DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

DRUGS FOR HUMAN USE

6795. L–F–12. (F.D.C. No. 46619. S. No. 26–661 T.)

QUANTITY: 30 vials at Hobart, Ind.

SHIPPED: 7–29–61, from Chicago, Ill.

LABEL IN PART: (Vial) "30 cc. Multiple Dose Sterile High Potency L–F–12 10–10–100 Each cc represents Vit. B_{12} Activity (from Liver Inj. USP Beef) equivalent to: Cyanocobalamin 10 mcgm. fortified with Folic Acid 10 mg. – Vit. B_{12} Crystalline 100 mcgm."

RESULTS OF INVESTIGATION: Analysis showed that the article contained 60 percent of the declared amount of vitamin B_{12}.

LIBELED: 11–6–61, N. Dist. Ind.

CHARGE: 501(c)—while held for sale, the strength of the article differed from, and its quality fell below, that which it purported or was represented to possess; and 502(a)—the label statement "Vit. B_{12} Crystalline 100 mcgm." was false and misleading as applied to a product containing less than the declared amount of vitamin B_{12}.

DISPOSITION: 1–8–62. Default—destruction.

6796. Lifolic B_{12} injection. (F.D.C. No. 46077. S. No. 18–499 R.)

QUANTITY: 82 individually ctnd. vials at Albuquerque, N. Mex.

SHIPPED: 3–27–61, from Los Angeles, Calif., by American Bio-Chemical Corp.

LABEL IN PART: (Vial and ctn.) "10 cc For Intramuscular Use Only * * * LIFOLIC—B_{12} Each cc contains: Vitamin B–12 U.S.P. 100 mcg. * * * Caution: * * * Produced for New Mexico Pharmacal Co. Albuquerque, New Mexico * * * No. 28519."

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately 70 percent of the declared amount of vitamin B_{12}.

LIBELED: 7–14–61, Dist. N. Mex.

CHARGE: 501(c)—when shipped, the strength of the article differed from, and its quality fell below, that which it purported and was represented to possess; and 502(a)—the label statement "Each cc contains: Vitamin B–12 U.S.P. 100 mcg." was false and misleading.

DISPOSITION: 8–23–61. Default—destruction.

6797. Con-Care Solution. (F.D.C. No. 45847. S. No. 48–902 R.)

QUANTITY: 130 2-oz. btls. at Denver, Colo.

SHIPPED: 3–24–61, from Salt Lake City, Utah, by Con-Care, Ltd.

LABEL IN PART: "Con-Care Regular Cleaning & Wetting Solution for Contact Lenses * * * Benzalkonium Chloride U.S.P. 0.004 Percent * * * Con-Care Ltd., P.O. Box 2136, Salt Lake City, Utah."

LIBELED: 6–28–61, Dist. Colo.

CHARGE: 501(c)—when shipped, the purity and quality of the article fell below that which it purported and was represented to possess since it purported to be suitable for use in the eye and for cleaning contact lenses, whereas it was not suitable for such purpose, since it was contaminated with viable microorganisms.

DISPOSITION: 8–11–61. Default—destruction.