

dissolved material in addition to those constituents permitted to be present in *cyanocobalamin injection*; 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: 3-23-59. Consent—destruction.

5642. Vitamin B₁₂ injection. (F.D.C. No. 40316. S. No. 43-464 M.)

QUANTITY: 3 ctns. containing a total of 1,550 10-cc. vials at St. Louis, Mo.

SHIPPED: 5-20-57, from Chicago, Ill., by Hallmark Laboratories, Inc.

LABEL IN PART: (Shipping ctns.) "Vitamin B₁₂ 1000 mcg. per cc (Cyanocobalamin, U.S.P.) in water for injection. Sodium chloride 0.9% Benzyl alcohol as bacteriostatic agent, 2% average dose: 1 cc for intramuscular and intravenous use. * * * Hallmark Laboratories, Inc., Chicago, Illinois."

RESULTS OF INVESTIGATION: Examination showed that each cubic centimeter of the article contained 978 micrograms of cyanocobalamin (vitamin B₁₂), 8.32 milligrams of sodium chloride, and a quantity of unidentified dissolved material.

LIBELED: 6-7-57, E. Dist. Mo.; amended libel 6-18-57 and 4-4-58.

CHARGE: 501(b)—when shipped, the quality and purity of the article fell below the standard for *cyanocobalamin injection* set forth in the United States Pharmacopeia since it contained a quantity of dissolved material which is not permitted by the standard as an ingredient of *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: Hallmark Laboratories, claimant, filed an answer denying that the article was adulterated or a new drug as charged. The Government filed written interrogatories which claimant answered in part and objected to in part. Subsequently, the Government filed a motion to compel further and more complete answers and also a motion for discovery and production of documents. The claimant took issue with the Government's motions, and after a hearing on 12-16-58, the court ordered the claimant to answer some of the interrogatories and sustained claimant's objections to the remainder. The Government's motion for discovery and production of documents was sustained. Thereafter, on 3-11-59, claimant having consented, a decree of condemnation was entered and the article was destroyed.

5643. Pyrdex. (F.D.C. No. 40882. S. No. 53-628 M.)

QUANTITY: 340 vials at Bellaire, Tex.

SHIPPED: 8-9-57, from Los Angeles, Calif., by E. S. Miller Laboratories, Inc.

LABEL IN PART: "No. 320 Pyrdex 10 CC. Vial Each CC. Contains Pyriline Maleate 25 Mg. Dextro-Amphetamine HCL 2 Mg. * * * Control #16071."

LIBELED: On or about 10-28-57, S. Dist. Tex.

CHARGE: 505(a)—the article was a new drug within the meaning of the law, and an application filed pursuant to the law was not effective with respect to the article.

DISPOSITION: 7-31-58. Consent—destruction.