The Gall Stone Remedy and System Cleanser was alleged to be misbranded in that its labeling bore false and fraudulent curative and therapeutic representations that its use in the treatment of gallstone and stomach trouble generally would afford a degree of relief without pain and would render an operation for relief therefrom unnecessary; that it was a remedy for gallstone, stomach trouble, indigestion, fainting spells, liver troubles, colic attacks, yellow jaundice, gas in the stomach, dizziness and appendicitis; that it was a cleanser of the system and capable of draining all the congestions of the alimentary tract without pain and with a soothing and healing effect; that it was a successful medical treatment for gallstones and the only such treatment; that it was capable of expelling hardened accumulations incident to gallstone without pain; and that by use of it an operation for the removal of gallstone could be avoided.

On May 20, 1938, a plea of guilty having been entered by the defendant, the court imposed a fine of $200.

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

29269. Misbranding of Butler's Cod Liver Oil Ointment. U. S. v. 1,313 Sample Packages, 1,327 1-Ounce Packages, and 136 5-Ounce Packages of Butler's Cod Liver Oil Ointment. Default decree of condemnation and destruction. (F. & D. No. 40987. Sample No. 47276–C.)

The labeling of this product bore false and fraudulent curative and therapeutic claims.

On December 15, 1937, the United States attorney for the Eastern District of Tennessee, acting upon a report by the Secretary of Agriculture, filed in the district court a libel praying seizure and condemnation of 2,776 packages of Butler's Cod Liver Oil Ointment at Chattanooga, Tenn.; alleging that the article had been shipped in interstate commerce on various dates between May 22, 1936, and July 13, 1937, from Cleveland, Ohio, by Strong, Cobb & Co., Inc.; and charging misbranding in violation of the Food and Drugs Act as amended. The article was labeled in part: "Anedemin Chemical Company."

Analysis of a sample of the article showed that it consisted essentially of petrolatum and a fish oil.

The article was alleged to be misbranded in that the labels on the tubes of all sizes bore the following statements regarding its therapeutic and curative effects, which were false and fraudulent: "Of value in the treatment of burns, wounds, * * * cuts * * * ulcers, etc."; and in that the cartons and circulars shipped with the 1-ounce size bore, among others, false and fraudulent representations that it was effective in the treatment of blood poisoning, surgical incisions, various skin affections, acne, fistula, that it was effective in alleviating pain, reducing fever, controlling secondary infection, cleansing the wound and stimulating epithelization, and that it was effective to accelerate healing and with practically no scar.

On May 3, 1938, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

M. L. WILSON, Acting Secretary of Agriculture.

29270. Misbranding of Saxon Blackberry Cordial Compound. U. S. v. 147 Packages of Saxon Blackberry Cordial Compound. Default decree of condemnation and destruction. (F. & D. No. 42163. Sample No. 12425–D.)

The labeling of this product bore false and fraudulent curative and therapeutic claims.

On April 11, 1938, the United States attorney for the Eastern District of New York, acting upon a report by the Secretary of Agriculture, filed in the district court a libel praying seizure and condemnation of 147 packages of the above-named drug product at Brooklyn, N. Y.; alleging that the article had been shipped in interstate commerce on or about May 12, 1937, and February 19, 1938, from Duquesne, Pa., by Royal Manufacturing Co. of Duquesne; and charging misbranding in violation of the Food and Drugs Act as amended. The article was labeled in part: (Carton) "The Saxon Company Duquesne, Pa."; (bottle) "The Saxon Company Cleveland"; (bottle and wrapper) "For Diarrhoea, Summer Complaint, Cholera Morbus, Cramps, Colic and similar complaints. * * * In severe cases it can be taken every hour. After the condition has been relieved, a dose after each meal for a day or two should be taken."

Analysis showed that it consisted essentially of water, sugar, glycerin, and alcohol with small proportions of salicylic acid and extracts of plant materials including ginger.

The article was alleged to be misbranded in that the statements appearing on the labels regarding its curative and therapeutic effects were false and fraudulent.

On May 17, 1938, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

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

29271. Adulteration and misbranding of pituitary extract obstetrical. U. S. v. Sharp & Dohme, Inc. Plea of not guilty. Tried to the court. Judgment of guilty. Fine, $50. (F. & D. No. 38646. Sample No. 8122–C.)

This product when assayed in accordance with the test laid down in the United States Pharmacopoeia was found to possess a potency materially in excess of—in some instances, double—the potency prescribed by the pharmacopoeia for pituitary extract obstetrical.

On May 14, 1937, the United States attorney for the Eastern District of Pennsylvania, acting upon a report by the Secretary of Agriculture, filed in the district court an information against Sharp & Dohme, Inc., trading at Philadelphia, Pa., alleging shipment by said defendant in violation of the Food and Drugs Act on or about November 14, 1935, from the State of Pennsylvania into the State of New Jersey of a quantity of pituitary extract obstetrical which was adulterated and misbranded. The article was labeled in part: "Sharp & Dohme Philadelphia—Baltimore."

The adulteration and misbranding charges appear in the court's opinion included herein.

On January 3, 1938, a plea of not guilty having been entered by the defendant, the case came on for trial before the court without a jury. The trial was continued from time to time and was concluded on June 17, 1938. On June 23, 1938, the court adjudged the defendant guilty and handed down the following opinion:

(MARIS, *Judge*): "This is a criminal prosecution begun by information charging the defendant with violation of the Food and Drugs Act. The first count charged the introduction in interstate commerce of a drug labeled in part, 'Pituitary Extract Obstetrical (10 International Units)' that was adulterated in that it was sold under and by a name recognized in the United States Pharmacopoeia and differed from the standard of strength as determined by the test laid down in the pharmacopoeia in that the drug possessed a potency of twice its labeled strength. The second count charged the misbranding of the same drug in that the labeled statement, above-quoted, was false and misleading when applied to a drug possessing twice its labeled strength. A jury trial was waived by the parties. It was agreed that the drug seized by the Government had been introduced in interstate commerce by the defendant and the sole question raised at the trial was whether it possessed a potency in excess of its labeled strength.

"The test laid down by the pharmacopoeia for assaying pituitary extract involved a comparison of the reaction to given quantities of standard pituitary powder and of the pituitary extract sought to be assayed of living muscle taken from the uterus of a virgin guinea pig and suspended in a nutrient solution. Such a biological assay is of course not nearly so exact in its results as a chemical analysis, since it depends for its success largely upon the character of the individual muscle used. However, while many of the individual tests prove inconclusive and unsatisfactory, it is nevertheless a fact that tests which are satisfactory are regularly obtained and may be readily identified as such. Such tests have been found in practice to give accurate results within a limit of 20 percent, plus or minus, and the procedure has been adopted as standard for testing this drug and it has been followed in practice for many years. The accuracy of this procedure was confirmed by a series of joint assays made with my approval of another specimen of defendant's product in the laboratories of the defendant and of the Food and Drug Administration at Washington.

"The pituitary extract here in question was labeled as having a strength of 10 international units per cubic centimeter. This is the equivalent of 100 percent of standard. The extract which was seized by the Government was subjected to 15 assays by the Food and Drug Administration which showed an average strength of 186 percent of standard, the individual assays running from 166 percent to 220 percent. A portion of the seized drug which was submitted by the Government to the defendant and subjected by it to four assays in its own laboratory showed results of 142 percent, 130 percent, 132 percent, and 130 percent of standard, an average of 133.5 percent.