

Further misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use in the treatment of the diseases and conditions for which the article was intended, namely, for all forms of rheumatics, tuberculosis, blood disorders, kidney and liver afflictions, syphilis, and tumors.

DISPOSITION: January 18, 1954. The individual defendants having entered pleas of guilty, the court imposed a fine of \$100 against each individual, but imposed no sentence against the partnership.

4314. Misbranding of rubber diaphragms. U. S. v. 166 Devices * * *. (F. D. C. No. 35680. Sample No. 55178-L.)

LABEL FILED: October 1, 1953, Eastern District of Wisconsin.

ALLEGED SHIPMENT: On or about August 25, 1953, by Hychex Products, from Chicago, Ill.

PRODUCT: 166 devices, consisting of *rubber diaphragms*, contraceptive type, each of which was contained in a cardboard box, at Milwaukee, Wis.

RESULTS OF INVESTIGATION: The device was a prescription device, and its label did not bear the legend "Caution Federal Law Restricts This Device To Sale By or On The Order of a Physician." Further, the device was not restricted by the dealer to sale by or on the order of a physician.

LABEL, IN PART: (Box Cover) "PreCare Mensinga Diaphragm."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the device failed to bear adequate directions for use.

DISPOSITION: January 27, 1954. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

4315. Adulteration and misbranding of testosterone, Lynntestro, and estrone. U. S. v. Milton A. Calesnick (Addison Laboratories). Plea of guilty. Defendant fined \$300 and placed on probation for 2 years. (F. D. C. No. 33794. Sample Nos. 22330-L, 41516-L, 56320-L.)

INFORMATION FILED: September 29, 1953, Eastern District of Pennsylvania, against Milton A. Calesnick, trading as Addison Laboratories, Philadelphia, Pa.

ALLEGED SHIPMENT: On or about April 30, June 30, and July 8, 1952, from the State of Pennsylvania into the States of New Jersey, Ohio, and Texas.

LABEL, IN PART: (Vials) "10 cc. Multiple-Dose Vial Testosterone Aqueous Macrosuspension Crystalline 100 mg./cc. Sterile—Intramuscular Distributed by Leon Rosengarten Dallas, Texas," "10 cc. Multiple-Dose Vial Lynntestro Aq Aqueous Macrosuspension Crystalline 100 mg./cc. Sterile—Intramuscular Distributed By Lynn Pharmacal Co. Camden, N. J.," and "10 cc. Multiple-Dose Vial List No. 1015 Estrone U. S. P. (2.0 mg. per cc.) * * * Mfg'd for The Caldwell & Bloor Co. Mansfield, Ohio."

NATURE OF CHARGE: *Testosterone* and *Lynntestro.* Adulteration, Section 501 (c), the purity and quality of the articles fell below that which they purported and were represented to possess. The articles were represented to be sterile, whereas they were not sterile but were contaminated with viable micro-organisms. Misbranding, Section 502 (a), the statement "Sterile" displayed upon the labels of the articles, was false and misleading.

Estrone. Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess since the article was represented to contain 2 milligrams of estrone per cubic centimeter, whereas the article in a number of the vials contained less than 2 milligrams of estrone per cubic centimeter; and, in a number of other vials, the article contained an excess of 2 milligrams of estrone per cubic centimeter. Misbranding, Section 502 (a), the label statements "Estrone U. S. P. (2.0 mg. per cc.) Each cc. contains a sterile aqueous macrosuspension of Estrone U. S. P. 2.0 mg." were false and misleading.

DISPOSITION: February 2, 1954. The defendant having entered a plea of guilty, the court fined him \$300 and placed him on probation for 2 years.

4316. Adulteration of ammonium chloride tablets. U. S. v. 1 Drum * * *.
(F. D. C. No. 36054. Sample No. 45675-L.)

LIBEL FILED: October 21, 1953, District of Massachusetts.

ALLEGED SHIPMENT: On or about March 24, 1953, by Nysco Laboratories, Inc. from Long Island City, N. Y.

PRODUCT: 1 drum containing 15,000 enteric coated *ammonium chloride tablets* at Wellesley, Mass.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Ammonium Chloride Tablets," a drug the name of which is recognized in the National Formulary, an official compendium, and the quality of the article fell below the official standard. The standard specifies that a coating may be applied to ammonium chloride tablets, provided that such coating will disintegrate in the alimentary tract. The tablets of the article would not disintegrate in the alimentary tract.

DISPOSITION: January 19, 1954. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS *

4317. Misbranding of Magique Lotion. U. S. v. 11 Cases, etc. (F. D. C. No. 35629. Sample Nos. 59170-L, 59171-L.)

LIBEL FILED: September 14, 1953, Southern District of Florida.

ALLEGED SHIPMENT: On or about July 9 and 18, 1953, by the Lovely Lady Products Co., from El Monte, Calif.

PRODUCT: *Magique Lotion.* 11 cases, each containing 24 cartons and each carton containing a circular entitled "The Magique Lotion Story" and 1 bottle of *Magique Lotion*, at Miami, Fla., together with a number of cards reading, in part, "Here is Another Little Hint on Magique Lotion."

*See also Nos. 4301, 4313, 4315.