DRUG FOR VETERINARY USE

5786. Blue Seal Growing Mash. (F.D.C. No. 42201. S. No. 7-887 P.)

QUANTITY: 132 100-lb. bags at Ellsworth, Maine.

SHIPPED: 7-9-58, from Lawrence, Mass., by H. K. Webster Co.

LABEL IN PART: (Tag) "BLUE SEAL GROWING MASH"; (bag) "BLUE SEAL GRAIN PRODUCTS * * * Manufactured by H. K. Webster Company."

RESULTS OF INVESTIGATION: The article was invoiced as "1 Lb. G.C. per ton."

LIBELED: 10-1-58, Dist. Maine.

CHARGE: 501(c)—when shipped, the quality of the article fell below that which it purported and was represented to possess since the article contained sulfaquinoxaline in place of glycarbylamide; 502(e)(2)—the label of the article failed to bear the common or usual name of each active ingredient contained therein since the presence of sulfaquinoxaline was not declared; and 502(f)(1)—the labeling of the article failed to bear adequate directions for use.

DISPOSITION: 11-18-58. Default—destruction.

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

DRUGS FOR HUMAN USE*

5787. Digitalis powder, digitalis tablets, and digitalis capsules. (F.D.C. No. 42223. S. Nos. 35-138/9 P.)

QUANTITY: 2 5-lb. tins, and 2 3-lb. tins of *digitalis powder*, 17 2,000-tablet btls., 1 1,500-tablet btl., 72 1,000-tablet btls., 1 500-tablet btl., and 1 100-tablet btl. of *digitalis tablets*, and 15 1,000-capsule btls., and 1 500-capsule btl. of *digitalis capsules*, at Philadelphia, Pa.

SHIPPED: The *digitalis powder* was shipped on 11-12-57, from Montreal, Canada, by F. E. Cornell & Co., Ltd.

LABEL IN PART: (Tin) "Allen's Selected Digitalis Leaves in Powder * * * E 62330 This Digitalis Powder contains 14.2 International Units per gramme, or one unit is contained in 0.07 gramme, which is equivalent to 0.076 gramme of the 3rd International Standard Digitalis Powder as determined by a biologic test carried out by the School of Pharmacy, University of London Stafford Allen & Sons, Ltd., London & Louis Medford, England Batch Number 9/M 3/56 2nd November 1956," (btl.) "Tablets [or "Capsules"] Allen's English Digitalis 1½ Grains * * * Standardized to U.S.P. requirements for Powdered Digitalis * * * Raymer Pharmacal Company, Philadelphia, Pa."

RESULTS OF INVESTIGATION: The *digitalis tablets* and *digitalis capsules* were manufactured at Philadelphia, Pa., by the Raymer Pharmacal Co., from *digitalis powder* which had been shipped as described above.

LIBELED: 10-13-58, E. Dist. Pa.

CHARGE: 501(b)—the strength of the articles, when shipped and while held for sale, differed from the standards for *digitalis powder*, *digitalis tablets*, and *digitalis capsules* set forth in the United States Pharmacopeia; and 502(a)—the following label statements: (powder) "This Digitalis Powder contains 14.2 International Units per gramme," and (tablets & capsules) "Digitalis

*See also Nos. 5783, 5786.

1½ Grains" were false and misleading as applied to the articles since the powder contained significantly less than 14.2 units of digitalis potency, and the tablets and capsules contained significantly less than 1½ grains of digitalis potency per tablet or capsule.

DISPOSITION: 12–22–58. Default—destruction.

5788. Videxcell tablets, Buta-B tablets (¼ grain), and Buta-B tablets (½ grain). (F.D.C. No. 41473. S. Nos. 3–492/4 P.)

QUANTITY: 367 100-tablet btls. of Videxcell, 297 100-tablet btls. of *Buta-B tablets* (*¼ grain*), and 501 100-tablet btls. of *Buta-B tablets* (*½ grain*), at Arlington, Va.

SHIPPED: Between 1–15–54 and 7–26–55, from Philadelphia, Pa.

LIBELED: 4–11–58, E. Dist. Va.; libel amended, 10–28–58.

CHARGE: *Videxcell tablets.* 501(c)—the strength of the article, while held for sale, differed from that which it was represented to possess, namely, crystalline vitamin A acetate, 1,500 units per tablet; and 502(a)—the label statement "Each Tablet Contains * * * Crystalline Vitamin A Acetate 1,500 Units" was false and misleading as applied to the article which contained less than the declared amount of vitamin A.

Buta-B tablets (*¼ grain*) and *Buta-B tablets* (*½ grain*). 501(c)—the strength of the articles, while held for sale, differed from that which they were represented to possess, namely, thiamin HCl, 5 milligrams per tablet; and 502(a)—the label statements "Each Table Contains Thiamin HCl * * * 5 mg." were false and misleading as applied to the articles which contained less than the declared amount of vitamin B_1.

The libel alleged also that two other articles, namely, Conciecaps and Arlvita-Tabs were adulterated and misbranded under the provisions of the law applicable to foods as reported in notices of judgment on foods.

DISPOSITION: 11–4–58. Default—destruction.

5789. Aspirin tablets. (F.D.C. No. 41995. S. No. 7–863 P.)

QUANTITY: 5 cases, 144 100-tablet btls. each, at New Haven, Conn.

SHIPPED: In January 1954, from Newark, N.J.

RESULTS OF INVESTIGATION: Analysis showed that the article contained 92 percent of the labeled amount of acetylsalicylic acid, and that it contained a significantly larger amount of free salicylic acid than the maximum of 0.15 percent permitted by the United States Pharmacopeia. The United States Pharmacopeia requires that *aspirin tablets* contain from 95 percent to 105 percent of the labeled amount of acetylsalicylic acid.

LIBELED: 8–23–58, Dist. Conn.

CHARGE: 501(b)—the strength, quality, and purity of the article, while held for sale, fell below the standard for *aspirin tablets* set forth in the United States Pharmacopeia since the article contained less than the required amount of acetylsalicylic acid and more than the permitted amount of free salicylic acid; and Section 502(a)—the label statement "Aspirin Tablets U.S.P. 5 Grains Each" was false and misleading.

DISPOSITION: 1–8–59. Default—destruction.

5790. Congo red injection. (F.D.C. No. 42113. S. No. 40–035 P.)

QUANTITY: 6 boxes, 25 10 cc. vials each, and 4 boxes, 6 10 cc. vials each, at San Francisco, Calif.