

**DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL
OR OWN STANDARDS***

3628. Adulteration of phenobarbital tablets. U. S. v. 4 Bottles, etc. (F. D. C. No. 31399. Sample Nos. 25563-L, 25565-L.)

LABEL FILED: July 27, 1951, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about May 25, 1951, by the Robin Pharmacal Corp., from New York, N. Y.

PRODUCT: *Phenobarbital tablets.* 4 25,000-tablet bottles, 12 1,000-tablet bottles, and 20 5,000-tablet bottles of green tablets, and 1 drum of 280,000 tablets, and 15 1,000-tablet bottles, 8 5,000-tablet bottles, and 3 25,000-tablet bottles of white tablets at Philadelphia, Pa.

RESULTS OF INVESTIGATION: The interstate shipment of the tablets was made in bulk containers. After receipt of the shipment, a portion of the tablets was repackaged into bottles and relabeled by the consignee.

Analysis showed that the green tablets contained not more than 62 percent of the labeled amount of phenobarbital, whereas the United States Pharmacopeia provides that phenobarbital tablets contain not less than 94 percent of the labeled amount of phenobarbital. Further analysis showed that the white tablets failed to meet the test specified in the United States Pharmacopeia regarding permissible variation in the weight of individual tablets and the time required by the tablets to disintegrate in water.

LABEL, IN PART: (Bottle) "Phenobarbital $\frac{1}{2}$ Grain * * * Green [or "White"]."

NATURE OF CHARGE: Adulteration, Section 501 (b), the product purported to be and was represented as "Phenobarbital Tablets," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and the strength (green tablets) differed from, and the quality (white tablets) fell below, the standard set forth in the compendium. The tablets were adulterated when introduced into, while in, and while held for sale after shipment in, interstate commerce.

DISPOSITION: November 29, 1951. Default decree of condemnation and destruction.

3629. Adulteration and misbranding of Estrotron (estrogenic hormone). U. S. v. 9 Dozen bottles * * *. (F. D. C. No. 31208. Sample No. 28281-L.)

LABEL FILED: June 21, 1951, Northern District of California.

ALLEGED SHIPMENT: On or about July 6 and 31, 1950 by the Pitman-Moore Co., Div. of Allied Laboratories, Inc., from Indianapolis, Ind.

PRODUCT: 9 dozen bottles of *Estrotron* at Sacramento, Calif. Examination showed that the product contained not more than 1.64 milligrams of estrogenic ketosteroids per cubic centimeter.

LABEL, IN PART: (Bottle and carton) "10 cc. Size * * * Estrotron 2 mg. (20,000 I. U.) per cc. in Peanut Oil A highly purified estrus producing extract from the urine of pregnant mares, consisting primarily of estrone with smaller quantities of naturally occurring estrogens, dissolved in Peanut Oil and standardized to 20,000 I. U. of activity per cc."

*See also No. 3621.