FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

1101–1150

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys acting upon reports submitted by direction of the Federal Security Administrator.

WATSON B. MILLER, *Acting Administrator, Federal Security Agency.*

WASHINGTON, D. C., *February 15, 1945.*

CONTENTS[1]

DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS[2]

1101. Misbranding of intrauterine paste. U. S. v. Anne M. Jenks (Dependon Products and Jenks Physicians Supplies). Plea of guilty. Fine, $200 and imprisonment for 9 months. (F. D. C. No. 9627. Sample Nos. 16897–E, 16898–E, 22384–E, 22398–E.)

On June 29, 1943, the grand jurors for the District of Minnesota returned an indictment against Anne M. Jenks, doing business as Dependon Products and "Jenks" Physicians Supplies, St. Paul, Minn., alleging shipment from the State of Minnesota into the States of Missouri and California within the period from on or about September 16 to November 19, 1941, of quantities of the above-named products, which was misbranded.

Analysis disclosed that the article consisted essentially of potassium iodide, soap, alcohol, and water, and that it contained no free iodine.

The article in one of the Missouri lots and one of the California lots was alleged to be misbranded in that the statements in its labeling, "Intrauterine Paste * * * Caution—To be used only by a physician with adequate and

[1] For omission of, or unsatisfactory, ingredients statement, see Nos. 1103, 1104; omission of name and place of business of manufacturer, packer, or distributor, No. 1104; failure to bear accurate statement of quantity of contents, No. 1104; inconspicuousness of required label information, No. 1105; cosmetic, subject to the drug provisions of the Act, No. 1133.

[2] See also No. 1139 for abortifacient also alleged to be unsafe and dangerous.

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