

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

6583. Vitamin B₁₂ tablets and Folibex 12 Capsulettes. (F.D.C. No. 45497. S. Nos. 3-417/8 R.)

QUANTITY: 46 100-tablet btl. of *vitamin B₁₂ tablets*; and 3 drums containing a total of approximately 56,840 tablets, 15 250-tablet btl., 41 100-tablet btl., and 78 50-tablet btl. of *Folibex 12 Capsulettes*, at Washington, D.C., in possession of Babbitt Cut Rate Stores, Inc.

SHIPPED: 3-19-60, from Long Island City, N.Y. (*vitamin B₁₂ tablets*), and 6-2-60, from Cleveland, Ohio (*Folibex 12 Capsulettes*).

LABEL IN PART: (Btl.) "Vitamin B₁₂ Tablets 50 mcg. * * * Distributed by National Vitamin Corporation, Washington, D.C. Indications: As an Appetite Stimulant"; (drum) "Manufactured for: Babbitt Drug Co. Washington, D.C. Contents 24,420 * * * No. 50 Dark Red Code: O.A.D.E. Lot No. 4557 Formula Contains"; and (btl.) "Folibex 12 Each Capsulette Contains: Vitamin B₁₂ . . . 10 mcg. (as present in concentrated extractives from streptomyces fermentations). Ferrous Sulfate Exsiccated. . . . 200 mg. Liver Fraction-2. . . . 300 mg. Folic Acid. . . . 0.33 mg. Vitamin C. . . . 75 mg. Distributed by General Vitamin Corp. Washington, D.C. * * * Average Adult Dose 3 Capsulettes Daily as Directed by the Physician."

RESULTS OF INVESTIGATION: The articles were shipped in bulk and repacked and labeled by the dealer.

LIBELED: 2-27-61, Dist. Columbia.

CHARGE: *Vitamin B₁₂ tablets*, 502(a)—while held for sale, the label statement "Indication: As an Appetite Stimulant" was false and misleading since it was contrary to fact.

Folibex 12 Capsulettes, 503(b) (4)—while held for sale, the article was subject to 503(b) (1) and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

The libel alleged also that another article was misbranded under the provisions of the Act relating to foods, as reported in notices of judgment on foods.

DISPOSITION: 6-8-61. Consent—claimed by Babbitt Cut Rate Stores, Inc., and released for relabeling.

6584. Amphetamine sulfate tablets. (F.D.C. No. 45472. S. No. 24-125 R.)

QUANTITY: 20,000 tablets at Kansas City, Kans., in the possession of John Richard Sallee.

SHIPPED: 2-16-61, from outside the State of Kansas.

LIBELED: 2-16-61, Dist. Kans.

CHARGE: 502(b)—while held for sale, the article failed to bear labels containing (1) the name and place of business of the manufacturer, packer, or distributor and (2) an accurate statement of the quantity of contents in terms of weight, measure, or numerical count; 502(e) (1)—the labels failed to bear the common or usual name of the drug; 502(f) (1)—the labeling failed to bear adequate directions for use and the article was not exempt from that requirement since it was a prescription drug in the possession of a person not lawfully engaged in dispensing prescription drugs; and 503(b) (4)—the article was subject to 503(b) (1) and it failed to bear the label statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 6-13-61. Default—destruction.