DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

4887. Savatan capsules. (F. D. C. No. 37996. S. No. 13–551 M.)

QUANTITY: 17 boxes at Philadelphia, Pa., in possession of Al Breitman, t/a Bright Cut Rate Drugs.

SHIPPED: 7–25–52, from St. Louis, Mo.

LABEL IN PART: (Box) "24 Capsules Savatan Each capsule contains Apiol (Green) 5 min. Caution: Federal law prohibits dispensing without prescription."

RESULTS OF INVESTIGATION: Bright Cut Rate Drugs was a retail establishment not regularly engaged in the dispensing of prescription drugs and did not have a licensed pharmacist in attendance.

LIBELED: 5–27–55, E. Dist. Pa.

CHARGE: 502 (f) (1)—the labeling of the article, while held for sale, failed to bear adequate directions for use, and the article was not exempted from such requirement since it was a prescription drug and was in the possession of a retail establishment which was not a retail, hospital, or clinic pharmacy, or a public health agency, regularly and lawfully engaged in dispensing prescription drugs.

DISPOSITION: 7–27–55. Default—destruction.

4888. Cephasal tablets. (F. D. C. No. 37904. S. No. 3–236 M.)

QUANTITY: 370 btls. at Hartford, Conn.

SHIPPED: During 1952 and 1953, from Newark, N. J., by Chase Chemical Co., Inc.

LABEL IN PART: (Btl.) "100 Tablets No. 253 Cephasal * * * Anodyne and Antipyretic Distributed by Richale Pharmaceutical Co. * * * Hartford, Conn. Each tablet contains: Acetylsalicylic Acid 3.5 grains Caffeine Citrated 0.5 grains Phenacetin 2.5 grains Ascorbic Acid 25.0 mg. To be used by or on the prescription of a physician only."

RESULTS OF INVESTIGATION: Examination showed that the article contained 21.3 milligrams of ascorbic acid, 2.62 grains of aspirin (acetylsalicylic acid), 0.47 grain of salicylic acid, and 0.22 grain of caffeine, per tablet.

LIBELED: 3–25–55, Dist. Conn.

CHARGE: 501 (c)—the strength of the article, while held for sale, differed from that which it was represented to possess; and 502 (a)—while held for sale, the label statement "Each tablet contains: Acetylsalicylic Acid 3.5 grains Caffeine Citrated 0.5 grains * * * Ascorbic Acid 25.0 mg." was false and misleading.

502 (a)—the statement on the label of the article, when shipped, namely, "To be used by or on the prescription of a physician only," was false and misleading since the statement represented that the article was one which should be used only under the supervision of a physician, when such was not the case; and 502 (f) (1)—the labeling of the article, when shipped, failed to bear adequate directions for use since its label failed to bear directions under which the article could safely be used by the layman and a statement of the purposes for which it was intended.

DISPOSITION: 5–18–55. Consent—destruction.