

5483. Vitamin B₁₂ 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 Balamín-1000 * * * For Intravenous or Intramuscular Use Each cc contains: 1000 Micrograms Vitamin B₁₂ 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 B₁₂), 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 btl. (lot No. 5881-VR), 45 btl. (lot No. 7264), and 45 btl. (lot No. 7308) of *elixir Sedalet*, and 6 ctns., 24 btl. each, of *penicillin tablets with sulfonamides*, at Falls Church, Va.

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

LABEL IN PART: (Btl.) "Marshall One Pint (473 cc) Elixir Sedalet Each Teaspoonful Contains: Phenobarbital $\frac{1}{4}$ 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 $\frac{1}{4}$ grain of phenobarbital per teaspoonful and (lot Nos. 7264 and 7308) contained less than 5 mg. of thiamine chloride