

852. Adulteration and misbranding of Leunbach' Paste. U. S. v. Merz & Company Chemical Works, Inc., and Adolph G. Schickert. Plea of guilty by Adolph G. Schickert, sentence 18 months in jail. Plea of nolo contendere by corporation. Sentence suspended. (F. D. C. No. 5505. Sample Nos. 5032-E, 5033-E, 12877-E, 14055-E to 14057-E, incl., 14059-E, 20127-E, 28933-E, 28934-E, 32419-E, 32420-E, 32473-E to 32475-E, incl., 33525-E.)

On October 31, 1941, the United States attorney for the District of New Jersey filed an information against Merz & Company Chemical Works, Inc., East Orange, N. J., and Adolph G. Schickert, alleging shipment within the period from on or about March 16, 1939, to on or about September 11, 1940, from the State of New Jersey into the States of Ohio, Georgia, California, Pennsylvania, and the District of Columbia, of quantities of Leunbach' Paste complete outfit and Leunbach' Paste refill tubes which were misbranded. On March 31, 1942, the grand jury for the District of New Jersey presented an indictment based on the same charges against the defendants. (The information which had been filed on October 31, 1941, was dismissed at the conclusion of the case.)

Examination showed that the Leunbach' Paste complete outfit contained a tube of paste and instruments for its application, and the refill tubes contained the same paste. Analysis of a sample of this paste showed that it contained potassium iodide, small proportions of thymol, benzoin, and myrrh incorporated in a soap base, alcohol, and water.

Portions of the article were alleged to be adulterated in that its purity fell below that which it purported and was represented to possess, in that the article by virtue of the use for which it was recommended and the conditions under which it was to be used, that is, injection into the cervix and pregnant uterus under conditions of the strictest asepsis, purported and was represented to be sterile, whereas it was not sterile but was contaminated with viable microorganisms.

All of the shipments were alleged to be misbranded in that the article was dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling. (The labeling of this product is set out substantially in Drugs and Devices Notices of Judgment No. 607.)

It was alleged to be further misbranded in that its labeling was false and misleading in its representations and suggestions that it was a safe and appropriate treatment for the therapeutic termination of pregnancy, whereas it was not a safe and appropriate treatment for the therapeutic termination of pregnancy, but was unsafe and dangerous, and capable of producing serious and even fatal consequences.

On October 14, 1942, Adolph Schickert entered a plea of guilty, and a plea of nolo contendere was entered on behalf of the corporation. On October 30, 1942, the court sentenced Schickert to serve 6 months on each of the 17 counts in the indictment, the periods imposed on the first 3 counts to be served consecutively, totaling 18 months, and the periods imposed on the remainder of the counts to be served concurrently with that imposed on count 1. On November 6, 1942, the court ordered sentence suspended as to the corporation.

853. Misbranding of Hunt's Salve. U. S. v. 5½ Dozen Packages of Hunt's Salve. Default decree of condemnation. Product ordered destroyed. (F. D. C. No. 7829. Sample No. 94230-E.)

On June 29, 1942, the United States attorney for the Eastern District of Arkansas filed a libel at Little Rock, Ark., against 5½ dozen packages of Hunt's Salve, alleging that the article was shipped in interstate commerce on or about May 5, 1942, by the Allied Drug Products Co. from Chattanooga, Tenn. The article was labeled in part: "Hunt's Salve Manufactured for A. B. Richards Med. Co. Sherman, Texas."

Examination showed that the article consisted essentially of chrysarobin 0.43 percent, sulfur iodine, and carbolic acid, in an ointment base. The amount of ointment contained in each can did not exceed 1¼ avoirdupois ounces.

The article was alleged to be misbranded (1) in that it would be dangerous to health when used as recommended: "Once or twice a day and always at bed time, apply Hunt's Salve; rub it in thoroughly"; (2) in that the statement, "Contents: 1½ oz. av.," was false and misleading since the actual amount of ointment did not exceed 1¼ avoirdupois ounces; and (3) in that the statements in the labeling representing and suggesting that the article would be effective to relieve itching and remove crusts associated with eczema, promote the healing of cuts, burns, scratches, and skin abrasions, and would give relief from itching caused by skin irritations, were false and misleading as the article was not effective for these purposes.