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

1204. Misbranding of Helping Hand Laxative Tonic. U. S. v. 310 Bottles of Helping Hand Laxative Tonic. Default decree of condemnation and destruction. (F. D. C. No. 11102. Sample No. 48710–F.)

On or about November 13, 1943, the United States attorney for the Western District of Kentucky filed a libel against 310 bottles of the above-named product at Bowling Green, Ky., alleging that the article had been shipped on or about June 24, 1943, from Nashville, Tenn., by the National Medicine Co.; and charging that it was misbranded.

Analysis disclosed that the article consisted essentially of Epsom salt, 108 grains per fluid ounce; iron and ammonium citrate, 1.1 grains per fluid ounce; and extracts of plant drugs, including laxative and bitter drugs, a sugar, a benzoate, alcohol, and water. The product contained no glycerin.

The article was alleged to be misbranded (1) in that the word "Tonic" in the name of the product, and the statements, "Acts as * * * tonic," "Recommended * * * to tone up the system," and "As * * * tonic," were false and misleading since the article contained no significant amount of any tonic ingredient and would not act as a tonic; (2) in that the labeling statements, "Active Ingredients * * * Iron and Ammonium Citrate * * * Glycerine," were misleading since the article contained no glycerin and the proportion of iron and ammonium citrate present was essentially inconsequential when the product was consumed in accordance with the directions on the label; and (3) in that its labeling failed to bear adequate directions for use, since the article was a laxative and the directions appearing in its labeling provided for continuous administration, whereas a laxative should not be used continuously.

On February 18, 1944, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1205. Misbranding of Doryl. U. S. v. 45 Ampuls of Doryl (and 4 other seizure actions against Doryl). Default decrees of condemnation and destruction. (F. D. C. Nos. 11504 to 11506, incl., 11512, 11546, 11553, 11568. Sample Nos. 29923–F, 29925–F, 29926–F, 30385–F, 30388–F, 30389–F, 35242–F, 48154–F, 57048–F, 57049–F, 58612–F, 58613–F.)

Between December 28, 1943, and January 14, 1944, the United States attorneys for the Northern District of California, the District of Columbia, the Eastern District of New York, the Western District of Kentucky, and the Southern District of Florida filed libels against the following quantities of Doryl: 26 ampuls at San Francisco, Calif., 9 ampuls at Oakland, Calif., 10 ampuls at San Mateo, Calif., 6 ampuls at Washington, D. C., 10 ampuls at Brooklyn, N. Y., 7 ampuls at Hopkinsville, Ky., and 10 ampuls at Miami, Fla., alleging, in the case of the District of Columbia lot, that the product was in interstate commerce, and, in the case of the other lots, that they had been shipped between the approximate dates of February 4, 1942, and May 6, 1943, from St. Louis, Mo., and Rahway, N. J., by Merck & Co., Inc.; and charging that all lots were misbranded. The article was labeled in part: "0.15 Gm. Ampul * * * Doryl (Carbamylcholine Chloride Merck)."

Examination of samples disclosed that the article had the composition stated upon its label.

The article was alleged to be misbranded (1) in that the statement on its label, "Do not use intravenously," was misleading since it suggested and implied that other methods of injections were safe, and its label failed to reveal the fact material in the light of such statement that the contents of the ampul were lethal when injected by any method; (2) in that its labeling bore no warning against injection of the article other than intravenously; (3) 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; and (4) in that its labeling failed to bear adequate directions for use since the statements in its 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.

Between April 17 and October 25, 1944, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

*See also Nos. 1201, 1202.