31114. Adulteration and misbranding of tartaric acid. U. S. v. American Cyanamid & Chemical Corporation. Judgment of guilty. Fine, $1. (F. & D. No. 42737. Sample No. 41668–E.)

The product involved in this action consisted of tartar emetic which had been shipped in response to an order for tartaric acid and which had been invoiced as tartaric acid.

On February 13, 1940, the United States attorney for the Eastern District of New York filed an information against the American Cyanamid & Chemical Corporation, having a place of business at Brooklyn, N. Y., alleging shipment in violation of the Food and Drugs Act on or about October 20, 1938, from the State of New York into the State of Pennsylvania of a quantity of a product invoiced as tartaric acid which was adulterated and misbranded. The article was labeled in part: (Reverse of tag) "Tartaric Acid U. S. P. Powdered"; (stenciled on container) "Tartar Emetic."

It was alleged to be adulterated in that its strength and purity fell below the professed standard or quality under which it was sold, since it was invoiced as "Tartaric Acid U. S. P.," a nonpoisonous substance; whereas it consisted of tartar emetic, a poisonous substance. It was alleged to be misbranded in that it consisted of tartar emetic, a poisonous substance, and was offered for sale and sold under the name of another article, namely, "Tartaric Acid U. S. P.," a nonpoisonous substance.

On March 25, 1940, the case having been submitted to the court without a jury on an agreed statement of facts, the court entered the following judgment:

INCH, *Judge*. "The criminal information herein for violation of the Food and Drug Act was duly filed February 13, 1940. At the trial the Government and defendant agreed on the facts. These have been duly stipulated and submitted in evidence. The only question remaining is one of law. It is clear that, at the most, this was merely a technical violation. It is agreed that it was due solely to the error of one of the shipping clerks in the employ of the defendant. Inasmuch as the defendant is responsible for the action of such clerk and the question of intention to violate the law is immaterial, and not an element of the offense, there seems to be no doubt but that a violation took place but it was one for which liability results solely because of the above plain and unusual mistake. I accordingly find the defendant guilty, but impose a nominal fine of $1.00."

31115. Adulteration and misbranding of solution of ephedrine sulfate and ephedrine sulfate capsules. U. S. v. Premo Pharmaceutical Laboratories, Inc. Plea of guilty. Fine, $400. (F. & D. No. 42741. Sample Nos. 12448–D, 12609–D.)

Psuedoephedrine had been substituted in large part for ephedrine in the solution and capsules involved in this case.

On October 14, 1940, the United States attorney for the Southern District of New York filed an information against the Premo Pharmaceutical Laboratories, Inc., New York, N. Y., alleging shipment by said company on or about January 17 and May 6, 1938, from the State of New York into the States of Connecticut and New Jersey of quantities of ephedrine sulfate solution and of ephedrine sulfate capsules which were adulterated and misbranded.

The solution was alleged to be adulterated in that it was sold under a name recognized in the National Formulary but differed from the standard of strength, quality, and purity as determined by the tests laid down therein since its specific rotation at 25° centigrade was plus 22.6°; whereas the National Formulary provides that the specific rotation of solution of ephedrine sulfate at 25° centigrade shall be between minus 28° and minus 30° and the standard of strength, quality, or purity of the article was not declared on the container. It was alleged to be adulterated further in that its strength and purity fell below the professed standard and quality under which it was sold since it was represented to consist of solution of ephedrine sulfate; whereas psuedoephedrine sulfate had been substituted in whole or in large part for ephedrine sulfate in the solution. The solution was alleged to be misbranded in that the statement "Solution * * * Ephedrine Sulfate N. F. VI," borne on the bottle label, was false and misleading since it was not a solution of ephedrine sulfate which conformed to the requirements of the National Formulary, 6th edition.

The capsules were alleged to be adulterated in that their strength and purity fell below the professed standard and quality under which they were sold since they were represented to consist of capsules each containing ⅜ grain (0.025 gram) of ephedrine sulfate; whereas they did not so consist but did consist of