4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

[Docket No. FDA-2018-N-0002]

New Animal Drugs; Withdrawal of Approval of New Animal Drug Application

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of a new animal drug application (NADA) and an abbreviated new animal drug application (ANADA) at the sponsors' request because these products are no longer manufactured or marketed.

DATES: Withdrawal of approval is effective [INSERT DATE 10 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Sujaya Dessai, Center for Veterinary Medicine (HFV-212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-402-5761, sujaya.dessai@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Elanco US Inc., 2500 Innovation Way, Greenfield, IN 46140, has requested that FDA withdraw approval of NADA 140-939 for use of RUMENSIN (monensin) and TYLAN (tylosin phosphate) Type A medicated articles in the manufacture of combination drug Type C medicated cattle feeds because the product is no longer manufactured or marketed.

Also, Sergeant's Pet Care Products, Inc., 10077 S. 134th St., Omaha, NE 68138 has requested that FDA withdraw approval of ANADA 200-600 for WORMX (pyrantel pamoate) Flavored Tablets because the product is no longer manufactured or marketed.

Therefore, under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, and in accordance with § 514.116 *Notice of withdrawal of approval of application* (21 CFR 514.116), notice is given that approval of NADA 140-939 and ANADA 200-600, and all supplements and amendments thereto, is hereby withdrawn, effective [INSERT DATE 10 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

Elsewhere in this issue of the *Federal Register*, FDA is amending the animal drug regulations to reflect the voluntary withdrawal of approval of these applications.

Dated: March 4, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

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