

article was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: August 21, 1951. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

3570. Adulteration and misbranding of Hemoplex and Livofer-B. U. S. v. Bellevue Laboratories, Inc., and Chaim Dick. Pleas of guilty. Fine of \$250 against corporation. Imposition of sentence against individual suspended and individual placed on probation for 1 year. (F. D. C. No. No. 29457. Sample Nos. 73652-K, 73666-K.)

INFORMATION FILED: September 24, 1951, Southern District of New York, against Bellevue Laboratories, Inc., New York, N. Y., and Chaim Dick, president-treasurer of the corporation.

ALLEGED SHIPMENT: On or about January 19, 1950, from the State of New York into the State of New Jersey.

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity of the articles fell below that which they purported and were represented to possess, in that the articles were not sterile and were not suitable for intramuscular injection since they were contaminated with viable sporeforming bacteria.

Misbranding, Section 502 (a), the statement "Sterile * * * For Intramuscular Use" displayed upon the label of the *Hemoplex* and the statement "Sterile * * * Intramuscular" displayed upon the label of the *Livofer-B* were false and misleading. Such statements represented and suggested that the articles were sterile and suitable for intramuscular injection, whereas the articles were not sterile and suitable for intramuscular injection since they were contaminated with viable sporeforming bacteria.

DISPOSITION: November 13, 1951. Pleas of guilty having been entered, the court imposed a fine of \$250 against the corporation and suspended the imposition of sentence against the individual defendant and placed him on probation for 1 year.

3571. Adulteration and misbranding of estrogenic substances. U. S. v. Estro Chemical Co., Inc., and Harold H. London. Pleas of guilty. Fine of \$800 against corporation. Imposition of sentence against individual suspended and individual placed on probation for 1 day. (F. D. C. No. 29430. Sample Nos. 11258-K, 11271-K, 15268-K, 52365-K, 62874-K, 62876-K.)

INFORMATION FILED: September 10, 1951, Southern District of New York, against the Estro Chemical Co., Inc., New York, N. Y., and Harold H. London, president of the corporation.

ALLEGED SHIPMENT: On or about September 10 and November 11 and 24, 1948, and August 15, 1949, from the State of New York into the States of New Jersey, Tennessee, Illinois, and Massachusetts.

LABEL, IN PART: "Aqua-Gyne Aqueous Estrogenic Substance 20,000 I. U. per cc." and "Aqueous Estrogyne 20,000 I. U."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the articles differed from that which they were represented to possess, in the following respects: A number of the vials in two of the shipments of *Aqua-Gyne* con-

tained less than 97 percent of the amount of ketosteroids necessary to produce a potency of 20,000 International Units of estrone per cubic centimeter, and some vials in one of the shipments of *Aqua-Gyne* contained less and some vials contained more than 97 percent of the amount of ketosteroids necessary to produce a potency of 20,000 International Units of estrone per cubic centimeter. The *Aqueous Estrogyne* possessed a potency of less than 20,000 International Units of estrone activity per cubic centimeter.

Misbranding, Section 502 (a), the *Aqua-Gyne* label statement "Each cc. * * * contains * * * (Ketosteroids as Estrone, approximately 97% by potency) * * * equivalent to 20,000 I. U. (assayed in terms of Estrone)" and the *Aqueous Estrogyne* label statement "1 cc. Aqueous Estrogyne 20,000 I. U. Estrone per cc." were false and misleading.

DISPOSITION: November 13, 1951. The corporation having entered a plea of guilty to the 8 counts of the information and the individual having entered a plea of guilty to the 6 counts of the information in which he was charged as a defendant, the court imposed a fine of \$800 against the corporation and suspended the imposition of sentence against the individual and placed him on probation for 1 day.

3572. Adulteration and misbranding of conjugated estrogens. U. S. v. 1 Drum
* * *. (F. D. C. No. 30965. Sample No. 19252-L.)

LIBEL FILED: June 27, 1951, District of Minnesota.

ALLEGED SHIPMENT: On or about April 12, 1951, by the Keith Victor Pharmaceutical Co., from St. Louis, Mo.

PRODUCT: 1 drum containing 23,850 tablets of *conjugated estrogens* at Minneapolis, Minn. Analysis showed that the product contained a total amount of estrogenic steroids calculated as 0.82 mg. of sodium estrone sulfate per tablet.

LABEL, IN PART: "Sugar Coated Estrogen 1.25 Mg. tablets each tablet contains naturally occurring water-soluble conjugated Estrogens equivalent in biological activity to 1.25 Mg. of Sodium Estrone Sulfate."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess.

Misbranding, Section 502 (a), the label statement "each tablet contains naturally occurring water-soluble conjugated Estrogens equivalent in biological activity to 1.25 Mg. of Sodium Estrone Sulfate" was false and misleading since the biological activity of the article was less than that declared.

DISPOSITION: September 5, 1951. Default decree of destruction.

3573. Adulteration and misbranding of conjugated estrogens. U. S. v. 3 Bottles
* * *. (F. D. C. No. 31220. Sample No. 813-L.)

LIBEL FILED: June 27, 1951, Southern District of Florida.

ALLEGED SHIPMENT: During or about December 1950, by the Robin Pharmacal Corp., from New York, N. Y.

PRODUCT: 3 1,000-tablet bottles of *conjugated estrogens* at Miami Beach, Fla. Analysis showed that the product contained a total amount of estrogenic steroids calculated to 0.59 milligram of sodium estrone sulfate per tablet.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, 1.25 mg. of