interstate commerce, the drug which was designated as *"Hope's Worm-Rid"* and labeled for use without a prescription in the treatment of worm infestation in humans, or any other drug of similar composition and labeling unless and until an application filed pursuant to 505(b) is effective with respect to such drug.

**6582. Dexules timed disintegration capsules and Phenamine tablets.** (F.D.C. No. 44896. S. Nos. 21–435/6 R.)

QUANTITY: 97 30-capsule btls. of *Dexules timed disintegration capsules* and 97 90-tablet btls. of *Phenamine tablets*, at Cleveland, Ohio.

SHIPPED: 5–10–60 and 6–1–60, from Syracuse, N.Y., by Approved Pharmaceuticals Corp.

LABEL IN PART: (Btl.) "Timed Disintegration Dexules All Day Appetite Suppressant Approved Pharmaceutical Corp. Syracuse * * * New York Each Capsule Contains: Phenylpropanolamine Hydrochloride 75 mg., Protein Hydrolysate 15 mg. specially prepared to disintegrate over a 8 to 10 hour period for continuous appetite suppression. Dosage * * * Caution * * * 01136" and "30 Day Treatment Phenamine For Appetite Suppression To Aid Weight Reduction Nydegger Pharmacy, 22 Colonial Arcade Dist. Cleveland 14, Ohio Each tablet contains Phenylpropanolamine Hydrochloride 25 mg. Dosage * * * Caution."

LIBELED: 9–20–60, N. Dist. Ohio.

CHARGE: *Dexules timed disintegration capsules*, 502(a)—when shipped, the bottle label of the article contained false and misleading representations that the article was adequate and effective as a treatment for appetite suppression; 502(a)—the statements "Just One Capsule Suppresses Appetite All-Day-Long" and "Just One-A-Day Reduce 5–10–20 Pounds," appearing on the shipping carton label, represented and suggested that the article was adequate and effective as an appetite suppressant, that it would suppress appetite all day long, and that it was adequate and effective to reduce weight, which statements were false and misleading since the article was not adequate and effective for such conditions and purposes; and 505(a)—the article was a new drug which may not be introduced into interstate commerce since an application filed pursuant to 505(b) was not effective with respect to such drug.

*Phenamine tablets*, 502(a)—when shipped, the bottle label of the article contained false and misleading representations that the article was adequate and effective as a treatment for appetite suppression and weight reduction; and 502(a)—the statements "Reduce," "Eat Less—No Hunger Pangs—Safe Now! Lose Weight Scientifically – A True Appetite Depressant," and "Appetite Depressant Tablets," appearing on the shipping carton label, represented and suggested that the article was adequate and effective as a treatment for appetite suppression and weight reduction, which statements were false and misleading since the article was not adequate and effective as a treatment for such conditions and purposes.

DISPOSITION: Nydegger Pharmacal Co., Cleveland, Ohio, and Approved Pharmaceuticals Corp., Syracuse, N.Y., claimants, filed an answer denying that the articles were misbranded. The Government then served interrogatories upon the claimants. On 6–6–61, the claimants having failed to answer the interrogatories, the court granted the Government's motion for default judgment, and entered a decree of condemnation and destruction.

## DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

**6583. Vitamin $B_{12}$ tablets and Folibex 12 Capsulettes.** (F.D.C. No. 45497. S. Nos. 3-417/8 R.)

QUANTITY: 46 100-tablet btls. of *vitamin $B_{12}$ tablets;* and 3 drums containing a total of approximately 56,840 tablets, 15 250-tablet btls., 41 100-tablet btls., and 78 50-tablet btls. 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 $B_{12}$ tablets*), and 6-2-60, from Cleveland, Ohio (*Folibex 12 Capsulettes*).

LABEL IN PART: (Btl.) "Vitamin $B_{12}$ 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 $B_{12}$ . . . 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 $B_{12}$ 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.