4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520 and 558

[Docket No. FDA-2015-N-0002]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of two new animal drug applications (NADAs) and two abbreviated new animal drug applications (ANADAs). This action is being taken at the sponsors' requests 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: The following three sponsors have requested that FDA withdraw approval of the NADAs and ANADAs listed in the following table because the products are no longer manufactured or marketed:

File No.	Sponsor	Product Name	21 CFR Section
140-680[1]	Pharmgate LLC, 1015 Ashes Dr., suite 102, Wilmington, NC	TYLAN (tylosin phosphate) Premix	558.625

File No.	Sponsor	Product Name	21 CFR Section
	28405		
140-681[1]	Pharmgate LLC, 1015 Ashes Dr., suite 102, Wilmington, NC 28405	TYLAN SULFA G (tylosin phosphate and sulfamethazine) Premix	558.630
200-028	Pegasus Laboratories, Inc., 8809 Ely Rd., Pensacola, FL 32514	EVICT 300 (pyrantel pamoate) Suspension	520.2043
200-383	Bayer HealthCare LLC, Animal Health Division, P.O. Box 390, Shawnee Mission, KS 66201	CLINDAROBE (clindamycin) Capsules	520.446

[1]These NADAs were identified as being affected by guidance for industry #213, "New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209," December 2013.

Therefore, under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, and in accordance with 21 CFR 514.116 Notice of withdrawal of approval of application, notice is given that approval of NADA 140-680, NADA 140-681, ANADA 200-028, and ANADA 200-383, and all supplements and amendments thereto, is hereby withdrawn, effective [INSERT DATE 10 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].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: December 4, 2015.

Bernadette Dunham,

Director,

Center for Veterinary Medicine.

[FR Doc. 2015-31040 Filed: 12/8/2015 8:45 am; Publication Date: 12/9/2015]