

DISPOSITION: 2-21-61. Consent—claimed by E. Vadillo Ruiz, Inc., New York, N.Y., and released under bond for export to the original foreign supplier, Dr. Bell Veterinary Medicine Co., Kingston, Canada.

### DRUG ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

6595. Elixir of phenobarbital and belladonna. (F.D.C. No. 45301. S. No. 2-739 R.)

QUANTITY: 4 50-gal. drums at Atlanta, Ga.

SHIPPED: 10-18-60, from Greenville, S.C.

LIBELED: 12-21-60, N. Dist. Ga.

CHARGE: 501(a)—contained plant fibers, metallic particles, and whole insects while held for sale.

DISPOSITION: 2-6-61. Default—destruction.

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

#### DRUGS FOR HUMAN USE\*

6596. Ferrous sulfate tablets. (F.D.C. No. 45505. S. No. 99-459 R.)

QUANTITY: 53 100-tablet btl. at Gardiner, Maine.

SHIPPED: 11-9-60, from Worcester, Mass., by Buffington's, Inc.

LABEL IN PART: (Btl.) "Entells VIRON \* \* \* Ferrous Sulfate Exsiccated 5 grains. Entells designates Buffington brand Enteric Coated Tablets. Dose: \* \* \* Buffington's Inc. \* \* \* Worcester, Mass."

LIBELED: 3-8-61, Dist. Maine.

CHARGE: 501(b)—when shipped, the article purported to be, and was represented as, *ferrous sulfate tablets*, a drug, the name of which is recognized in the United States Pharmacopeia, an official compendium, and was represented to be enteric-coated, and its quality fell below the official standard for enteric-coated tablets since the articles failed to meet the disintegration requirements for enteric-coated tablets as provided in the official compendium; and 502(a)—the label statement "Ferrous Sulfate Exsiccated 5 grains" was false and misleading as applied to the article which purported to supply 5 grains of ferrous sulfate in a form assimilable to the body but failed to do so.

DISPOSITION: 3-23-61. Default—destruction.

6597. Cecobee vitamin injectable. (F.D.C. No. 45521. S. No. 14-934 R.)

QUANTITY: 80 ctnd. vials at Cincinnati, Ohio.

SHIPPED: 1-27-61, from Philadelphia, Pa., by Philadelphia Ampoule Laboratories, Inc.

LABEL IN PART: (Bulk ctn.) "20 cc. No. 1109 Multiple Dose Vial B<sub>12</sub> Plex C A Stable B Complex with B-12 and C Caution: \* \* \* Phila. Ampoule Laboratories Philadelphia 23, Pa. \* \* \* Each cc. contains: \* \* \* Thiamine HCl 50 mg."

RESULTS OF INVESTIGATION: Analysis showed that the article contained approximately 70 percent of the declared amount of vitamin B<sub>12</sub>.

The article was shipped in bulk cartons of 50 unlabeled vials each and after receipt by the dealer, each vial was labeled and packed in individual cartons.

\*See also No. 6593.