5483. Vitamin B_{12} injection. (F.D.C. No. 40987. S. No. 75–640 M.)

QUANTITY: 87 vials at Los Angeles, Calif.

SHIPPED: 10–22–57 and 10–31–57, from Philadelphia, Pa., by Philadelphia Ampoule Laboratories.

LABEL IN PART: "10 cc * * * Multiple Dose Vial Brown Balamin-1000 * * * For Intravenous or Intramuscular Use Each cc contains: 1000 Micrograms Vitamin B_{12} Crystalline U.S.P. Preservative: Benzyl Alcohol 1.5% This product made with Isotonic Sodium Chloride Solution USP."

RESULTS OF INVESTIGATION: Examination showed that each cubic centimeter of the article contained 1,027 micrograms of cyanocobalamin (vitamin B_{12}), 7.46 milligrams of sodium chloride, and a substantial amount of unidentified dissolved material, the presence of which was not stated on the label.

LIBELED: 12–13–57, S. Dist. Calif.

CHARGE: 501(b)—the article purported to be and was represented as "Cyanocobalamin Injection," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and the quality and purity of the article, when shipped, fell below the standard set forth in the compendium since the article contained a substantial amount of unidentified dissolved material, the presence of which is not permitted under the terms of the United States Pharmacopeia monograph for cyanocobalamin injection; and 505(a)—the article, because of the presence of unidentified dissolved material, was a new drug within the meaning of the law, and an application filed pursuant to the law was not effective.

DISPOSITION: 1–20–58. Default—destruction.

DRUGS REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED

5484. Elixir Sedalet and penicillin tablets with sulfonamides. F.D.C. No. 40655. S. Nos. 67–551/3 M, 67–557 M.)

QUANTITY: 720 btls. (lot No. 5881–VR), 45 btls. (lot No. 7264), and 45 btls. (lot No. 7308) of *elixir Sedalet*, and 6 ctns., 24 btls. each, of *penicillin tablets with sulfonamides*, at Falls Church, Va.

SHIPPED: 7–15–55, from Bethesda, Md., by Marshall Laboratories, Inc.

LABEL IN PART: (Btls.) "Marshall One Pint (473 cc) Elixir Sedalet Each Teaspoonful Contains: Phenobarbital ¼ gr. (16 mg.) Thiamin Chloride 5 mg." and "Pendiamer '200' Brand of Penicillin Tablets with Sulfonamides * * * Each tablet contains: Penicillin G Potassium Crystalline 200,000 U * * * Lot #5883."

RESULTS OF INVESTIGATION: Examination showed that the *elixir Sedalet* contained (lot No. 5881–VR) 128 percent of the declared amount of phenobarbital and (lot Nos. 7264 and 7308) less than 80 percent of the declared amount of thiamine chloride, and that the *penicillin tablets with sulfonamides* contained 69.5 percent of the declared amount of penicillin and were labeled with the expiration date "Feb. 1956."

LIBELED: 9–19–57, E. Dist. Va.

CHARGE: *Elixir Sedalet.* 501(c)—when shipped, the strength of the article differed from that which it was represented to possess since the article (lot No. 5881–VR) contained more than ¼ grain of phenobarbital per teaspoonful and (lot Nos. 7264 and 7308) contained less than 5 mg. of thiamine chloride

per teaspoonful; and 502(a)—the label statements (lot No. 5881-VR) "Each Teaspoonful Contains * * * Phenobarbital ¼ gr." and (lot Nos. 7264 and 7308) "Each Teaspoonful Contains * * * Thiamin Chloride 5 mg." were false and misleading.

Penicillin tablets with sulfonamides. 501 (c)—when shipped, the strength of the article differed from that which it was represented to possess since it contained less than 200,000 units of penicillin G potassium crystalline per tablet; 502(a)—the label statement "Each tablet contains: Penicillin G Potassium Crystalline 200,000 U" was false and misleading; and 502(l) (2)—the article purported to be and was represented as a drug composed in part of penicillin and was from a batch for which a certificate issued in accordance with regulations was not in effect.

DISPOSITION: 1–14–58. Default—destruction.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS

5485. Elixir Albephen and elixir Merbutal. (F.D.C. No. 40468. S. Nos. 67–474 M, 67–478 M.)

INFORMATION FILED: 2–5–58, Dist. Md., against Meredyth Co., a partnership, Silver Spring, Md., and Irwin T. Sealfon, a partner.

ALLEGED VIOLATION: Between 9–23–55 and 5–16–57, the defendants caused a quantity of *elixir Albephen* in 1-gal. btls. to be repacked into 1-pt. btls. and a quantity of *elixir Merbutal* in 1-gal. btls. to be repacked into 1-oz. btls., which acts of repacking resulted in the repacked articles being misbranded while held for sale after shipment in interstate commerce.

LABEL IN PART: (Btl.) "One Pint Elixir Albephen Each Ounce Contains: D. Amphetamine Sulfate 15 mg. Thiamin HCL 30 mg. Riboflavin 2.7 mg. Niacin 40 mg. Alcohol 10% Distributors The Meredyth Company Washington, D.C. The M Co." and "Physicians Sample One Ounce Elixir Merbutal Each 5cc (One teaspoonful) contains: Sodium-5-ethyl-secondary butyl barbiturate 3 grs. (brand of Butabarbital sodium) Distributors The Meredyth Company Washington, D.C."

CHARGE: *Elixir Albephen.* 502 (a)—the label statement "Each Ounce Contains: D. Amphetamine Sulfate 15 mg. Thiamin HCL 30 mg. Riboflavin 2.7 mg. Niacin 40 mg. Alcohol 10%" was false and misleading since each ounce of the article contained no d. amphetamine sulfate, no thiamine HCl, no riboflavin, and no niacin, and contained more than 10 percent of alcohol; 502(d)—the article contained phenobarbital, a derivative of barbituric acid, which had been found to be, and by regulations designated as, habit forming, and the label failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming"; 502(e) (2)—the label of the article failed to bear the common or usual name of the active ingredient, phenobarbital, the name, and quantity or proportion of hyoscyamine sulfate, atropine sulfate, and hyoscine hydrobromide, and the quantity, kind, and proportion of alcohol contained in the article; and 503(b) (4)—the article was a drug subject to 503(b) (1), and the label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

Elixir Merbutal. 502(a)—the label statement "Each 5cc (one teaspoonful) contains: Sodium-5-ethyl-secondary butyl barbiturate 3 grs. (brand of butabarbital sodium)" was false and misleading in that each 5cc of the drug