continuous supervision and employing modern surgical asespis," were false and misleading since such statements represented and suggested that the article would be safe and appropriate for injection into the uterine cavity, whereas the article, whether used by a physician with adequate and continued supervision and employing modern surgical asepsis or otherwise, would not be safe and appropriate for injection into the uterine cavity, but would be unsafe and dangerous when used for such purpose, and was capable of producing serious and even fatal consequences.

The article in the remainder of the California and Missouri lots was alleged to be misbranded in that it was dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in its labeling. This portion of the Missouri lots was alleged to be misbranded further (1) in that the statements appearing in its labeling, "Intrauterine Paste * * * Caution—To be used only by a physician with adequate and continuous supervision and employing modern surgical asespis," and "For Induction of Labor * * * For Incomplete Miscarriage," were false and misleading since they represented and suggested that the article would be safe and appropriate for injection into the uterine cavity for purposes of inducing labor, terminating pregnancy, or removing retained portions of the products of conception, whereas the article, whether used by a physician with adequate and continued supervision and employing modern surgical asepsis or otherwise, would not be safe and appropriate for such purposes, but would be unsafe and dangerous and was capable of producing serious and even fatal consequences; and (2) in that the statements on the labeling, "For Dysmenorrhea * * * For Endometritis, Cervical and Uterine Discharges" were false and misleading since the article would not be an effective medicament for the treatment of dysmenorrhea, endometritis, or cervical or uterine discharges.

On September 11, 1943, the defendant entered a plea of guilty, and on November 2, 1943, the court imposed a fine of $200 and a sentence of 9 months in jail.

1102. Adulteration and misbranding of sodium citrate solution. U. S. v. 1,500 Boxes of Sodium Citrate Solution (and 7 other seizure actions against the same product). Decrees of condemnation and destruction. (F. D. C. Nos. 9182, 9184, 9232, 9265, 9310, 9311, 9385, 9388. Sample Nos. 3633–F, 5762–F, 10076–F, 16611–F, 29380–F, 29472–F, 34613–F, 37501–F, 41782–F.)

Between January 14 and February 23, 1943, the United States attorneys for the Western District of Texas, the Northern District of Georgia, the Eastern District of Virginia, the District of Kansas, the Eastern District of Missouri, the District of Colorado, the Southern District of Georgia, and the Northern District of Ohio filed libels against the following quantities of sodium citrate solution: 2,750 ampuls at Savannah, Ga.; 1,500 boxes at San Antonio, Tex.; 4,000 boxes at Atlanta, Ga.; 2,875 cartons at Richmond, Va.; 3,500 cartons at Kansas City, Kans.; 1,100 cartons at St. Louis, Mo.; 600 packages at Denver, Colo.; and 4,000 boxes at Toledo, Ohio, each box, carton, and package containing 6 ampuls. They alleged that the article, which had been consigned by the National Drug Co., had been shipped from Philadelphia, Pa., within the period from on or about November 12 to December 31, 1942; and charged that it was adulterated and misbranded. On February 27, 1943, an amended libel was filed against the lot at Toledo to correct the code reference of that lot. On March 18, 1943, the libel against the lot at Savannah was amended to cover the amount of 5,700 ampuls in lieu of 2,750 ampuls; and a portion of the lot at Savannah having been erroneously seized by the marshal, an order was entered providing for the return to the United States Army Medical Depot of 10,500 ampuls out of the total seizure of 16,200 ampuls.

The article was alleged to be adulterated in that it purported to be a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, as "Anticoagulant Solution of Sodium Citrate No. 3—Sterile Anticoagulant Solution of Sodium Citrate for Parenteral Use," but its quality and purity fell below the standard set forth in the Pharmacopoeia since it failed to meet the pyrogen test set forth therein.

