4312. Misbranding of ovarian substance desiccated powder. U. S. v. 23 Bottles, etc. (F. D. C. No. 36223. Sample No. 62209–L.)

LIBEL FILED: January 5, 1954, Eastern District of Missouri.

ALLEGED SHIPMENT: On or about April 3, August 12, October 2, and November 16, 1953, from Chicago, Ill., and Omaha, Nebr.

PRODUCT: 23 1-ounce bottles, 2 4-ounce bottles, and 1 16-ounce bottle of *ovarian substance desiccated powder* at St. Louis, Mo., in possession of Narco Drug Co., Inc.

RESULTS OF INVESTIGATION: The product was shipped in bulk to St. Louis, Mo., and after its arrival there, was repackaged and relabeled upon instructions of Narco Drug Co., Inc.

LABEL, IN PART: (Bottle) "Narco * * * Ovarian Substance Desiccated * * * Caution: To be dispensed only by or on the prescription of a physician. Distributed by Narco Drug Co., Inc."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the repackaged article failed to bear adequate directions for use, and the article was not entitled to any exemption from that requirement. The article was misbranded in this respect while held for sale after shipment in interstate commerce.

DISPOSITION: February 2, 1954. Default decree of condemnation. The court ordered that the product be delivered to the Food and Drug Administration.

4313. Misbranding of Indian Arrow herb preparation. U. S. v. Indian Arrow Herb Products Co., Pedro W. Whitson, and Ruth Whitson. Pleas of guilty entered by individuals. Fine of $100 against each individual; no sentence imposed against company. (F. D. C. No. 35563. Sample No. 66031–L.)

INFORMATION FILED: December 22, 1953, Southern District of Ohio, against the Indian Arrow Herb Products Co., a partnership, and Pedro W. Whitson and Ruth Whitson, partners in the partnership.

ALLEGED SHIPMENT: On or about February 6, 1953, from the State of Ohio into the State of Illinois.

LABEL, IN PART: (Bottle) "Indian Arrow Herb Preparation Laxative Stomachic Contains the following active herb ingredients: Mayapple Root, Cascara Segrada Bark, Blacksnake Root, Bitter Root, Wild Cherry Bark, White Ash Bark, Wahoo Bark, Chamomille Herb, with Sarsaparilla Root, Elm Bark, Sugar, Caramel added for flavor and color and water * * * Contents 8 Fluid Ounces Prepared By Indian Arrow Herb Products Company P. W. Whitson, Herbalist 1559 Central Ave. Cincinnati (14), Ohio."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the accompanying labeling of the article, consisting of a letter dated February 12, 1953, were false and misleading. The statements represented and suggested that the article would be an adequate and effective treatment for all forms of rheumatics, tuberculosis, blood disorders, kidney and liver afflictions, syphilis, and tumors. The article would not be an adequate and effective treatment for such diseases and conditions.

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.)

LIBEL 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."