2717. Misbranding of Thermapax Health Applicator. U. S. v. 6 Devices * * *. (F. D. C. No. 26672. Sample No. 53117–K.)

LIBEL FILED: March 2, 1949, Northern District of Alabama.

ALLEGED SHIPMENT: On or about February 26, 1949, by Rhys Davies, from Fort Wayne, Ind.

PRODUCT: 6 devices known as *Thermapax Health Applicator* at Birmingham, Ala. The device consisted of an electric heating coil in a metal helmet.

LABEL, IN PART: "Thermo-Magno-Ray Thermapax Health Applicator."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement "Health Applicator" represented and suggested that the article was beneficial in regaining and maintaining health, whereas the article was not beneficial for such purposes; and, Section 502 (f) (1), the labeling of the article bore no directions for use.

DISPOSITION: April 25, 1949. Rhys Davies, claimant, having consented to the entry of a decree, judgment of condemnation was entered and the devices were ordered released under bond for relabeling, under the supervision of the Federal Security Agency.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

2718. Adulteration of solution of thiamine hydrochloride. U. S. v. 94 Vials * * *. (F. D. C. No. 25683. Sample Nos. 43456–K, 43457–K.)

LIBEL FILED: October 15, 1948, Northern District of Illinois.

ALLEGED SHIPMENT: On or about August 2, 1948, by the Dabney Pharmacal Co., from Louisville, Ky.

PRODUCT: 94 30-cc. vials of solution of *thiamine hydrochloride* at Chicago, Ill.

LABEL, IN PART: "Solution Thiamine Hydrochloride For Intramuscular or Subcutaneous use."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Thiamine Hydrochloride Injection," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its quality and purity fell below the official standard since the article was contaminated with undissolved material.

DISPOSITION: March 17, 1949. Default decree of condemnation and destruction.

2719. Adulteration and misbranding of chorionic gonadotropin. U. S. v. 60 vials * * *. (F. D. C. No. 26584. Sample No. 11266–K.)

LIBEL FILED: March 3, 1949, Southern District of New York.

ALLEGED SHIPMENT: On or about October 28, 1948, by Associated Ross-Good Laboratories, Inc., from Philadelphia, Pa.

PRODUCT: 60 10-cc. vials of *chorionic gonadotropin* at New York, N. Y. The article was shipped unlabeled and was labeled by the consignee.

LABEL, IN PART: "Sterile Chorionic Gonadotropin for Intramuscular Injection."

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported to possess since it was for parenteral administration and was not sterile.

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*See also No. 2729.

Misbranding, Section 502 (a), the label statement "sterile" was false and misleading as applied to an article that was not sterile but was contaminated with viable micro-organisms. The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: April 19, 1949. Default decree of condemnation and destruction.

2720. Adulteration and misbranding of estrogenic substance. U. S. v. 48 Vials * * *. (F. D. C. No. 26613. Sample Nos. 11258–K, 11271–K.)

LIBEL FILED: February 24, 1949, District of New Jersey.

ALLEGED SHIPMENT: On or about November 24, 1948, by Estro Chemical Co., Inc., from New York, N. Y.

PRODUCT: 48 10-cc. vials of *estrogenic substance* at Union City, N. J. The product was shipped under a label identical to that set forth below, except that the brand name "Aqua-Gyne" and the name and address of the manufacturer, the Estro Chemical Co., appeared thereon in place of the brand name "Aquacrine" and the name and address of the distributor, the Endocrine Co.

LABEL, IN PART: "Aquacrine Aqueous Estrogenic Substance * * * Distributed By Endocrine Company, Union City, N. J."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, 97 percent of the amount of estrone necessary to produce a potency of 20,000 International Units per cubic centimeter.

Misbranding, Section 502 (a), the label statement "Each cc * * * contains * * * Estrogenic Substances (predominantly Estrone) * * * (Ketosteroids as Estrone, approximately 97% by potency). * * * equivalent to 20,000 I. U. (assayed in terms of Estrone)" was false and misleading as applied to the article, which contained materially less than 97 percent of the amount of estrone necessary to produce a potency of 20,000 International Units per cubic centimeter.

DISPOSITION: May 2, 1949. Default decree of condemnation. The product was ordered delivered to the Food and Drug Administration, for experimental purposes.

2721. Adulteration and misbranding of chloro-iodo-hydroxy-quinoline. U. S. v. 1 Drum * * *. (F. D. C. No. 26938. Sample No. 11345–K.)

LIBEL FILED: March 21, 1949, District of New Jersey.

ALLEGED SHIPMENT: On or about May 25, 1948, by the R. S. A. Corp., from Ardsley, N. Y.

PRODUCT: 1 25-pound drum of *chloro-iodo-hydroxy-quinoline* at South Hackensack, N. J.

NATURE OF CHARGE: Adulteration, Section 501 (d) (2), di-iodo-hydroxy-quinoline had been substituted in part for chloro-iodo-hydroxy-quinoline.

Misbranding, Section 502 (a), the name "Chloro-Iodo-Hydroxyquinoline" was false and misleading as applied to the article, which consisted of a mixture of chloro-iodo-hydroxy-quinoline and di-iodo-hydroxy-quinoline.

DISPOSITION: May 2, 1949. Default decree of condemnation. One pound of the product was ordered delivered to the Food and Drug Administration, for experimental purposes, and the remainder was ordered destroyed.