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.

"As I have said, the prescribed test is generally considered valid within limits of 20 percent, plus or minus, and is so described in the pharmacopoeia. Pituitary extract assayed as not more than 120 percent of standard would accordingly be within allowable limits for extract stated to have a strength of 10 international units. The evidence of both the Government and the defendant in this case, however, as I have indicated, shows beyond doubt that the defendant's product here involved was substantially overstrength and far beyond the limits laid down in the pharmacopoeia. The conclusion is inescapable that the defendant is guilty of violating the Food and Drugs Act.

"In reaching this conclusion I have not overlooked the evidence of assays made by the defendant of samples taken at the time of manufacture from the batch of extract from which the product here in question is said to have been taken. I feel, however, the evidence of identity of the product assayed with that here involved is not sufficiently definite to overcome the direct evidence of the results of the later assays made upon the particular product involved in this prosecution. Nor do I think the evidence excludes the possibility that the product of which the Government complains was in fact surgical pituitary extract of the strength of 20 international units, which the defendant admittedly was manufacturing at about the same time and which may have been labeled '10 International Units' by mistake.

"Upon full consideration of all the evidence, I find the defendant guilty as charged in both counts of the information."

On June 29, 1938, a fine of $25 was imposed on each of the two counts of the information.

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

29272. Misbranding of Dexene. U. S. v. Sanovapor Laboratories, Inc., Gordon A. Guthrie, and Ethelbert Kennedy Walker. Plea of guilty by Gordon A. Guthrie. Fine, $50. Nolle prosequi entered as to remaining defendants. (F. & D. No. 37036. Sample No. 49135–B.)

The labeling of this product bore a device and representations regarding its curative and therapeutic effects that were false and fraudulent.

On June 18, 1936, the United States attorney for the Southern District of West Virginia, acting upon a report by the Secretary of Agriculture, filed in the district court an information against the Sanovapor Laboratories, Inc., Huntington, W. Va., Gordon A. Guthrie, and Ethelbert Kennedy Walker, alleging shipment by said defendants in violation of the Food and Drugs Act as amended, on or about September 6, 1935, from the State of West Virginia into the State of Kansas, of a quantity of Dexene that was misbranded. On July 14, 1937, an amended information was filed. The article was labeled in part: "Dexene * * * Prepared by the Sanovapor Laboratories, Inc. Laboratories Huntington, W. Va. Akron, Ohio."

Analysis of the product showed that it consisted of a yellow aqueous solution containing 0.24 percent of sulphur dioxide.

The amended information alleged that the word "Dexene," borne on the bottles and on the carton, was a device regarding the curative and therapeutic effect of the article in that the word "Dexene" meant to purchasers that it was a remedy for diabetes, the word having attained such meaning through long existing general knowledge, the result of the following facts:

1. An application that the word "Dexene" be designated as a trade mark for a remedy for diabetes was duly filed in the United States Patent Office on April 29, 1931, under serial No. 313976 and said name "Dexene" was registered in accordance therewith on September 1, 1931, as a trade name for "A preparation Used In The Treatment of Diabetes."

2. That subsequent to the registration of the word "Dexene" and on September 1, 1931, the article was marked and branded as was the shipment involved in this case, and there was enclosed in the cartons containing the bottles a circular or booklet describing the product Dexene as a treatment, remedy, and cure for the disease diabetes, which booklet was shipped from time to time in interstate commerce, so that prospective purchasers and the public in general acquired general knowledge that the product Dexene was offered as a treatment, remedy, or cure for diabetes—although said booklet was not contained in the carton in which the article or drugs involved in this case was enclosed—the said booklet containing the following statements as to the curative and therapeutic value of the article: "The medicinal or therapeutic value of Dexene in Diabetes Mellitus will be readily understood by those affected with the disease, and particularly by the profession who will view with interest the