ported and was represented to possess since it purported to be and was represented as tablets each of which contained 0.5 gram, or 7.72 grains, of sulfathiazole and no other physiologically active ingredient; whereas in 12 of the 14 shipments there were tablets which contained inconsequential amounts of, or no, sulfathiazole but did contain phenobarbital in amounts varying from 4.23 grains to 6.03 grains per tablet, and in the remaining 2 shipments there were tablets containing phenobarbital in amounts varying from 0.03 grain to 0.24 grain. (2) (12 of the 14 shipments.) In that tablets which contained inconsequential amounts of, or no, sulfathiazole but did contain phenobarbital in amounts varying from 4.23 grains to 6.03 grains per tablet, or (remaining 2 shipments) tablets which contained phenobarbital in amounts varying from 0.03 grain to 0.24 grain, had been substituted in part for tablets containing ½ gram (7.72 grain) of sulfathiazole and no other physiologically active ingredient.

Misbranding was alleged with respect to all or part of the tablets (in 6 shipments), which were in their original labeled containers, in that they would be dangerous to health when used in the dosage or with the frequency or duration suggested in the labeling, i. e., "0.5 Gm. (7.72 grains) Sulfathiazole Winthrop (2-sulfanilamido thiazole) * * * Caution: To be used only by or under the direct supervision of a physician," since the statement suggested administration of the drug in dosages appropriate for the administration of 0.5 gram (7.72 grain) tablets of sulfathiazole, whereas if administered in dosages appropriate for the administration of sulfathiazole tablets of such strength, they would be dangerous to health because of admixture therewith of tablets containing phenobarbital in amounts varying from 0.274 gram (4.23 grains) to 0.391 gram (6.03 grains) per tablet.

All shipments of the article were alleged to be misbranded in that a number of tablets containing phenobarbital, a physiologically active ingredient, in amounts hereinbefore stated, had been offered for sale under the name of another drug, namely, "Tablets 0.5 Gm. (7.72 grains) Sulfathiazole," or "Sulfathiazole Tabs [or "Tablets"] 0.5 Gm."

Portions of the article, i. e., those which were in their original labeled containers were alleged to be misbranded further: (1) In that the statement on the label, "Tablets 0.5 Gm. (7.72 grains) Sulfathiazole," was false and misleading since it represented and suggested that the drug consisted of tablets each containing 0.5 gram (7.72 grains) of sulfathiazole and no other physiologically active ingredient; whereas it consisted of tablets some of which contained an inconsequential amount of, or no, sulfathiazole, but did contain phenobarbital in amounts varying from 4.23 grains to 6.03 grains per tablet. (2) In that the labeling was misleading since it failed to reveal the fact material with respect to the consequences which might result from its use under conditions prescribed in the labeling or under such conditions of use as are customary or usual, i. e., the fact that there was present in said drug a number of tablets that contained phenobarbital, a physiologically active ingredient, in amounts varying from 0.274 gram (4.23 grains) to 0.391 gram (6.03 grains) per tablet, and that when administered in dosages in which sulfathiazole is customarily administered it would produce phenobarbital poisoning.

On January 28, 1942, the defendant entered a plea of guilty and the court imposed a fine of $1,000 on each of the counts charging that the product was dangerous to health, and a fine of $350 on each of the additional 28 counts, totaling $15,800.

657. Adulteration and misbranding of Interferin. U. S. v. 3 Tubes and 3 Boxes each containing 1 Tube of Interferin. Default decrees of condemnation and destruction. (F. D. C. Nos. 6320, 6741. Sample Nos. 14766–E, 54630–E.)

This product would be dangerous to health when use as recommended or suggested in its labeling.

On December 1, 1941, and January 20, 1942, the United States attorney for the Eastern District of Pennsylvania filed libels against the above-named drug product at Philadelphia, Pa., alleging that the article had been shipped in interstate commerce on or about November 3 and 27, 1941, by the Keefer Laboratories from Chicago, Ill.: and charging that it was misbranded and that a portion was also adulterated.

