

6098. Terephthalic acid. (F.D.C. No. 43565. S. Nos. 53-963/4 P.)

QUANTITY: 47 cases, each containing 10 bags, and 6 cases, each containing 10 tins, at Springdale, Ark.

SHIPPED: Between 8-17-59 and 8-31-59, from Vineland, N.J., by Vineland Poultry Laboratories.

LABEL IN PART: (Bag) "Vineland Activator Solubilized Terephthalic Acid For Veterinary Use Only Caution: * * * Net Contents 260 Grams [or tin "1½ lbs.]" Vineland Poultry Laboratories, Vineland, N.J. Los Angeles, Cal."

RESULTS OF INVESTIGATION: The article was not subject to exemption from the requirement that its label bear adequate directions for use since it was not delivered for use only in the manufacture of a new drug limited to investigational use. Instead the article was used in the preparation of poultry feed which was sold on a straight commercial basis for use by poultry raisers of the area.

LIBELED: 9-28-59, W. Dist. Ark.

CHARGE: 502(f)(1)—when shipped, the label of the article failed to bear adequate directions for use.

DISPOSITION: 12-12-59. Default—destruction.

6099. Terephthalic acid (Dupont TPA). (F.D.C. No. 43362. S. No. 57-127 P.)

QUANTITY: 11 75-lb. drums at Gainesville, Ga.

SHIPPED: 7-23-59 and 7-27-59, from Gibbstown, N.J., by E. I. du Pont de Nemours & Co.

LABEL IN PART: "DuPont TPA Terephthalic Acid Technical Grade * * * E. I. du Pont de Nemours & Co. Inc. Wilmington 98, Delaware Caution: Manufacturing, Processing or Repacking in the preparation of a New Drug is limited by federal law to investigational use. An effective new drug application will be required before a product containing this material may be marketed."

RESULTS OF INVESTIGATION: Investigation showed that the article was to be used in the preparation of poultry feed which was sold on a straight commercial basis for use by poultry raisers; and therefore the article was not subject to the exemption afforded by the regulations from bearing adequate directions for use since the delivery was not made for use only in the manufacture of a new drug limited to investigational use.

LIBELED: 8-25-59, N. Dist. Ga.

CHARGE: 502(f)(1)—when shipped, the labeling of the article failed to bear adequate directions for use.

DISPOSITION: 10-16-59. Default—destruction.

**DRUGS AND DEVICE ACTIONABLE BECAUSE OF DEVIATION FROM
OFFICIAL OR OWN STANDARDS****DRUGS FOR HUMAN USE****6100. Terpin hydrate. (F.D.C. No. 43797. S. No. 77-928 P.)**

QUANTITY: 2 25-lb. drums at Detroit, Mich.

SHIPPED: 4-1-59, from Philadelphia, Pa., by Physicians Drug & Supply Co.

LABEL IN PART: "C29816 Physicians Drug & Supply Co. * * * Philadelphia 6 Pa. * * * No. 9680 D. 74 Terpin Hydrate N.F. * * * 5.335."

RESULTS OF INVESTIGATION: Analysis showed that the article failed to comply with the National Formulary specifications for *terpin hydrate* in that it had an odor not permitted by the National Formulary.

LIBELED: 11-10-59, E. Dist. Mich.

CHARGE: 501(b)—when shipped, the quality and purity of the article fell below the standard for *terpin hydrate* set forth in the National Formulary.

DISPOSITION: 12-7-59. Default—destruction.

6101. Contact lens wetting solution. (F.D.C. No. 43914. S. No. 70-347 P.)

QUANTITY: 236 btl. at Philadelphia, Pa.

SHIPPED: 8-4-59, from Wauconda, Ill., by Micon Laboratories.

LABEL IN PART: "5 cc. Sample Mi-Con Wetting Solution * * * Micon Laboratories, 905 Jackson Street, Wauconda, Ill.

LIBELED: 11-13-59, E. Dist. Pa.

CHARGE: 501(c)—when shipped, the purity and quality of the article fell below that which it purported or 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 uses and purposes because it was contaminated with large numbers of viable micro-organisms.

DISPOSITION: 12-16-59. Default—destruction.

6102. Obes-Ebb tablets and thyroid tablets. (F.D.C. No. 43330. S. Nos. 52-887 P, 52-891 P, 53-565/6 P.)

QUANTITY: 491 1,000-tablet btl. of *Obes-Ebb tablets* and 8 1,000-tablet btl. of *thyroid tablets* at Los Angeles, Calif.

SHIPPED: 3-17-59 and 3-31-59, from Hoboken, N.J., by General Pharmacal Co., Inc.

LABEL IN PART: "Green No. 1 Obes-Ebb * * * Amphetamine Sulfate 10 Mgm. Thyroid 1 Gr., Aloin $\frac{1}{4}$ Gr. Atropine Sulfate 1/360 Gr. * * * General Pharmacal Co. Hoboken, New Jersey * * * 2619"; "Yellow No. 2 Obes-Ebb * * * Thyroid 1 Gr., * * * 2635"; "Brown No. 3 Obes-Ebb, Each Tablet Contains: Phenobarbital $\frac{1}{4}$ Grain * * * Thyroid 1 Grain * * * 2636"; "FHJ Tablets Thyroid * * * Contains 2 Grain Thyroid Powder USP * * * F. H. J. Laboratories, Inc., New York, N.Y. Control 2637."

RESULTS OF INVESTIGATION: Examination showed that the articles (all lots) contained less than the labeled amounts of thyroid.

LIBELED: 8-4-59, S. Dist. Calif.

CHARGE: 501(b)—when shipped, the strength of the *thyroid tablets* differed from, and their quality fell below, the standard for *thyroid tablets* set forth in the United States Pharmacopeia; 501(c)—the strength of the *Obes-Ebb tablets* differed from that which they purported and were represented to possess; and 502(a)—the label statements (*Obes-Ebb tablets*) "Each Tablet Contains Thyroid 1 Gr." and (*thyroid tablets*) "Contains 2 Grain Thyroid Powder USP" were false and misleading.

DISPOSITION: 8-26-59. Default—destruction.

6103. Li-Folic-B₁₂. (F.D.C. No. 43415. S. No. 76-043 P.)

QUANTITY: 273 vials at St. Louis, Mo.

SHIPPED: 3-9-59, from Dayton, Ohio, by Durr Products, Inc.