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.)

LIBEL 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*

yielded alkaloids of belladonna leaf in excess of the maximum provided by the Pharmacopeia, and the *paregoric* yielded anhydrous morphine in excess of the maximum so provided.

DISPOSITION: February 13, 1952. A plea of guilty having been entered on behalf of the defendant corporation, the court imposed a fine of $525.

3690. Adulteration and misbranding of conjugated estrogens. U. S. v. 11,288 Tablets * * *. (F. D. C. No. 32429. Sample No. 11619–L.)

LIBEL FILED: January 11, 1952, Northern District of Ohio.

ALLEGED SHIPMENT: On or about April 9, 1951, by the Keith-Victor Pharmacal Co., from St. Louis, Mo.

PRODUCT: 24 bottles containing a total of 11,288 tablets of *conjugated estrogens* at Cleveland, Ohio. Analysis showed that the product contained a total amount of estrogenic steroids calculated as 0.71 mg. of sodium estrone sulfate per tablet.

RESULTS OF INVESTIGATION: The tablets were contained in a drum when shipped in interstate commerce, and after receipt by the consignee, they were repackaged into bottles and relabeled.

LABEL, IN PART: (Drum) "Lot No. 7971 30,000 Sugar Coated Estrogen 1.25 Mg. Tablets."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess.

Misbranding, Section 502 (a), the following statement on the drum label was false and misleading as applied to an article whose equivalent in biological activity was less than that declared: "Each tablet contains: Naturally-occurring water-soluble conjugated estrogens equivalent in biological activity to 1.25 mg. of sodium estrone sulfate * * *."

DISPOSITION: March 11, 1952. Default decree of condemnation and destruction.

3691. Adulteration and misbranding of Beferm Elixir. U. S. v. 4 Bottles * * *. (F. D. C. No. 32452. Sample No. 10712–L.)

LIBEL FILED: January 28, 1952, Northern District of Illinois.

ALLEGED SHIPMENT: On or about October 26, 1951, from Woodworth, Wis.

PRODUCT: 4 1-gallon bottles of *Beferm Elixir* at Chicago, Ill. Analysis showed that the product contained approximately 62 percent of the declared amount of vitamin B_1 and approximately 60 percent of the declared amount of vitamin B_{12}.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, 25 mg. of vitamin B_1 and 10 mcg. of vitamin B_{12} in each fluid ounce.

Misbranding, Section 502 (a), the label statement "Each fluid ounce contains: * * * Vitamin B_1 25 mg. * * * Vitamin B_{12} (crystalline) 10 mcg." was false and misleading as applied to an article which contained less than the declared amounts of vitamins B_1 and B_{12}.

The article was adulterated and misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: March 10, 1952. Default decree of condemnation and destruction.