

which accompanied a portion of the product, regarding its efficacy in stimulating infected areas and in eliminating the danger of infections. The article was alleged to be further misbranded in that the following statements on the tube and carton, "UltraJel \* \* \* as a uterine evacuant \* \* \*," and in the circular entitled "Directions For Use," "UltraJel \* \* \* As A Uterine Evacuant \* \* \* UltraJel has been used successfully for induction of labor in full term deliveries, and for the expulsion of either entire or parts of placenta," and in the circular entitled "UltraJel Indicated as an aid," "UltraJel \* \* \* as a uterine evacuant \* \* \* As a Uterine Evacuant UltraJel may be used as an aid in legal therapeutically indicated cases, premature and full term. \* \* \* UltraJel in many cases, eliminates the necessity of surgery," were false and misleading since the article would not be safe and appropriate for introduction into the uterine cavity but was unsafe and capable of producing serious and even fatal consequences.

The article was alleged to be misbranded further in that it was dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling.

The defendants having filed a motion to quash on July 15, 1943, and that motion having been denied on November 1, 1943, pleas of guilty were entered and the court, on April 20, 1944, imposed fines of \$1,000 against the corporation and \$1 against each of the individual defendants.

**1254. Misbranding of procaine hydrochloride. U. S. v. 1 Package, 8 Packages, and 19 Packages of Procaine Hydrochloride. Default decrees of condemnation and destruction. (F. D. C. Nos. 11679, 11682. Sample Nos. 56892-F, 56893-F, 65986-F.)**

On or about January 21 and 27, 1944, the United States attorneys for the District of New Jersey and the District of Connecticut filed libels against the following quantities of the above-named product: 1 package containing 10 ampuls at Elizabeth, N. J., and 8 packages containing 100 ampuls each, and 19 packages containing 10 ampuls each at Middletown, Conn.; alleging that the article had been shipped between the approximate dates of October 14 and December 13, 1943, by the Loeser Laboratory, Inc., from New York, N. Y.; and charging that it was misbranded. The article was labeled in part: "No. 401 [or "405"] \* \* \* Procaine Hydrochloride \* \* \* Loeser Laboratory, Inc. New York, N. Y. Subsidiary of the Wm. M. Merrell Company."

The article was alleged to be misbranded in that the statements in its labeling, "Procaine Hydrochloride, U. S. P. 200 mg. [ or "50 mg." ]," were false and misleading since the amount of procaine hydrochloride in each ampul was not only greatly in excess of that declared on the label, but there was an excessive variation between the quantity present in the individual ampuls. The article was alleged to be misbranded further in that it was dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling, i. e., "for spinal anesthesia by admixture with spinal fluid \* \* \* To be used only by or on the prescription of a physician."

On March 6 and 25, 1944, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

**1255. Adulteration and misbranding of procaine hydrochloride solution, with epinephrine. U. S. v. 38 Packages of Procaine Hydrochloride Solution (and 3 other seizure actions against procaine hydrochloride solution). Default decrees of condemnation and destruction. (F. D. C. Nos. 12348, 12407, 12509, 12774. Sample Nos. 35967-F, 35968-F, 50975-F, 63447-F, 75324-F, 75349-F.)**

Between the approximate dates of May 10 and June 28, 1944, the United States attorneys for the Northern District of Georgia, the Eastern District of Pennsylvania, and the Northern District of Ohio filed libels against the following amounts of procaine hydrochloride solution: 52 packages, each containing 25 cartridges, at Atlanta, Ga.; 38 packages, each containing 25 cartridges, at Philadelphia, Pa.; and 200 cartridges at Youngstown, Ohio; alleging that the article had been shipped between the approximate dates of March 8 and May 15, 1944, by A. Pfingst and Pfingst & Co., New York, N. Y.; and charging that it was adulterated and misbranded. The article was labeled in part: "Procaine Hydrochloride [or "HCl"] Solution 2% with Epinephrine."

The article was alleged to be adulterated in that its purity and quality fell below that which it purported to possess since the article was not sterile, but was contaminated with living micro-organisms.

