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]

1951–2000

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.

MAURICE COLLINS, *Acting Administrator, Federal Security Agency.*
WASHINGTON, D. C., *May 29, 1947.*

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DRUGS AND DEVICES ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

1951. Adulteration and misbranding of Livo-Plex. U. S. v. Vincent Christina and Co., Inc., and Vincent Christina. Pleas of guilty. Fine, $1,500. (F. D. C. No. 15497. Sample Nos. 53586–F, 53588–F, 58700–F.)

INFORMATION FILED: April 17, 1946, Southern District of New York, against Vincent Christina and Co., Inc., New York, N. Y., and Vincent Christina, president of the corporation.

ALLEGED SHIPMENT: On or about May 2 and June 1 and 19, 1944, from the State of New York into the State of Maryland.

PRODUCT: *Livo-Plex.* Bacteriological examination showed that the product was contaminated with living micro-organisms.

LABEL, IN PART: "Vial 10 cc. Livo-Plex * * * For Intramuscular Use."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality and purity of the article fell below that which it purported and was represented to possess. Its labeling bore the statement "For Intramuscular Use," which implied that it was an appropriate drug to be used for injection into the muscular tissues, a use which requires a sterile product, whereas the article was unsterile and was contaminated with viable micro-organisms.

Misbranding, Section 502 (j), the article would be dangerous to health when used in the dosage suggested in the labeling, "Each 1 cc contains: Injectable

* For failure to bear a label containing an accurate statement of the quantity of the contents, see Nos. 1955, 1956, 1962, 1966, 1978; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 1956, 1962; cosmetic, actionable under the drug provisions of the Act, No. 1978.

Liver 100 gms., Thiamine HCl (B_1) 10 mg., Riboflavin (B_2) 0.1 mg., Pyridoxine HCl (B_6) 1 mg., Nicotinamide 10 mg., Calcium Pantothenate 0.1 mg., Phenol 0.5% For Intramuscular Use Caution: To be used only by or on the prescription of a physician." The labeling suggested the injection of the article into the muscular tissues in a dosage of 1 cc., or in a dosage appropriate for intramuscular injection. The article when used as suggested would be dangerous to health by reason of its contamination with viable micro-organisms.

DISPOSITION: April 30, 1946. The defendants having entered pleas of guilty, the court imposed a fine of $250, jointly and severally, on each of six counts, a total fine of $1,500.

1952. Misbranding of crystalline sulfanilamide. U. S. v. 500 Envelopes of Crystalline Sulfanilamide. Default decree of condemnation and destruction. (F. D. C. No. 20507. Sample No. 8660–H.)

LIBEL FILED: July 11, 1946, Southern District of New York.

ALLEGED SHIPMENT: On or about February 15 and 23, 1945, by the A. E. Halperin Co., Inc., from Boston, Mass.

PRODUCT: 500 envelopes of *crystalline sulfanilamide* at New York, N. Y.

LABEL, IN PART: "5 Grams Sterile Crystalline Sulfanilamide."

NATURE OF CHARGE: Misbranding, Section 502 (j), the product was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in the following labeling: "Directions * * * After controlling hemorrhage, sprinkle powder in wound, covering the depth and injured surfaces lightly, then cover with sterile dressing and bandage."

DISPOSITION: July 31, 1946. No claimant having appeared, judgment of condemnation was entered and it was ordered that the Federal Security Agency be permitted to take samples of the product, and that the remainder be destroyed.

1953. Misbranding of Kohl's All Soothing Ointment. U. S. v. 141 Cartons of Kohl's All Soothing Ointment. Default decree of condemnation and destruction. (F. D. C. No. 20706. Sample No. 14085–H.)

LIBEL FILED: August 8, 1946, Southern District of Ohio.

ALLEGED SHIPMENT: On or about March 27, 1946, by the Commerce Drug Co., from Brooklyn, N. Y.

PRODUCT: 141 cartons, each containing 1 tin, of *Kohl's All Soothing Ointment* at Cincinnati, Ohio. Examination showed that the product consisted essentially of carbolic acid, not less than 5.1 percent, boric acid, zinc oxide, sulfur, menthol, thymol, camphor, juniper tar, and wood tar, in an ointment base.

LABEL, IN PART: (Circular enclosed in carton) "Worn-out and injured tissue is benefited, healing processes hastened, * * * It is harmless * * * Having a favorable influence on skin injuries such as * * * Frost Bites * * * Old Sores, Ulcers and Wounds (accompanied by offensive discharges) * * * Simple Eczema."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in a circular enclosed in the carton of the article were false and misleading since they represented and suggested that the article would be harmless; that it would be effective in benefiting worn-out and injured tissues; that it would be effective in hastening healing processes; and that it would be effective in the treatment of frost bites, old sores, ulcers and wounds accompanied by offensive discharges, and simple eczema. The article was not harmless, and it would not be effective for the purposes represented.

Further misbranding, Section 502 (j), the article would be dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in the following labeling: "Apply freely, on cloth or bandage, to the injured part. Renew the dressing frequently, as required." In addition, it would be dangerous to health when used in accordance with the representations for its use on extensive areas of the body, as in the treatment of sunburn and ivy poisoning.

The article was alleged also to be misbranded under the Federal Caustic Poison Act, as reported in notices of judgment on caustic poisons.

DISPOSITION: September 6, 1946. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.