than 1.25 U. S. P. digitalis units, whereas each tablet when so assayed was found to possess a potency of more than 1.25 U. S. P. digitalis units.

Misbranding, Section 502 (a), the label statement "As assayed by the method described in U. S. P. XII for Digitalis, each tablet has a potency of 1.25 U. S. P. Digitalis units" was false and misleading; and, Section 502 (j), the article was dangerous to health when used in the dosage and with the frequency and duration suggested in the labeling, i. e., "As assayed by the method described in U. S. P. XII for Digitalis, each tablet has a potency of 1.25 U. S. P. Digitalis units * * * Caution: To be used only by or on the prescription of a physician." The quoted labeling suggested administration of the article in dosages appropriate for administration of tablets having a potency of 1.25 U. S. P. digitalis units, whereas if the drug were prescribed by a physician in reliance upon such statement of potency, the patient would receive approximately 2½ times the intended dosage of a potent drug.

DISPOSITION: November 5, 1947. A plea of guilty having been entered, the court imposed a fine of $100 on each of the two counts of the information.

2302. Misbranding of Thytocin with Pilocarpine. U. S. v. George A. Breon & Co., Inc. Plea of nolo contendere. Fine, $300 and costs. (F. D. C. No. 23262, Sample Nos. 50403–H, 55226–H, 83028–H.)

INFORMATION FILED: May 28, 1948, Western District of Missouri, against George A. Breon & Co., Inc., Kansas City, Mo.

ALLEGED SHIPMENT: On or about August 12, September 7, and October 23, 1946, from the State of Missouri into the States of Louisiana, Georgia, and Tennessee.

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statements "Each tablet contains: * * * Pilocarpine hydrochloride . . . 1/30 gr." was false and misleading, since each tablet of the article contained more than 1/30 grain of pilocarpine hydrochloride, i. e., in a portion of the article, approximately 0.429 grain and, in the remainder, 0.406 grain.

Further misbranding, Section 502 (j), the article was dangerous to health when used in the dosage and with the frequency and duration suggested in the labeling "Each tablet contains: * * * Pilocarpine hydrochloride . . . 1/30 gr. * * * Caution: To be dispensed only by or on the prescription of a physician." The labeling suggested administration of the article in dosages appropriate for administration of tablets having a potency of 1/30 grain of pilocarpine hydrochloride, whereas the article if administered in dosages appropriate for the administration of tablets having such potency, would be dangerous to health, since if prescribed by a physician in reliance upon such statement of potency, the patient would receive approximately 12 or 13 times the intended dosage of a potent drug.

DISPOSITION: June 23, 1948. A plea of nolo contendere having been entered, the court imposed a fine of $300 and costs.

2303. Adulteration and misbranding of Firmo cream. U. S. v. 12 Dozen Jars, etc. (F. D. C. No. 23401. Sample No. 90367–H.)

LIBEL FILED: August 6, 1947, District of Columbia.

PRODUCT: 12 dozen 2-ounce jars and 30 dozen 4-ounce jars of *Firmo cream*, together with a number of circulars. The product and circulars were in interstate commerce in the District of Columbia, in the possession of, and held for sale by, Maynard H. Smith, Washington, D. C. Examination showed that the product contained estradiol.

LABEL, IN PART: "Firmo Contains 7500 I. U. of Natural Estrogenic Hormones Per Oz. of Cream Directions Each night thoroughly cleanse the skin, then gently massage a generous amount of the cream into the tissue * * * Continental Sales Co. Wash., D. C."

NATURE OF CHARGE: Adulteration, Section 501 (d), an article containing estradiol had been substituted for an article containing natural estrogenic hormones.

Misbranding, Section 502 (a), the statements in the labeling which represented and suggested that the article was an aphrodisiac, were false and misleading, since the article was not an aphrodisiac; Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use; and, Sec-

tion 502 (j), the article was dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling.

DISPOSITION: April 9, 1948. Default decree of condemnation and destruction.

DRUG REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED

2304. Misbranding of penicillin sodium. U. S. v. 998 Cartons * * *. (F. D. C. No. 23192. Sample No. 64200–H.)

LIBEL FILED: June 18, 1947, Southern District of New York.

ALLEGED SHIPMENT: On or about March 28, 1947, by Barich, Inc., from Rutherford, N. J.

PRODUCT: 998 cartons, each containing 5 vials, of *penicillin sodium* at New York, N. Y.

LABEL, IN PART: (Cartons) "5 vials 100,000 Units Each Penicillin Sodium (Crystalline) * * * Eto Pharmacal Company, New York 17, New York."

NATURE OF CHARGE: Misbranding, Section 502 (a), the labeling of the article was misleading, since it failed to reveal the fact that Eto Pharmacal Company was not the manufacturer of the article, which fact was material in the light of the unmodified words "Eto Pharmacal Company" appearing on the label; and the label statement "Lot No. B 5 * * * Nov. 1, 49" was misleading, in that it represented and suggested that the article had been certified under such identifying mark in accordance with regulations promulgated by the Federal Security Administrator, whereas such was not the case.

Further misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use; and, Section 502 (l), the article was represented as a drug composed wholly of penicillin sodium, a derivative of a kind of penicillin, and it was not from a batch with respect to which a certificate or release had been issued pursuant to law.

DISPOSITION: December 17, 1947. Ekstrand & Tholand, Inc., claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond to be brought into compliance with the law, under the supervision of the Food and Drug Administration.

2305. Misbranding of penicillin sodium. U. S. v. 36 Cartons, etc. (F. D. C. No. 23178. Sample Nos. 54399–H, 54400–H.)

LIBEL FILED: June 6, 1947, Middle District of North Carolina.

ALLEGED SHIPMENT: On or about May 15, 1947, by the Institutional Products Co., from New York, N. Y.

PRODUCT: 36 cartons, each containing 5 500,000-unit vials, and 87 cartons, each containing 5 200,000-unit vials, of penicillin sodium at Winston-Salem, N. C.

LABEL, IN PART: "Penicillin Sodium Proctor * * * Proctor Laboratories 475 Fifth Avenue, New York * * * Lot No. 90 [or "Lot No. 77"]."

NATURE OF CHARGE: Misbranding, Section 502 (a), the labeling was misleading, since it failed to reveal the fact that Proctor Laboratories was not the manufacturer of the article, which fact was material in the light of the unmodified words "Proctor Laboratories" appearing thereon; and the label statements "Lot No. 90," appearing on the 36-carton lot, and "Lot No. 77, appearing on the 87-carton lot, were misleading, since they represented and suggested that the article had been certified under such identifying marks in accordance with the regulations, when such was not the case.

Further misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use; and, Section 502 (l), the article was represented as a drug composed wholly of penicillin sodium, a derivative of a kind of penicillin, and it was not from a batch with respect to which a certificate or release had been issued pursuant to the provisions of the Act.

DISPOSITION: March 24, 1948. Default decree of condemnation. The product was ordered delivered to a Federal institution.