United States Department of Agriculture

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FOOD AND DRUGS ACT

[Given pursuant to section 4 of the Food and Drugs Act]

22951–23000

[Approved by the Acting Secretary of Agriculture, Washington, D. C., March 19, 1935]

22951. Alleged adulteration and misbranding of fluidextract of ergot. U. S. v. 35 Bottles and 59 Bottles of Fluidextract Ergot. Tried to the court. Judgment for claimant. Libels dismissed. (F. & D. nos. 26144, 26508. I. S. nos. 12866, 22130. S. nos. 4468, 4638.)

On March 30 and June 23, 1931, the United States attorney for the Northern District of California, acting upon reports by the Secretary of Agriculture, filed in the district court libels praying seizure and condemnation of thirty-five 4-ounce bottles and fifty-nine 1-pint bottles of fluidextract of ergot at San Francisco, Calif., consigned by Parke Davis & Co., Detroit, Mich., alleging that the article had been shipped in interstate commerce from Detroit, Mich., in part on or about December 18, 1930, and in part on or about January 9, 1931, and charging adulteration and misbranding in violation of the Food and Drugs Act.

It was alleged in the libels that the article was adulterated in that it was sold under a name recognized in the United States Pharmacopoeia, and differed from the standard of strength as determined by the test laid down in the said pharmacopoeia.

Misbranding was alleged for the reason that the statements on the label, "Fluid Extract Ergot, U.S.P. * * * Standard (By Physiological Assay)", were false and misleading.

Parke Davis & Co. appeared as claimant and filed answers denying the adulteration and misbranding charges. On March 6, 1934, a jury having been waived and the two libels having been consolidated into one cause of action, the case came on for trial before the court.

On March 9, 1934, the court having heard the evidence and arguments of counsel, entered judgment for the claimant and on July 12, 1934, the libels were ordered dismissed.

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

22952. Alleged adulteration and misbranding of pituitary extract. U. S. v. Eli Lilly & Co. Tried to the court. Judgment of not guilty. (F. & D. no. 29415. I. S. nos. 25277, 25862.)

This case was based on interstate shipments of pituitary extract which was alleged to have an activity greatly in excess of the maximum produced by pituitary extract prepared as directed by the United States Pharmacopoeia.

On July 29, 1933, the United States attorney for the Southern District of Indiana, acting upon a report by the Secretary of Agriculture, filed in the district court an information against Eli Lilly & Co., a corporation, Indianapolis, Ind., alleging shipment by said company in violation of the Food and Drugs Act, on or about December 12, 1930, from the State of Indiana into the State of Illinois, and on or about May 13, 1931, from the State of Indiana into the State of Minnesota of quantities of pituitary extract. The article was labeled in part: "Lilly's Pituitary Extract * * * U. S. P. Strength Eli Lilly and Co. Indianapolis, Ind."

It was alleged in the information that the article was adulterated in that it 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 tests laid down in the said pharmacopoeia official at the time of investigation of the article, in that said pharmacopoeia provides that solution of pituitary contain the water-soluble principle or principles from the fresh posterior lobe of the pituitary body of cattle, 1 cc having an activity upon the isolated uterus of the virgin guinea pig, corresponding to not less than 80 percent and not more than 120 percent of that produced by 0.005 g of the standard powdered pituitary prepared as directed; whereas 1 cc of said article possessed an activity upon the isolated uterus of the virgin guinea pig, corresponding (in the sample taken from the first shipment) to 266 percent and (in the sample taken from the second shipment) to 220 percent of that produced by 0.005 g of the standard powdered pituitary prepared as directed by said United States Pharmacopoeia; and the standard of strength, quality, and purity of the said article was not declared on the container thereof.

Adulteration was alleged for the further reason that the strength and purity of the article 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, whereas it was not pituitary extract that conformed to said standard.

Misbranding was alleged for the reason that the following statements appearing in the labeling were false and misleading: (Box and individual ampoule carton) "Pituitary Extract * * * U. S. P. Strength A * * * Standardized Solution of the Active Principle of the Posterior Lobe of Pituitary Glands"; (ampoule) "Pituitary Ext. * * * U. S. P. Strength"; (circular) "The physician in prescribing Lilly's Pituitary Extract, can be assured of obtaining an extract * * * uniform in strength."

On August 19, 1933, the defendant was arraigned and a plea of not guilty was entered. On June 8, 1934, a jury having been waived and the case having come on for trial before the court, the defendant was found not guilty.

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

22953. Adulteration and misbranding of tincture of aconite, cinchophen tablets, aromatic spirits of ammonia, and mineral oil. U. S. v. Gibson-Howell Co., Inc. Plea of guilty. Fine, $600. (F. & D. no. 30316. Sample nos. 10221-A, 10225-A, 21655-A, 21657-A, 21671-A, 31656-A.)

This case was based on interstate shipments of tincture of aconite, aromatic spirits of ammonia, and alleged heavy mineral oil, which differed from the standard established by the United States Pharmacopoeia, and of a shipment of cinchophen tablets which contained less cinchophen than declared on the label. The mineral oil was falsely branded as to the name of the manufacturer and place of manufacture.

On April 6, 1934, the United States attorney for the District of New Jersey, acting upon a report by the Secretary of Agriculture, filed in the district court an information against the Gibson-Howell Co., Inc., a corporation, Jersey City, N. J., alleging shipment by said company, in violation of the Food and Drugs Act, between the dates of January 14 and March 24, 1933, from the State of New Jersey into the State of New York, of quantities of tincture of aconite, cinchophen tablets, aromatic spirits of ammonia, and mineral oil which were adulterated and misbranded. The articles were labeled, variously: "Tincture of Aconite U. S. P. * * * Prepared for Whelan Drug Company, Inc., New York"; "Cinchophen (Phenylcinchoninic acid) * * * 7½ gr. * * * Distributed by Whelan Laboratories, Inc., New York"; "Honor Pycchoe Macho * * * Imported Russian Mineral Oil * * * Honor Research Laboratories, New York * * * Heavy Genuine Imported"; "Aromatic Spirits Ammonia U. S. P. * * * Distributed By Whelan Laboratories, Inc., New York."

It was alleged in the information that the tincture of aconite, aromatic spirits ammonia, and mineral oil 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 official at the time of investigation, in the following respects:

The tincture of aconite, when administered subcutaneously to guinea pigs had a minimum lethal dose of not less than 0.0015 cc for each gram of body weight of guinea pig, whereas the pharmacopoeia provides that tincture of aconite shall have a minimum lethal dose of not more than 0.00045 cc for each gram of body weight of guinea pig; the aromatic spirits amonia contained less than 90 cc of ammonia water per 1,000 cc, samples from the two shipments