

court ordered, however, that the execution of the sentence of 1 year be suspended upon payment of the fine.

The fine was paid on February 25, 1952, and on February 28 the sentence of 1 year in prison was suspended, and the defendant was placed on probation for 1 year.

3686. Misbranding of testosterone. U. S. v. Joseph C. Mills. Plea of guilty. Defendant sentenced to 7 days in prison. (F. D. C. No. 32745. Sample No. 28263-L.)

INFORMATION FILED: January 21, 1952, District of Arizona, against Joseph C. Mills, Tucson, Ariz.

ALLEGED SHIPMENT: On or about January 25, 1951, from the State of Arizona into the State of California, of a number of unlabeled ampuls of testosterone.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and it failed to bear a label containing the common or usual name of each active ingredient; and, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use.

Further misbranding, Section 502 (f) (2), the labeling of the article failed to bear adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, and against unsafe dosage and method and duration of administration, and such manner and form, as are necessary for the protection of users, in that the article was for use by injection into or through the skin and contained 24.7 milligrams of testosterone (male sex hormone) per cubic centimeter; and the labeling of the article failed to warn that its use by females may have masculinizing effects such as the development of excessive hair growth on the face and body, coarsening of the voice, acne, suppression of normal menstruation, enlargement of the clitoris, and decreasing the size of the breasts; that its use by males with carcinoma of the prostate may result in acceleration of the malignant growth; and that its use by children may induce precocious puberty.

DISPOSITION: March 12, 1952. A plea of guilty having been entered, the court imposed a sentence of 7 days in prison.

DRUGS ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

3687. Adulteration of celandine herb. U. S. v. 6 Bales * * *. (F. D. C. No. 32678. Sample No. 12093-L.)

LABEL FILED: February 19, 1952, Southern District of Ohio.

ALLEGED SHIPMENT: On or about January 5, 1951, from Jersey City, N. J.

PRODUCT: 6 bales, each containing 162 pounds, of *celandine herb* at Cincinnati, Ohio.

LABEL, IN PART: "Imported Great Celandine Herb * * * for Manufacturing or Repacking Use Only."

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy substance by reason of the presence of insects, insect fragments, and rodent hairs. The article was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: March 19, 1952. Default decree of condemnation and destruction.

3688. Adulteration of psyllium husks (*Plantago*). U. S. v. 113 Bags, etc.
(F. D. C. No. 31166. Sample Nos. 23106-L, 23107-L.)

LABEL FILED: June 1, 1951, Eastern District of New York.

ALLEGED SHIPMENT: On or about September 23 and October 20, 1950, from Sidhpur, India.

PRODUCT: 232 bags of *psyllium husks* (*Plantago*) at Brooklyn, N. Y.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the product consisted in whole or in part of a filthy substance by reason of the presence of insects. The product was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: June 22, 1951. Prentiss Drug & Chemical Co., Inc., Brooklyn, N. Y., having appeared as claimant, judgment of condemnation was entered and the court ordered that the product be released under bond to be brought into compliance with the law, by fumigating, cutting, sifting or blowing, and destruction of the unfit portion, under the supervision of the Food and Drug Administration. Salvage operations resulted in the release of 18,883 pounds of the product. The remaining 2,200 pounds were denatured and destroyed.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

3689. Adulteration and misbranding of belladonna tincture and paregoric. U. S. v. Ormont Drug & Chemical Co., Inc. Plea of guilty. Fine, \$525.
(F. D. C. No. 31267. Sample Nos. 74838-K, 91904-K, 91919-K, 92268-K, 22798-L to 22800-L, incl.)

INFORMATION FILED: January 7, 1952, Eastern District of New York, against Ormont Drug & Chemical Co., Inc., Long Island City, N. Y.

ALLEGED SHIPMENT: On or about June 21, September 8, October 13 and 19, November 9 and 16, and December 20, 1950, from the State of New York into the States of New Jersey and Connecticut.

LABEL, IN PART: "Ormont * * * Belladonna Tincture U. S. P. (Tinctura Belladonnae)" and "Ormont * * * Paregoric U. S. P. Tinctura Opii Camphorata."

NATURE OF CHARGE: Adulteration, Section 501 (b), both products were represented to be drugs, the names of which are recognized in the United States Pharmacopeia, an official compendium, and their strength differed from the standards set forth in such compendium; and their differences in strength from the official standards were not stated on their labels. The *belladonna tincture* yielded more than 33 milligrams of the alkaloids of belladonna leaf per 100 cc., and the *paregoric* yielded more than 45 milligrams of anhydrous morphine per 100 cc.

Misbranding, Section 502 (a) the statements "Belladonna Tincture U. S. P." and "Paregoric U. S. P." borne on the labels of the respective products were false and misleading since the statements represented and suggested that the drugs were of the strength established in the United States Pharmacopeia, whereas they were not of such strength in that the *belladonna tincture*