Analysis showed that the article consisted essentially of potassium soap (approximately 11.3 percent), sodium soap (approximately 12.5 percent), potassium iodide (approximately 6 percent), benzoic acid (0.4 percent), fats and/or oils (0.4 percent), alcohol, and water.

The article in one of the shipments was alleged to be adulterated in that its purity and quality fell below that which it purported to possess since it was offered for use by injection into the uterus thereby implying that it was sterile; whereas it was not sterile but was contaminated with viable bacteria of a disease-producing type.

The article in the said shipment was alleged to be misbranded in that it was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in the leaflet enclosed in the retail carton: "Attach uterine canule to tube and insert through the cervical canal approximately 2 inches into the uterus so that the tip of the canule rests in the cavum uteri. Now slowly inject Interferin, slightly moving the canule in different directions so that the tip of the canule will not press against the uterine tissue wall. Allow three minutes intermission if the patient is restless; a complete instillation should require about ten minutes. Dosis inject one third (⅓) of the tube in cases of pregnancy up to two months; a half (½) in three month cases; a full tube in four month cases; still later cases, 1½ tubes. Generally speaking a little more Interferin will produce a quicker expulsion of the fetus." The said shipment was alleged to be misbranded further in that statements in the labeling which represented that the article had been successfully on the market since 1933 and had proved its value in more than 5,000 cases without a single fatality known; that it had been developed after extensive research; that it offered very definite advantages over old methods; and that it was efficacious and appropriate for the following therapeutic group indications, "A. Dead fetus, mole, missed abortion. B. Living fetus. 1) Ovum diseases. 2) Pregnancy toxemias. 3) Complications at labor. 4) Genital tract diseases. 5) Systematic diseases. T. B. of the lungs, cardiac, kidney, blood, skin, syphilis. 6) Endocrine disorders. 7) Organic and functional nervous system diseases, intractable vomiting. 8) Special organ diseases, eye, blindness, ear. 9) Unclassified diseases, column fractures, caries. 10) Rape, incest. 11) Eugenic factors; heredity diseases, insanity, epilepsy, in which in addition to abortion sterilization is indicated. 12) Social economic indications. Illegitimacy, desertion, widowhood, overburdened impoverished physical depleted mothers"; and that it was effective and humane were false and misleading since they created the impression that it was a safe and appropriate medicament for effecting abortion; whereas it was not but was a dangerous drug. The said shipment was alleged to be misbranded further in that the statements, "The placenta is usually expelled a few minutes after the fetus," "Severe hemorrhages are very rarely observed after the use of Interferin," "the Interferin method is positively superior to dilation and curettage in cases of gravidity from two and a half to six months," were false and misleading since the placenta would not usually be expelled a few minutes after the fetus, severe hemorrhages would frequently occur after use of the article, and its use was not superior to dilation and curettage in such cases.

The article in the remaining shipment was alleged to be misbranded in that the name "Interferin" which had become impregnated with the meaning that the article was designed for introduction into the uterine cavity for the purpose of interfering with the normal progress of pregnancy, was false and misleading since the name represented and suggested that the article was safe and appropriate for interfering with the normal progress of pregnancy; whereas it was not safe or appropriate for such use but was unsafe and dangerous and capable of producing serious or even fatal consequences. It was alleged to be misbranded further in that its label failed to bear adequate directions for use since there were no adequate directions for the use above referred to.

On January 5 and February 16, 1942, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

658. Misbranding of Voltamp Battery No. 7. U. S. v. 1 Voltamp Battery No. 7. Default decree of condemnation. Product ordered delivered to Government. (F. D. C. No. 4822. Sample No. 69056–E.)

This device consisted of a case containing batteries, an electric coil, and attachments for applying electric current to the body. It was accompanied by a circular in which it was recommended for use in conditions involving paralysis and would be dangerous to health when used in such conditions involving paralysis and would be dangerous to health when used in such conditions. The circular also bore false and misleading claims regarding its efficacy in an enormous number of disease conditions.

On May 24, 1941, the United States attorney for the Northern District of New York filed a libel against one Voltamp Battery No. 7 at Schenectady, N. Y., alleg-