4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520 and 558

[Docket No. FDA-2016-N-0002]

# New Animal Drugs; Withdrawal of Approval of a 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 five new animal drug applications (NADAs) and an abbreviated new animal drug application (ANADA). This action is being taken 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: The sponsors of the following applications have requested that FDA withdraw approval of the NADAs and ANADA listed in the following table because the products are no longer manufactured or marketed:

| File No. | Sponsor | Product Name | 21 CFR Section |
|---|---|---|---|
| 007-076[1] | Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland | SULFA-NOX Liquid (sulfaquinoxaline) 3.44% Solution | 520.2325a |
| 008-244[1] | Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland | SULFA-NOX Concentrate (sulfaquinoxaline) 12.85% Solution | 520.2325a |
| 041-955[1] | Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland | Erythromycin Medicated Premix | 558.248 |
| 049-729[1] | Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland | PURINA Sulfa (sulfamethazine) 12.5% Solution | 522.2260a |
| 100-128[1] | Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland | Supersweet Medipak TYLAN 10 | 558.625 |
| 200-307[1] | Vetoquinol N.-A., Inc., 2000 chemin Georges, Lavaltrie (PQ), Canada J5T 3S5 | Penicillin G Potassium, USP, Soluble Powder | 520.1696b |

[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 § 514.116 Notice of withdrawal of approval of application (21 CFR 514.116), notice is given that approval of NADAs 007-076, 008-244, 041-955, 049-729, 100-128, and ANADA 200-307, 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: May 31, 2016.

Tracey Forfa,

Acting Director,

Center for Veterinary Medicine.

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