858. Misbranding of citrate of magnesia. U. S. v. 99 Cases of Citrate of Magnesia. Consent decree of condemnation. Product ordered released under bond for relabeling. (F. D. C. No. 7399. Sample Nos. 40679–E, 40680–E.)

On April 27, 1942, the United States attorney for the Eastern District of Pennsylvania filed a libel at Philadelphia, Pa., against 99 cases of citrate of magnesia. On June 22, and September 18, 1942, amendments to the libel were filed. It was alleged in the libel as so amended that the product had been shipped by the United States Pharmacal Co. from Newark, N. J., on or about June 24, 1941.

The article was alleged to be misbranded (1) in that the labeling failed to bear adequate warnings against use in those pathological conditions wherein its use might be dangerous to health, since it failed to warn that the article was not to be used when abdominal pain, nausea, vomiting, or other symptoms of appendicitis were present; and (2) in that the labeling failed to bear adequate warning against unsafe methods or duration of administration, since it failed to warn that frequent or continued use of the preparation might result in dependence on laxatives.

On September 18, 1942, Benly Products Company, Philadelphia, Pa., claimant, having admitted the allegations of the libel and having consented to the entry of a decree, judgment of condemnation was entered and it was ordered that the product be released under bond for relabeling.

859. Misbranding of "Q–T." U. S. v. 35 Packages and 23 Packages of "Q–T." Default decrees of condemnation. Product ordered destroyed. (F. D. C. No. 8269. Sample Nos. 21719–F, 21720–F.)

On August 31 and October 14, 1942, the United States attorney for the Western District of Pennsylvania filed libels at Pittsburgh, Pa., against 23 4-ounce bottles, and 35 2-ounce bottles of "Q-T," alleging that the article had been shipped in interstate commerce on or about May 22 and July 4, 1942, by the Allied Pharmacal Co. from Cleveland, Ohio. The article was labeled in part: "Q-T For Adults Only, Contains Gold and Sodium Chloride and Ammonium Chloride. * * * This preparation was formerly called Quits."

Examination of a sample of the article showed that it contained 0.16 grain of gold and sodium chloride per fluid ounce, and 6.3 grains of ammonium chloride per fluid ounce.

The article was alleged to be misbranded in that the labeling failed to bear adequate directions for use since it did not state the conditions for which the article was to be used.

On October 19, 1942, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

860. Adulteration and misbranding of phenobarbital tablets. U. S. v. The Physicians' Chemical and Drug Co. and Melvin L. Berger. Plea of not guilty by the corporation. Verdict of guilty. Fine, $500. Case against Melvin L. Berger dismissed. (F. D. C. No. 7233. Sample No. 72204–E.)

On or about October 15, 1942, the United States attorney for the Northern District of Illinois filed an information against the Physicians' Chemical and Drug Co., Chicago, Ill., and Melvin L. Berger, alleging shipment on or about October 8, 1941, from the State of Illinois into the State of California of a quantity of phenobarbital tablets. The tablets were labeled in part: "Phenobarbital ½," and "Phenobarbital-Gr. ½."

The article was alleged to be misbranded in that the label statements represented and suggested that each tablet contained not more than ½ grain of phenobarbital, whereas each tablet contained not less than 0.58 grain of phenobarbital.

It was also alleged to be adulterated in that it purported to be and was represented as a drug, the name of which is recognized in the National Formulary, its strength differed from the standard set forth in that compendium, and its difference in strength was not plainly stated on the label. The National Formulary provides that "Tablets of Phenobarbital contain not more than 107.5 percent of the labeled amount of phenobarbital for tablets of more than 0.07 Gm.,—and not more than 109 percent for tablets of 0.07 Gm. or less, including all tolerances." In this case each tablet contained not less than 116 percent of the labeled amount of phenobarbital.

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*See also Nos. 852, 854–856.

On March 26, 1943, the case came on for trial before the court without a jury. The corporation was found guilty, and the court imposed a fine of $500. On motion of the defendants the action against the individual defendant was dismissed by the court.

861. Adulteration and misbranding of triple distilled water. U. S. v. Kenneth Gaylord Ziegler (Ziegler Pharmacal Co.). Plea of guilty. Fine, $450. (F. D. C. No. 6418. Sample Nos. 46751–E, 57061–E.)

On April 20, 1942, the United States attorney for the Western District of New York filed an information against Kenneth Gaylord Ziegler, trading as Ziegler Pharmacal Co., Buffalo, N. Y., alleging shipment of a quantity of triple distilled water on or about March 6 and September 4, 1941, from the State of New York into the State of Missouri and the Territory of Puerto Rico.

Analyses of a sample of the article from the shipment made into the State of Missouri showed that the product was not sterile and that it contained viable mold micro-organisms.

The article was alleged to be adulterated in that it was a drug the name of which is recognized in the National Formulary, and its quality and purity fell below the standard set forth in that compendium since the ampuls did not contain sterile redistilled water, but contained water that was contaminated with viable mold. It was further adulterated in that it consisted in whole or in part of a filthy substance.

Examination of a sample taken from the shipment into Puerto Rico showed that the average net contents was less than 10 cc. per ampul, namely, 9.25 cc. per ampul. The article was not a clear liquid since some of the ampuls examined contained solid particles. The article did not meet the test for oxidizable substances in that when it was treated according to the test laid down in the National Formulary the color of the liquid disappeared in less than 10 minutes when 0.2 cc. of twentieth-normal potassium permanganate was added, indicating that the article contained oxidizable substances in excess of the maximum tolerance permitted by the National Formulary.

The article was alleged to be adulterated in that it purported to be and was represented as a drug, the name of which is recognized in the National Formulary, and its quality and purity fell below the standard set forth in that compendium and its difference in quality and purity from such standard was not stated on the label.

It was alleged to be misbranded in that the statement, "10 cc. Plus," borne on the label was false and misleading as each of the ampuls contained materially less than 10 cc. of the drug.

On November 23, 1942, a plea of guilty having been entered, the court imposed a fine of $150 on each of the 3 counts of the information.

862. Adulteration and misbranding of triple distilled water. U. S. v. Diarsenol Company, Inc. Plea of guilty. Fine, $500. (F. D. C. No. 6507. Sample Nos. 11275–E to 11277–E, incl.)

This product failed to conform to the requirements of the National Formulary.

On July 13, 1942, the United States attorney for the Western District of New York filed an information against the Diarsenol Company, Inc., Buffalo, N. Y., alleging shipment from on or about March 29 to May 22, 1941, from the State of New York into the State of Texas of quantities of ampuls of triple distilled water.

Analysis of a sample of the product showed that it did not comply with the requirements of the National Formulary for purity in that the hydrogen-ion concentration was above pH 7.0. It was found also that 14 percent of the ampuls did not contain the quantity of contents declared on the label, nor did it meet the National Formulary requirements for fill of 10-cc. ampuls, since 40 percent of the ampuls contained less than 10.50 cc. of liquid. Tests conducted on the ampuls themselves showed that the glass failed to comply with the National Formulary requirements for ampul glass. In addition, another portion was found not to comply with the National Formulary requirements for triple distilled water in that it contained excessive oxidizable substances.

The article was alleged to be adulterated in that it purported to be and was represented as a drug recognized in the National Formulary and its quality fell below the standard set forth in that compendium since it contained a hydrogen-ion concentration of more than pH 7.0, which digression from the standard was not plainly stated on the label. The article in the said two lots was alleged to be misbranded (1) in that the statement "10 cc." shown on the