It was alleged to be misbranded in that it was dangerous to health when used in the dosage prescribed, recommended, and suggested in the labeling thereof, "The contents of a 50 cc. ampul containing the 2½% solution, mixed with 450 cc. of blood produces a transfusion mixture"; and in that the statement in its labeling, "Ampul Sterile Solution Sodium Citrate, 2½% N. F. For use in transfusions to prevent the clotting of blood," was misleading since the article contained pyrogens and was not suitable for use in transfusions, and since the

National Formulary does not recognize the name "Ampul Sterile Solution Sodium Citrate, 2½%."

Between February 26 and April 26, 1943, no claim having been presented for the release of the product, judgments of condemnation were entered and it was ordered destroyed.

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

1103. Misbranding of Formula No. 1520. U. S. v. 2 Cases of Formula No. 1520. Default decree of condemnation and destruction. (F. D. C. No. 10259. Sample No. 22782–F.)

On July 15, 1943, the United States attorney for the Eastern District of Pennsylvania filed a libel against 2 cases of Formula No. 1520 at Philadelphia, Pa., alleging that the article had been shipped on or about June 11, 1943, from New York, N. Y., by J. L. Hopkins and Company; and charging that it was misbranded.

The article consisted of a mixture of Epsom salt, sulfur, baking soda, and plant drugs including senna.

It was alleged to be misbranded (1) in that its label failed to bear the common or usual name of each active ingredient; (2) in that its label failed to bear adequate directions for use since no directions for use appeared on the label; (3) in that its label failed to bear adequate warnings against use since the article was a laxative and its label failed to warn that a laxative should not be taken in cases of nausea, vomiting, abdominal pain, or other symptoms of appendicitis; and (4) in that its label failed to bear adequate warnings against unsafe duration of administration since its label failed to warn that frequent or continued use of a laxative might result in dependence upon a laxative to move the bowels.

On August 30, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1104. Misbranding of mixed drugs. U. S. v. 4 Cartons of Mixed Drugs. Default decree of condemnation and destruction. (F. D. C. No. 10139. Sample No. 22779–F.)

On June 23, 1943, the United States attorney for the Eastern District of Pennsylvania filed a libel against an article consisting of 4 cartons containing 2 unlabeled packages (about 10 pounds each) of mixed drugs, 9 1-pound packages of powdered sugar, and miscellaneous labeling, at Philadelphia, Pa., alleging that the article had been shipped on or about June 9, 1943, from New York, N. Y., by Elsie Bleeker; and charging that it was misbranded. The cartons, some of which bore the name "Natura," others "Nu-Vita," all carried the statement: "Contents: Licorice, Sulphur, Cascara Sag., Senna, Bicarb. Soda, Magnesium Sulphate, USP, Sugar."

Examination of the unlabeled mixed drugs showed that they contained senna, Epsom salt (magnesium sulfate), sodium bicarbonate, and sulfur.

The article was alleged to be misbranded because of false and misleading statements appearing in its labeling which represented and suggested that it was an effective treatment for low or high blood pressure, rheumatism, backache, getting up nights, child bed-wetting, and swollen feet; that it was an "Herb Powder"; and that it was a product of either Mexico or America. It was alleged to be misbranded further (1) in that it failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of contents; (2) in that its label failed to bear the common or usual name of each active ingredient of the preparation; (3) in that its labeling failed to bear adequate directions for use since the article was a laxative and the directions which appeared in the labeling provided for continuous administration, whereas a laxative should not be used continuously; and (4) in that its labeling failed to bear adequate warnings against unsafe duration of administration since its labeling failed to warn that frequent or continued use of a laxative might result in dependence upon a laxative to move the bowels.

On July 12, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

1105. Misbranding of Dr. Sibbett's Improved Big Six and Original Big Six. U. S. v. 23½ Dozen Bottles and 3¾ Dozen Bottles of Dr. Sibbett's Improved Big Six, and 1¾ Dozen Bottles of Dr. Sibbett's Original Big Six. Default decree of condemnation and destruction. (F. D. C. No. 9985. Sample Nos. 37674–F, 37675–F.)

On May 21, 1943, the United States attorney for the Eastern District of Michigan filed a libel against 23½ dozen bottles, each containing 3 fluid ounces, and