DRUG ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

4181. Misbranding of Special Formula cream. U. S. v. 8 Jars * * *. (F. D. C. No. 35320. Sample No. 58957–L.)

LIBEL FILED: June 22, 1953, Western District of Michigan.

ALLEGED SHIPMENT: On or about March 31, 1952, by Bette Knowlton, from Miami, Fla.

PRODUCT: 8 jars of *Special Formula cream* at Grand Rapids, Mich. Examination showed that the article contained estrogenic hormones equivalent to 54,000 International Units (5.4 mg.) of estrone per ounce.

RESULTS OF INVESTIGATION: On or about March 23, 1952, the consignee received at Miami, Fla., from the Bette Knowlton Laboratories, a 26-page mimeographed booklet dated May 14, 1951, entitled "Bette Knowlton Reference Manual," to be used in the sale and use of the Bette Knowlton products. This booklet subsequently was transported by the consignee from Miami, Fla., to Grand Rapids, Mich. In addition, Bette Knowlton shipped from Miami, Fla., to Grand Rapids, Mich., on or about February 1, 1953, a number of leaflets entitled "Bette Knowlton Fortune In Loveliness" and one booklet entitled "Bette Knowlton Reference Notes."

LABEL, IN PART: (Jar) "Bette Knowlton Special Formula Cream 2 Oz. * * * Hormone & Vitamin A Formula. Contains Type A Natural Extrogenic Substance, 50,000 I. U. per oz., and Vitamin A, 10,000 units per oz."

NATURE OF CHARGE: Misbranding, Section 502 (j), the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling, namely, the jar label and the above-mentioned leaflets and booklets, since the labeling provided for the daily application of 1,800 International Units of estrogens as estrone over an extended and indefinite period of time, an amount which would cause injury to health.

DISPOSITION: July 9, 1953. Default decree of condemnation and destruction.

NEW DRUG SHIPPED WITHOUT EFFECTIVE APPLICATION

4182. Pyrilamine maleate-dextro-amphetamine sulfate. U. S. v. 187 Cartoned Vials * * *. (F. D. C. No. 35259. Sample No. 70469–L.)

LIBEL FILED: May 13, 1953, Northern District of Ohio.

ALLEGED SHIPMENT: On or about February 13, 1953, by Addison Laboratories, from Philadelphia, Pa.

PRODUCT: 187 cartoned vials of *pyrilamine maleate-dextro-amphetamine sulfate* at Mansfield, Ohio. Analysis showed that the product contained essentially the amount of pyrilamine maleate stated on its label and 0.5 percent of phenol.

LABEL, IN PART: (Vial) "10 cc. Multiple-Dose Vial List No.: 1059 Pyrilamine Maleate-Dextro Amphetamine Sulphate Each cc. contains: Pyranisamine maleate 25 mg., Dextro Amphetamine Sulphate 2 mg."

NATURE OF CHARGE: Section 505 (a), the article was a new drug within the meaning of the law, and an application filed pursuant to the law was not effective with respect to the article.

DISPOSITION: June 11, 1953. Default decree of condemnation and destruction.