



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Withdrawal of Approval of Part of a New Animal Drug Application; Chlortetracycline, Procaine Penicillin, and Sulfamethazine

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of withdrawal of approval.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of those parts of a new animal drug application (NADA) for a 3-way, fixed-ratio, combination drug Type A medicated article that pertain to use of the procaine penicillin component for production indications in swine. This action is being taken at the sponsor's request because the 3-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, 240-402-0817, cindy.burnsteel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Pharmgate LLC (Pharmgate), 1015 Ashes Dr., suite 102, Wilmington, NC 28405 has requested that FDA withdraw approval of those parts of NADA 138-934 for PENNCHLOR SP 500 (chlortetracycline, procaine penicillin, and sulfamethazine) Type A medicated article that pertain to use of the procaine penicillin component for the production indications of growth promotion and increased feed efficiency in swine. Pharmgate

requested voluntary withdrawal of approval of these indications for use because PENNCHLOR SP 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 § 514.116 Notice of withdrawal of approval of application (21 CFR 514.116), notice is given that approval of those parts of NADA 138-934 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penicillin for the production indications of growth promotion and increased feed efficiency in swine are hereby withdrawn, effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].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 138-934 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 138-934.

Dated: September 6, 2016.

William T. Flynn,

Acting Director,

Center for Veterinary Medicine.

[FR Doc. 2016-21984 Filed: 9/13/2016 8:45 am; Publication Date: 9/14/2016]