

DRUG FOR VETERINARY USE

5464. Bacitracin ointment (veterinary). (F.D.C. No. 40873. S. No. 78-016 M.)

QUANTITY: 3,216 boxes, each containing 1 syringe, at Lincoln, Nebr.

SHIPPED: 8-16-57, from Inglewood, Calif., by Delta Laboratories.

LABEL IN PART: "Mitox Active Ingredients Per Syringe Bacitracin 3200 Units * * * Veterinarians only * * * Control No. 2175 Expiration Date: Feb. '59."

RESULTS OF INVESTIGATION: Examination showed that the article contained substantially less bacitracin than the label declared.

LIBELED: 10-25-57, Dist. Nebr.

CHARGE: 501(c)—the strength of the article, when shipped, differed from that which it purported and was represented to possess, namely, 3,200 units per syringe; and 502(a)—the label statement "Per Syringe Bacitracin 3200 Units" was false and misleading; and 502(1)—the article contained bacitracin, and it was not from a batch with respect to which a certificate or release had been issued.

DISPOSITION: 12-5-57. Default—destruction.

DRUGS IN VIOLATION OF PRESCRIPTION LABELING REQUIREMENTS*

5465. Penicillin. (F.D.C. No. 40934. S. Nos. 76-701/2 M.)

QUANTITY: 47 10-cc. vials and 97 10-cc. vials at Millbury, Mass.

SHIPPED: 3-25-57 and 4-2-57, from Baltimore, Md.

LABEL IN PART: (47-vial lot) "10 cc Crystalline Procaine Penicillin G in Aqueous Suspension 300,000 units per cc"; (97-vial lot) "1,000,000 Units Potassium Penicillin Crystalline 'G'."

RESULTS OF INVESTIGATION: The article was in the possession of a dealer in veterinary supplies, and its labeling did not bear adequate directions for use in the treatment of animals.

LIBELED: 11-4-57, Dist. Mass.

CHARGE: 502(f)(1)—while held for sale, the labeling of the article failed to bear adequate directions for use; and 503(b)(4)—the article was not intended for use by man, and its label bore the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 12-16-57 and 12-24-57. Default—destruction.

5466. X 100 Cosmetic Solution. (F.D.C. No. 40623. S. No. 41-877 M.)

QUANTITY: 2 1-gal.-size btls., each containing $\frac{2}{3}$ of a gal.; 21 btls., each containing 1 oz.; and 10 btls., each containing $\frac{1}{2}$ oz., at Buffalo, N.Y.

SHIPPED: 5-15-57, from Detroit, Mich., by R. Tacon.

LABEL IN PART: (1-gal. btls.) "X 100 Cosmetic Solution Contains 10,000 I.U. Δ 1, 3, 5, Estratriene a 3,17 Diol per oz. For External Use Only Distributed by R. Tacon Detroit Mich."

RESULTS OF INVESTIGATION: The article in the 1-oz. and $\frac{1}{2}$ -oz. btls. was re-packed by the dealer from the 1-gal. btls. described above. The article was employed by the dealer as a hair and scalp treatment, consisting of the application of $\frac{1}{2}$ -fluid oz. to the hair and scalp as a single "treatment."

*See also Nos. 5461, 5463.