The article was alleged to be misbranded in that it was dangerous to health when used in the dosage suggested in the labeling thereof, that is, when the

contents of the cartridge were injected into the tissues. A portion of the article was alleged to be further misbranded in that it failed to bear a label containing an accurate statement of the quantity of the contents of the package. The label of this portion bore no statement of the quantity of the contents of each cartridge.

Between May 29 and July 26, 1944, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

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

**1256. Misbranding of sulfathiazole tablets. U. S. v. Samuel S. Punskey (Franklin Pharmacy). Plea of nolo contendere. Fine, \$1,000. Execution of sentence suspended and defendant placed on probation for 1 year. (F. D. C. No. 10605. Sample Nos. 20577-F, 20698-F, 20701-F.)**

On December 15, 1943, the grand jurors for the District of Maine returned an indictment against Samuel S. Punskey, trading as the Franklin Pharmacy, Portland, Maine, alleging that a number of bottles of sulfathiazole tablets had been shipped from the State of New York into the State of Maine on or about November 13, 1942. It was charged in the indictment that on or about December 24, 1942, one bottle of the article, which was in the same condition as when shipped in interstate commerce, was sold and delivered to the defendant; that on or about August 24, 25, and 26, 1943, and while a number of tablets of the article contained in the aforesaid bottle were being held for sale after shipment in interstate commerce, the defendant removed a number of tablets from the bottle, repacked them in unlabeled boxes, and disposed of the boxes of tablets by sale; and that those acts of removal, repacking, and disposal resulted in the tablets being misbranded since the boxes containing them bore no directions for use.

On December 28, 1943, the defendant having entered a plea of nolo contendere, the court imposed a fine of \$1,000 which was suspended, and placed the defendant on probation for 1 year.

**1257. Adulteration of Stero-Uteroids and misbranding of Natur-Pep. U. S. v. Lloyd M. Curts and Charles D. Folse (Curts-Folse Laboratories). Pleas of guilty. Fine, \$200. (F. D. C. No. 8831. Sample Nos. 2642-F, 3045-F, 3548-F, 3549-F.)**

On July 14, 1943, the United States attorney for the District of Kansas filed an information against Lloyd M. Curts and Charles D. Folse, copartners trading as the Curts-Folse Laboratories, Kansas City, Kans., alleging shipment of a quantity of the above-named products from the State of Kansas into the State of Missouri from on or about March 27 to November 16, 1942.

The article known as Stero-Uteroids was alleged to be adulterated in that its purity fell below that which it purported or was represented to possess since, by reason of its name, it purported and was represented to be a sterile product, whereas it was not a sterile product, but was contaminated with viable pathogenic micro-organisms, *Clostridium tetani*.

Analysis of the Natur-Pep disclosed that the article consisted essentially of Epsom salt (30.9 percent), water, and small amounts of iron phosphate, sodium and potassium compound, methenamine, a salicylate, and extracts of plant drugs including a laxative plant drug. The article was alleged to be misbranded (1) because of false and misleading statements in its labeling which represented and suggested that it was not habit forming; that it possessed tonic properties which would increase pep; that it would restore health, cleanse and stimulate the lining of the stomach and cause the gastric juices to flow freely, increase the flow of bile, bring back the vigorous feeling so essential to happiness, flush out the excess poisons that accumulate in the tiny tubes of the kidneys, and give complete relief from bladder irritation, weakness, "night rising," and other miseries such as dizziness, spots before the eyes, loss of pep, puffiness under the eyes, and stiffness in the back and lower limbs; that it was an hematinic tonic for the blood; that it would restore deficient red blood cells, cure constipation, regulate the bowels, and strengthen or tone soft, weak, and flabby intestinal muscles; and that it would be efficacious in the treatment of nervous, weak, and rundown conditions, poor appetite, swollen limbs, and stiff joints; (2) the statement on its label, "Natur-Pep Tonic Is Prepared From Ingredients of Recognized Medicinal value: Extract Cascara Sagrada Iron Pyrophosphate Strontium Salicylate Oleum Coriandar Methyl Salicylate Extract Gentian Alcohol 1/2% Hexamethylenamine Extract Glycyrrhiza Magnesium Sulphate Potassium Acetate Sodium Salicylate Oleum Anise Glycerine," was misleading since it suggested and created the impression that the article contained therapeutically significant quantities of each and every one of the ingredients named, whereas the article