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

label was false and misleading since each of the ampuls contained a less amount; (2) in that it was not packaged as prescribed in the National Formulary, since the glass used for the ampuls did not pass the test for solubility and reaction required by that compendium; and (3) in that the ampuls did not contain the excess volume (0.5 cc.) which the National Formulary requires should be measured into ampuls purporting to contain a 10-cc. dose of a mobile solution. One of the shipments was alleged to be adulterated in that it fell below the standard set forth in the National Formulary, since it contained an excess of oxidizable substances, and this fact was not plainly stated on its label.

On October 26, 1942, a plea of guilty having been entered, the court imposed a fine of $100 on each of the 5 counts in the information.

863. Adulteration and misbranding of tincture of iron and elixir of iron, quinine and strychnine. U. S. v. L. Perrigo Company. Plea of nolo contendere. Fine, $150. (F. D. C. No. 7699. Sample Nos. 47545–E, 47547–E, 66255–E.)

On November 13, 1942, the United States attorney for the Western District of Michigan filed an information against L. Perrigo Co., a corporation, Allegan, Mich., alleging shipment of quantities of the above-named products on or about March 6 and May 2, 1941, from the State of Michigan into the State of Indiana.

The United States Pharmacopoeia provides that tincture of iron shall contain an amount of ferric chloride corresponding to not less than 4.5 grams of iron. Analysis of a sample of Tincture Iron U. S. P. showed that it contained an amount of ferric chloride corresponding to not more than 3.15 grams of iron per 100 cc. 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 United States Pharmacopoeia, and its strength differed from and its quality fell below the standard set forth in that compendium as the drug contained ferric chloride corresponding to not more than 3.15 grams of iron per 100 cc. It was alleged to be misbranded in that the statement, "Tincture Iron U. S. P.," appearing on the label was false and misleading when applied to a drug which did not conform to the requirements of the United States Pharmacopoeia.

A drug compounded in accordance with the formula for elixir of iron, quinine and strychnine set forth in the National Formulary must contain an amount of ferric citrochloride equivalent to not less than 5.60 grams of iron per 1,000 cc., and must contain not less than 8 grams of quinine hydrochloride per 1,000 cc. Examination of a sample from each of 2 shipments of Elixir Iron, Quinine and Strychnine, N. F., showed that the article in one shipment contained an amount of ferric citrochloride equivalent to not more than 2.80 grams of iron per 1,000 cc., and not more than 4.90 grams of quinine hydrochloride per 1,000 cc. A sample from the second shipment contained not less than 9.5 grams of quinine hydrochloride per 1,000 cc. The article was alleged to be adulterated in that it purported to be and was represented as a product recognized in the National Formulary and its strength differed from and its quality fell below the standard set forth in such compendium. It was alleged to be misbranded in that the statement, "Elixir Iron, Quinine and Strychnine, N. F.," appearing on the label was false and misleading when applied to an article which did not conform to the requirements of the National Formulary.

On November 30, 1942, a plea of nolo contendere having been entered, the court found the defendant guilty and assessed a fine of $25 on each count, or a total of $150.

864. Adulteration and misbranding of Real's Antiseptic Medicated Skin Cream, aromatic spirit of ammonia, and sweet spirit of nitre. U. S. v. Baker Drug Corp. Plea of guilty. Imposition of sentence suspended for 3 years on condition that the defendant would not violate the Food, Drug, and Cosmetic Act and would pay a fine of $200 under the Probation Statute. (F. D. C. No. 7746. Sample Nos. 78865–E, 87895–E, 87896–E.)

On November 18, 1942, the United States attorney for the Eastern District of Virginia filed an information against the Baker Drug Corporation, Norfolk, Va., alleging shipment of quantities of the above-named products on or about February 12 and March 21, 1942, from the State of Virginia into the States of Pennsylvania and North Carolina. The former shipment was made in the name of Jos. Friedberg.

Analysis of a sample of Real's Antiseptic Medicated Skin Cream showed the product to consist essentially of small proportions of potassium hydroxide, volatile oils, including menthol, eucalyptol, and oil of bergamont, and a trace of phenol, incorporated in a base of stearic acid, petrolatum, and beeswax. Bacteriological examination showed the article to be devoid of antiseptic properties.