DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

4010. Adulteration and misbranding of amphetamine sulfate tablets. U. S. v. 11 Bottles * * *. (F. D. C. No. 31380. Sample No. 11171-L.)

LIBEL FILED: July 23, 1951, Northern District of Ohio.

ALLEGED SHIPMENT: On or about the first quarter of 1950 by the International Pharmaceutical Laboratories, from Great Neck, N. Y.

PRODUCT: 11 unlabeled 1,000-tablet bottles of *amphetamine sulfate tablets.* Examination showed that each tablet contained not more than 8.6 milligrams of amphetamine sulfate. The product was represented by a representative of the shipper to be 10-milligram amphetamine sulfate tablets.

NATURE OF CHARGE: Adulteration, Section 501 (d) (2), a substance, namely, 8.6-milligram *amphetamine sulfate tablets*, had been substituted for 10-milligram amphetamine sulfate tablets.

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; and, Section 502 (e) (1), the label of the article failed to bear the common or usual name of the article, namely, "*amphetamine sulfate tablets.*"

DISPOSITION: The Lipton Drug Sales Co., Cleveland, Ohio, claimant, filed an answer admitting that the drug was shipped unlabeled but denying that the drug was adulterated and misbranded, together with a set of interrogatories to be answered by the Government.

After the Government answered the interrogatories, it filed a motion for summary judgment. On November 20, 1951, the court granted the Government's motion, on the ground that there was no genuine issue on the material fact that the product was transported from New York to Ohio without being labeled and was therefore subject to seizure as a misbranded drug. On January 21, 1952, a decree was entered providing for the condemnation and destruction of the product.

4011. Adulteration of sulfadiazine tablets. U. S. v. 13 Bottles * * *. (F. D. C. No. 33275. Sample No. 37685-L.)

LIBEL FILED: June 3, 1952, Eastern District of New York.

ALLEGED SHIPMENT: On or about May 7, 1952, by the Berkeley Drug Co., from Boston, Mass.

PRODUCT: 13 1,000-tablet bottles of *sulfadiazine tablets* at Brooklyn, N. Y.

LABEL, IN PART: (Bottle) "1000 Sulfadiazine * * * (2-Sulfanilamidopyrimidine) Compressed Tablets (scored) 0.5 Gm. (7.7 Grains)."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Sulfadiazine Tablets," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and its strength differed from the official standard. The standard provides that sulfadiazine tablets contain not less than 95 percent of the labeled amount of sulfadiazine, whereas the article contained not more than 77 percent of the labeled amount of sulfadiazine.

DISPOSITION: May 26, 1953. Default decree of condemnation and destruction.