

North Carolina, and Michigan. The article was labeled in part: (Ampul) "0.15 Gm. * * * Doryl * * * (Carbamylcholine Chloride Merck)."

Examination showed that the article possessed the composition declared on its label.

The article was alleged to be misbranded (1) in that the labeling of the article was misleading since the boxes and cartons containing the ampuls and the ampul labels bore the statement "Do Not Use Intravenously," which suggested and implied that other methods of injection were safe and appropriate, whereas other methods of injection were not safe and appropriate, and the labeling of the article failed to reveal the fact, material in the light of such labeling, that the article was lethal when injected by any method; (2) in that the directions for use which appeared on the labeling of the article, "Do Not Use Intravenously" and "Sufficient to make 20 cc. of a 0.75% Solution for Ophthalmologic Use," were inadequate since they failed to reveal that the article was not to be used for injection by any method, but only in solutions for ophthalmologic use; (3) in that the labeling of the article failed to warn against injection other than intravenously; and (4) in that its container was so made, formed, and filled as to be misleading since the container was in a form in which drugs intended for injection are customarily packaged.

On February 2, 1945, a plea of nolo contendere having been entered on behalf of the defendant, the court imposed a fine of \$1,000 on each of 15 counts in the indictment, a total fine of \$15,000.

1352. Misbranding of Doryl. U. S. v. 10 Ampuls of Doryl (and 3 other seizure actions against Doryl). Default decrees of condemnation and destruction. (F. D. C. Nos. 11498, 11501 to 11503, incl. Sample Nos. 51265-F, 51266-F, 51571-F, 51575-F.)

On December 27 and 28, 1943, the United States attorney for the District of Massachusetts filed libels against 19 ampuls of Doryl at Boston, Mass., and 4 ampuls of Doryl at Woburn, Mass., alleging that the article had been shipped by Merck & Co., Inc., from Rahway, N. J., between the approximate dates of March 11 and May 11, 1943. The article was labeled in part: "0.15 Gm. Ampul * * * Doryl (Carbamylcholine Chloride Merck) Do not use intravenously. * * * Sufficient to make 20 cc. of a 0.75% Solution for Ophthalmologic Use."

The article was alleged to be misbranded (1) in that its labeling failed to bear adequate directions for use since the statements in the labeling, "Do not use intravenously" and "for Ophthalmologic Use," were inadequate since they failed to reveal that the article was intended not to be used for injection, but only in solution for ophthalmologic purposes; (2) in that its labeling failed to bear adequate warnings since the labeling did not clearly warn that the preparation was not intended for injection and would be lethal if so used; (3) in that the statement "Do not use intravenously," appearing in the labeling of an article packaged in ampul form, was misleading since it suggested that the article was suitable for injection otherwise than intravenously, whereas the article, when injected, would cause death; and (4) in that its container was so made, formed, and filled as to be misleading since it was in a form in which drugs intended for injection are sometimes packaged.

On March 12, 1945, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

1353. Misbranding of Salvitae, Salugen, and Syrup of Ambrozoin. U. S. v. American Apothecaries Co., Inc. Plea of guilty. Fine, \$400. (F. D. C. No. 6423. Sample Nos. 51112-E, 51114-E, 51115-E.)

On June 28, 1943, the United States attorney for the Eastern District of New York filed an information against the American Apothecaries Co., Inc., Long Island City, N. Y., alleging shipment of a quantity of the above-named products on or about March 10, 1941, from the State New York into the State of Massachusetts.

Analysis of a sample of the Salvitae disclosed that it consisted essentially of sodium sulfate, magnesium sulfate, sodium bicarbonate, compounds of lithium, potassium and sodium, and strontium, carbonates, citrates, tartrates, caffeine, and methenamine. The article was alleged to be misbranded because of false and misleading statements in its labeling which represented and suggested that it would be an effective aid in the treatment of gingivitis, soft, bleeding gums, receding gums, and for conditions due to a deficiency in the alkalinity of the salivary secretions; that the article would augment, stimulate, and encourage the natural activity of the eliminative organs; that it would promote metabolism; that it