FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

2301–2350

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys acting upon reports submitted by direction of the Federal Security Administrator.

OSCAR R. EWING, *Administrator, Federal Security Agency.*

WASHINGTON, D. C., *September 10, 1948.*

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DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

2301. Adulteration and misbranding of Anademin Tablets. U. S. v. Anademin Chemical Co. Plea of guilty. Fine, $200. (F. D. C. No. 21457. Sample No. 14079–H.)

INFORMATION FILED: May 5, 1947, Eastern District of Tennessee, against the Anademin Chemical Co., a corporation, Chattanooga, Tenn.

ALLEGED SHIPMENT: On or about April 8, 1946, from the State of Tennessee into the State of Ohio.

LABEL, IN PART: "Tablets Anademin Strophanthus 1/1500 grain (containing 1/15000 grain of Strophanthin), Squill 4¾ grains, Canadian Hemp (Apocynum) 1/64 grain and Elder Flowers (Sambucus) 1/32 grain * * * Assay: 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."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess, in that each tablet was represented to possess a potency, as assayed by the method described in the United States Pharmacopoeia XII for digitalis, of not more

*For presence of a habit-forming narcotic without warning statement, see No. 2309; omission of, or unsatisfactory, ingredients statements, Nos. 2306, 2307, 2331, 2333, 2342; imitation of, and sale under name of, another drug, No. 2312; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 2306, 2307, 2330, 2342; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 2330; cosmetics, subject to the drug provisions of the Act, Nos. 2331, 2337.

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-