4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

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

Withdrawal of Approval of Part of a New Animal Drug Application; Procaine Penicillin

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of those parts of a new animal drug application (NADA) for a three-way, fixed-ratio, combination drug Type A medicated article that pertain to use of the procaine penicillin component for growth promotion indications in swine. This action is being taken at the sponsor's request because the three-way Type A medicated article is no longer manufactured.

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

FOR FURTHER INFORMATION CONTACT: Cindy L. Burnsteel, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8341, cindy.burnsteel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Zoetis Inc. (Zoetis), 333 Portage St., Kalamazoo, MI 49007 has requested that FDA withdraw approval of those parts of NADA 035-688 for AUREOMIX Granular 500 (chlortetracycline, procaine penicillin, and sulfamethazine) Type A medicated article that pertain to use of the procaine penicillin component for growth promotion indications in swine. Zoetis requested voluntary withdrawal of approval of these indications for

use because AUREOMIX Granular 500 Type A medicated article is no longer manufactured.

Therefore, under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director of 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 those parts of NADA 035-688 that pertain to use of procaine penicillin for the production indications of growth promotion and increased feed efficiency in swine are hereby withdrawn, effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

NADA 035-688 was 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.

Elsewhere in this issue of the Federal Register, FDA is amending the animal drug regulations to reflect the withdrawal of approval of these parts of NADA 035-688.

Dated: June 25, 2014.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

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