

tis, and Tincture Aloe \* \* \* Fem-A-Line Laboratories, 2716 North Henderson Dallas, Texas \* \* \* Directions: Teaspoonful 30 minutes before meals and at bed-time in one-fourth glass of hot water \* \* \* Avoid continuous use" and (reused gal. btl.) "Lactated Pepsin Not NF (the word 'Mixed' was handwritten across the label)."

ACCOMPANYING LABELING: Leaflets entitled "Fem-A-Line An Aid To Nature."

RESULTS OF INVESTIGATION: The article was manufactured by the dealer from ingredients which had been shipped in interstate commerce. Some of the article was bottled and labeled and the remainder was stored in the gallon bottles labeled "Lactated Pepsin (Mixed)."

LIBELED: 8-17-61, N. Dist. Tex.

CHARGE: 502(a)—while held for sale, the labeling contained false and misleading representations that the article was adequate and effective to assist retarded menstruation caused by severe colds or other unnatural suppression of the menses; 502(j)—the article was dangerous to health when used as directed in its labeling; and 503(b)(4)—the article was subject to the provisions of 503(b)(1) and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 11-1-61. Default—destruction.

**6902. Glass syringes.** (F.D.C. No. 46818. S. No. 18-317 T.)

QUANTITY: 1 doz. 2-cc. glass syringes at Palestine, Tex., in possession of Reynolds Clinic.

SHIPPED: On unknown dates, from outside the State of Texas.

ACCOMPANYING LABELING: Leaflets entitled "The Koch Treatment (Glyoxylide)," "Koch Diet," and "Order Form."

LIBELED: 11-21-61, E. Dist. Tex.

CHARGE: 502(f)(1)—the labeling failed to bear adequate directions for use; 502(f)(2)—the labeling failed to bear adequate warnings against use in those pathological conditions where its use may be dangerous to health and against unsafe methods of application; and 502(j)—the article was dangerous to health when used with the frequency prescribed, recommended, and suggested in its labeling.

DISPOSITION: 1-5-62. Default—delivered to the Food and Drug Administration.

#### DRUG FOR VETERINARY USE

**6903. Medicated turkey feed (5 seizure actions).** (F.D.C. Nos. 46276, 46422/5. S. Nos. 81-148/9 R, 81-395/9 R, 6-441 T.)

QUANTITY: 20 100-lb bags (crumbles), 310 100-lb. bags and 60 75-lb. bags (pellets), at Millis, Marlboro, Framingham Center, North Andover, and Lanesboro, Mass.

SHIPPED: Between 6-30-61 and 7-31-61, from Oneonta, N.Y., by Elmore Milling Co., Inc.

LABEL IN PART: (Tag) "Elmore Turkey Growing Mash Medicated (1H) \* \* \* Active Drug Ingredients: 4-nitrophenylarsonic acid (Histostat) 0.025% \* \* \* Manufactured by Elmore Milling Company, Inc., Oneonta, N.Y. (Pellets) [or "Crumbles"] [some bags bear another tag reading "Small" or "Pellets"]."

RESULTS OF INVESTIGATION: Examination showed that the article contained more than the declared amount of 4-nitrophenylarsonic acid.

**LIBELED:** 8-21-61, 8-29-61, and 8-30-61, Dist. Mass.

**CHARGE:** 501(c)—when shipped, the strength of the article differed from that which it purported to possess; 502(a)—the label statement "4-nitrophenyl-arsonic acid (Histostat) 0.025%" was false and misleading as applied to a product which contained more than the declared amount of this ingredient; and 502(j)—the article was dangerous to the health of turkeys when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling.

**DISPOSITION:** 2-16-62. Consent—claimed by Elmore Milling Co., Inc., and released under bond to be brought into compliance with the law.

## NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

### DRUGS FOR HUMAN USE

**6904. Vitamin B<sub>12</sub>-B<sub>1</sub>, Elixir Vinivita, and Expectogen.** (F.D.C. No. 46942. S. Nos. 37-804/6 T.)

**QUANTITY:** 16 btl. of *Vitamin B<sub>12</sub>-B<sub>1</sub>*, 151 1-pt. btl. of *Elixir Vinivita*, and 203 1-pt. btl. of *Expectogen*, at Montgomery, Ala.

**SHIPPED:** Between 2-27-61 and 9-26-61, from St. Louis, Mo., by E. W. Heun Co.

**LABEL IN PART:** (Btl.) "Vitamin B<sub>12</sub>-B<sub>1</sub> Each 5 cc. (1 teaspoonful) contains: Vitamin B-12, N.F. 25 mcg. Vitamin B-1 U.S.P. 10 mg. Manufactured for King Pharmaceutical Co., Inc., Montgomery 3, Alabama."; "King's One Pint Elixir Vinivita Improved Each 5 cc. (1 teaspoonful) contains: \* \* \* Distributed by King Pharmaceutical Co., Inc., Montgomery, Alabama \* \* \* Caution: Federal law prohibits dispensing without a prescription."; and "King's One Pint Expectogen For Relief of Coughs Due to Colds Each Fluid Ounce Represents: Dextromethorphan Hydrobromide 60 mg. Chlorpheniramine Maleate 12 mg. Potassium Guaiaccol Sulfonate 8 gr. Ammonium Chloride 8 gr. Tartar Emetic 1/12 gr. Chloroform 2 min. \* \* \* Distributed by King Pharmaceutical Co., Inc., Montgomery, Alabama. Dosage: Adults, orally 1 or 2 teaspoonsful every four hours as required. Children 6-12 years, one-half adult dose. For younger children consult physician."

**LIBELED:** 1-29-62, M. Dist. Ala.

**CHARGE:** (*Vitamin B<sub>12</sub>-B<sub>1</sub>*), 502(a)—when shipped, the bottle label contained false and misleading representations that the article was adequate and effective for promoting growth and appetite in a child who does not eat adequately or well; as an adjunct in treating the chronically ill or undernourished child; as a nutritional supplement in chronic diarrhea and celiac diseases; and for shortening convalescence through increasing the appetite; (*Elixir Vinivita*), 502(a)—the bottle label contained false and misleading representations that the article was adequate and effective as a treatment for or preventive of chronic fatigue, poor appetite, and iron and vitamin deficiencies; 503(b)(4)—the article was not subject to the provisions of 503(b)(1) and its label bore the statement "Caution: Federal law prohibits dispensing without prescription"; and (*Expectogen*), 505(a)—the article was a new drug which may not be introduced into interstate commerce since an application filed pursuant to law was not effective with respect to such drug.

**DISPOSITION:** 2-2-62. Consent—destruction.