

DISPOSITION: 11-21-61. Default—destruction.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS*

6911. Amphetamine sulfate tablets. (F.D.C. No. 45558. S. Nos. 23-991 R, 24-251 R.)

INFORMATION FILED: 3-23-61, Dist. Kans., against John Richard Sallee.

ALLEGED VIOLATION: On 12-9-60, a number of unlabeled paper bags containing *amphetamine sulfate tablets* were caused to be shipped from Missouri to Kansas.

CHARGE: When shipped, the tablets failed to bear a label containing, 502(b) (1)—the name and place of business of the manufacturer, packer, or distributor; 502(b) (2)—an accurate statement of the quantity of contents in terms of numerical count; 502(e) (1)—the common or usual name of the drug; 502(f) (1)—adequate directions for use; 502(f) (2)—adequate warnings against use; and 503(b) (4)—the tablets were drugs subject to 503(b) (1) and they did not bear a label containing the statement "Caution: Federal law prohibits dispensing without prescription."

PLEA: Guilty.

DISPOSITION: 6-8-61. 1 year imprisonment to run concurrently with the sentence imposed on the defendant as reported in notices of judgment on drugs and devices, No. 6961 (F.D.C. No. 45254).

6912. Various prescription drugs. (F.D.C. No. 45932. S. Nos. 36-112 R, 36-114/18 R.)

QUANTITY: 2 ctns., 3 shopping bags, and 8,149 btl., pkgs., and/or boxes, having an approximate total value of \$5,000, at Palisades Park, N.J., in possession of Marshel Sales Co. (Samuel Udin).

SHIPPED: On unknown dates, by various drug handlers.

LABEL IN PART: (Some labels) "Complimentary," "Physician's Sample," or similar wording.

RESULTS OF INVESTIGATION: Some of the articles were unlabeled bottles which had been repacked by the dealer from physicians' samples received from various drug manufacturers' salesmen from outside the State of New Jersey. Some of the articles consisted of quantities of prescription drugs originally intended for use as samples for physicians and others lawfully engaged in dispensing prescription drugs, and bearing labels containing "Caution: Federal law prohibits dispensing without prescription" and the words "Complimentary," "Physicians Sample," or similar wording, and the names and addresses of manufacturers, packers, or distributors located outside the State of New Jersey.

LIBELED: 6-9-61, Dist. N.J.; amended libel 6-13-61.

CHARGE: 502(a)—while held for sale, the statements "Complimentary," "Physicians Sample," and similar wording borne on the labels of the articles of drug which had not yet been repacked by the dealer were false and misleading as applied to such articles in possession of a repacker and intended for sale and not intended for use as "complimentary—not for sale" samples for physicians and others lawfully engaged in dispensing prescription drugs; 502(b)—the repacked articles of drug failed to bear a label containing (1) the

*See also Nos. 6901, 6904, 6908.

name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of the contents; 502(e) (1)—the repacked articles of drug failed to bear the common or usual name of the drug; 502(f) (1)—the labeling of the repacked articles of drug failed to bear adequate directions for use, and the articles were not exempt from that requirement since they were drugs subject to the provisions of 503(b) (1) and their labels failed to bear an identifying lot number as required by regulations; 503(b) (4)—the repacked articles of drug failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 7-26-61. Default—destruction.

6913. Various prescription drugs. (F.D.C. No. 46457. S. Nos. 43/48 T.)

QUANTITY: 2,789 tablets and capsules and 42 btls. of liquids at Jacksonville, Fla., in possession of Fuqua's San Marco Pharmacy.

SHIPPED: On unknown dates, by various drug handlers.

LABEL IN PART: (Some labels) "Professional Sample."

RESULTS OF INVESTIGATION: The articles consisted of quantities of prescription drugs repacked from physicians' samples into containers having labels bearing brand names indicative of manufacture outside the State of Florida and bearing the words "Professional Sample" or similar wording and the names and addresses of the manufacturers, packers, or distributors outside the State of Florida; quantities of prescription drugs which were not yet repacked, originally intended for use as samples, and still in the original sample packages bearing the names and addresses of manufacturers, packers, or distributors outside the State of Florida; and quantities of prescription drugs in unlabeled containers.

LIBELED: 9-15-61, S. Dist. Fla.

CHARGE: 502(a)—while held for sale, the statement "Professional Sample" or similar wording on the labels of a number of the articles of drug was false and misleading as applied to the articles in the possession of a repacker and intended for sale and not intended for use as "complimentary—not for sale" samples for physicians and others lawfully engaged in dispensing prescription drugs; 502(b)—the unlabeled articles of drug failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor and (2) an accurate statement of the quantity of contents; 502(e) (1)—the unlabeled articles of drug failed to bear labels containing the common or usual name of the drugs; 502(f) (1)—the labeling of the articles in unlabeled containers failed to bear adequate directions for use; and 503(b) (4)—the unlabeled articles of drug were subject to the provisions of 503(b) (1) and failed to bear labels containing the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 11-14-61. Default—destruction.

6914. Various prescription drugs. (F.D.C. No. 46094. S. Nos. 97-641/56 R, 97-659/60 R, 97-741/5 R.)

QUANTITY: 5,105 tablets and capsules in 202 boxes, folders, vials, and btls., at Erie, Pa., in possession of Eckerd's Kwik-Chek, Inc.

SHIPPED: Between 6-9-59 and 6-28-61, from Buffalo, N.Y., by Niagara Drug Co. of Buffalo, Inc., and on an unknown date by an unknown drug handler.