

LABEL IN PART: (Some labels) "For Investigational Use Not to be Sold," "Professional Sample," "Complimentary," and "Physician's Professional Package."

LIBELED: 8-4-61, W. Dist. Pa.

CHARGE: 502(a)—when shipped and while held for sale, the statements "Professional Sample," "Complimentary," "Physician's Professional Package," and similar wording on the labels of a number of the articles of drug were false and misleading as applied to articles in the possession of a repacker and intended for sale and not intended for use as "complimentary-not for sale" samples for physicians or others lawfully engaged in dispensing prescription drugs; and the statement "For Investigational Use Not To Be Sold" on the label of one of the drugs, when shipped, was false and misleading as applied to an article which was intended for sale and not intended for investigational use; 502(b)(1)—a number of the articles of drug failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; 502(f)(1)—the labeling of a number of the articles failed to bear adequate directions for use and they were not exempt from that requirement since they were subject to the provisions of 503(b)(1) and their labels failed to bear an identifying lot or control number from which it was possible to determine the complete manufacturing history as is required by regulations; and 503(b)(4)—a number of the articles of drug were subject to the provisions of 503(b)(1) and their labels failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 10-16-61. Default—destruction.

6915. Various prescription drugs. (F.D.C. No. 46739. S. Nos. 12-881/3 T, 12-886 T, 12-888 T, 12-892 T, 12-894 T, 12-898/900 T.)

QUANTITY: Various quantities of tablets and capsules at Chicago, Ill., in possession of Solomon Cooper Drugs.

SHIPPED: On unknown dates, by various drug handlers.

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 Illinois, and the words "Physician's Sample," "Physician's Professional Package," "Professional Sample," "Complimentary," or similar wording; and quantities of prescription drugs which were not yet repacked, originally intended for use as samples, and bearing labels containing the words "Professional Sample," "Physician's Professional Package," "Sample Not To Be Sold," "Complimentary," or similar wording, and the names and addresses of the manufacturers, packers, or distributors located outside the State of Illinois.

LIBELED: 11-21-61, N. Dist. Ill.

CHARGE: 502(a)—while held for sale, the sample legends appearing on the labels affixed to the articles were false and misleading as applied to the articles in the possession of the 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, and the labeling of a number of articles whose expiration dates had expired also was misleading as applied to the articles which were not suitable for use after their expiration date had expired; 502(b)—a number of the 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(f) (1)—the labeling of a number of the articles failed to bear adequate directions for use and they were not exempt from that requirement since they were subject to the provisions of 503(b) (1) and their labels failed to bear an identifying lot or control number from which it was possible to determine the complete manufacturing history as is required by regulations, and the labeling of a number of the articles whose expiration dates had expired also failed to bear adequate directions for use after their expiration dates; and 503(b) (4)—the articles of drug were subject to the provisions of 503(b) (1) and the labels of a number of the articles failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 12-27-61. Default—destruction.

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

6916. Amphetamine tablets and capsules. (F.D.C. No. 45434. S. No. 65-474 R.)

QUANTITY: Unknown quantities at Salemburg, N.C., in possession of DeWitt Clinton Bowman, t/a Carolina Drug Associates.

SHIPPED: Prior to 3-1-61, from outside the State of North Carolina.

LIBELED: 2-24-61, E. Dist. N.C.; amended libel 5-26-61.

CHARGE: 502(f) (1)—while held for sale, the labeling of the articles failed to bear adequate directions for use for the purpose for which they were intended and the articles were not exempt from such requirement since they were not to be dispensed in accordance with 503(b).

DISPOSITION: 1-18-62 and 1-26-62. Default—delivered for use of various hospitals.

6917. Amphetamine tablets and capsules. (F.D.C. No. 45533. S. Nos 65-476/7 R.)

QUANTITY: Unknown quantities at Salemburg, N.C., in possession of DeWitt Clinton Bowman, t/a Carolina Drug Associates.

SHIPPED: Prior to 3-1-61, from outside the State of North Carolina.

LIBELED: 3-1-61, E. Dist. N.C.; amended libel 5-26-61.

CHARGE: 502(f) (1)—while held for sale, the labeling of the articles failed to bear adequate directions for use for the purpose for which they were intended and the articles were not exempt from such requirements since they were not to be dispensed in accordance with 503(b).

DISPOSITION: 1-18-62. Default—delivered for use of a Federal hospital.

6918. Nutri-Bio food supplements. (F.D.C. No. 46814. S. Nos. 54-916 T, 55-001/4 T.)

QUANTITY: 213 ctns., containing 2 pkgs. of 13 plastic envelopes each; 53 ctns., 60 envelopes each; 48 ctns., containing 3 pkgs. of 8 envelopes each; 15 1-lb. pkgs. and 2 3-lb. pkgs., at Charlotte, N.C., in possession of T & G Enterprises.

SHIPPED: Between 8-1-61 and 11-30-61, from Beverly Hills, Calif.

LABEL IN PART: (213-ctn. lot) "Nutri-Bio dietary food supplement natural or organic Vitamins and Minerals from natural food sources * * * 728 Mineral Tablets 364 Vitamin Tablets"; (53-ctn. lot) "Nutri-Bio baby-bio 60 five gram Baby-Paks 300 grams net wt.; (48-ctn. lot) "Nutri-Bio * * * dietary

*See also Nos. 6902, 6908, 6911-6915.