



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

[Docket No. FDA-2014-N-0002]

Withdrawal of Approval of New Animal Drug Applications; Chlortetracycline; Sulfathiazole;
Penicillin

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of withdrawal of approval.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of a new animal drug application (NADA) and two abbreviated new animal drug applications (ANADAs) for three-way, fixed-ratio combination drug Type A medicated articles containing chlortetracycline, sulfathiazole, and penicillin. This action is being taken at the sponsor's 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: David Alterman, Center for Veterinary Medicine (HFV-212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-453-6843.

SUPPLEMENTARY INFORMATION: Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007 has requested that FDA withdraw approval of the following NADA and two ANADAs because the products are no longer manufactured or marketed:

NADA/ ANADA	Proprietary Name
039-077	CSP 250 (chlortetracycline, sulfathiazole, and penicillin) Type A medicated article
200-140	AUREOZOL (chlortetracycline, sulfathiazole, and penicillin) Type A medicated article
200-167	AUREOZOL 500 Granular (chlortetracycline, sulfathiazole, and penicillin) Type A medicated article

The NADAs listed were identified as being affected by guidance for industry (GFI) #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that approval of NADA 039-077, ANADA 200-140, and ANADA 200-167, and all supplements and amendments thereto, is hereby withdrawn, effective [INSERT DATE 10 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].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 12, 2014.

Bernadette Dunham,

Director,

Center for Veterinary Medicine.