of the perfectly fresh posterior lobe of the pituitary, it was represented to be physiologically standardized by the isolated uterus method and its potency adjusted so that each cubic centimeter of the article contained 20 units; whereas in fact the article was not pituitary extract which conformed to the standard laid down in the United States Pharmacopoeia; it did not have twice the strength of the liquor pituitarii prescribed by the United States Pharmacopoeia; it did not contain 20 international units per cubic centimeter, it was not double strength solution, 1 cubic centimeter of the article did not contain 20 units, it was not pituitary extract that contained quantitatively all the known physiologically active constituents of the perfectly fresh posterior lobe of the pituitary, it was not physiologically standardized by the isolated uterus method, and its potency was not adjusted so that 1 cubic centimeter contained 20 units.

The article was alleged to be misbranded in that the statements, "Twice the strength of Liquor Pituitarii U. S. P. X 20 International Units per cc. This double strength solution * * *", borne on the box containing the ampoules, the statement, "1 cc. * * * Pituitary Extract * * * 20 Units * * * Twice the strength of Liquor Pituitarii U. S. P. X 20 International Units per cc.", borne on the cartons enclosing the ampoules, and the statement, "Pituitary Extract * * * containing quantitatively all the known physiologically active constituents of the perfectly fresh posterior lobe of the pituitary. * * * physiologically standardized by the isolated uterus method and its potency adjusted as follows: * * * 1 cc to contain 20 units", contained in a circular enclosed in the box containing the ampoules of the article, were false and misleading in that they represented that it was pituitary extract that conformed to the standard laid down in the United States Pharmacopoeia; that it had twice the strength of liquor pituitarii prescribed by the United States Pharmacopoeia; that it contained 20 international units per cubic centimeter; that it was double strength solution; that 1 cubic centimeter of the article contained 20 units; that it was pituitary extract that contained quantitatively all the known physiologically active constituents of the perfectly fresh posterior lobe of the pituitary; that it had been physiologically standardized by the isolated uterus method and its potency adjusted so that 1 cubic centimeter contained 20 units; whereas in fact it was not pituitary extract which conformed to the standard laid down in the United States Pharmacopoeia, it did not have twice the strength of liquor pituitarii prescribed by the United States Pharmacopoeia, it did not contain 20 international units per cubic centimeter; it was not a double strength solution, 1 cubic centimeter of the article did not contain 20 units, it was not pituitary extract which contained quantitatively all the known physiologically active constituents of the perfectly fresh posterior lobe of the pituitary, it was not physiologically standardized by the isolated uterus method, and its potency was not adjusted so that each cubic centimeter contained 20 units.

On December 21, 1936, a plea of guilty was entered on behalf of the defendant corporation and the court imposed a fine of \$100.

HARRY L. BROWN, *Acting Secretary of Agriculture.*