

FEDERAL SECURITY AGENCY RECEIVED

FOOD AND DRUG ADMINISTRATION

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DENVER STATION

**NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG,
AND COSMETIC ACT**

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

1351-1400

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys acting upon reports submitted by direction of the Federal Security Administrator.

MAURICE COLLINS, *Acting Administrator, Federal Security Agency.*

WASHINGTON, D. C., December 21, 1945.

CONTENTS*

	Page		Page
Drugs actionable because of failure to bear adequate directions or warning statements.....	433	Drugs and devices actionable because of false and misleading claims.....	455
Drugs actionable because of deviation from official or own standards.....	449	Drugs for human use.....	455
		Drugs for veterinary use.....	466
		Index.....	470

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

1351. Misbranding of Doryl. U. S. v. Merck & Co., Inc. Plea of nolo contendere. Fine, \$15,000. (F. D. C. No. 11414. Sample Nos. 8475-F, 29923-F, 29926-F, 30384-F, 35242-F, 48851-F, 49311-F, 50487-F, 51266-F, 51571-F, 51618-F, 53252-F, 54015-F, 59510-F.)

The defendant prepared and sold a product under the name "Doryl" which consisted of ampuls containing a solution of 0.25 milligram of carbamylcholine chloride, dissolved in 1 cc. of water, intended for injection with a hypodermic needle. The defendant also prepared and sold under the same name the product involved in this case, which consisted of ampuls containing 0.15 gram of the same drug in powder form and which was 600 times the amount of the drug contained in the solution. The powder was intended for ophthalmologic use as eye drops. The ampuls of the solution and the powder had a generally similar appearance, the word "Doryl" being the most conspicuous word on both labels. A solution containing the powder, if injected, would be lethal.

On December 19, 1944, the grand jurors for the District of New Jersey returned an indictment against Merck & Co., Inc., Rahway, N. J., alleging shipment of a number of ampuls of Doryl between the approximate dates of December 18, 1941, and May 11, 1943, from the State of New Jersey into the States of Wisconsin, Missouri, California, Florida, Kentucky, Ohio, Pennsylvania, Massachusetts,

*For failure to bear an accurate statement of the quantity of the contents, see Nos. 1354, 1361, 1376, 1385, 1388, 1393; deceptive packaging, Nos. 1351, 1352, 1392; omission of, or unsatisfactory, ingredients statements, Nos. 1354, 1379, 1381, 1391; inconspicuousness of required label information, No. 1358; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 1361; substitution of a drug, and its sale under the name of another drug, No. 1365; giving of a false guaranty, No. 1365; cosmetics, subject to the drug provisions of the Act, Nos. 1359, 1360, 1391, 1392.

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 packable 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