

■ 16. In § 558.68, revise paragraph (e)(1)(ii) to read as follows:

**§ 558.68 Avilamycin.**  
\* \* \* \* \*

(e) \* \* \*  
(1) \* \* \*

Avilamycin in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(ii) 13.6 to 40.9 .....	Monensin 90 to 110; as provided by No. 058198 in § 510.600(c) of this chapter.	Broiler chickens: For the prevention of mortality caused by necrotic enteritis associated with <i>Clostridium perfringens</i> in broiler chickens; and as an aid in the prevention of coccidiosis caused by <i>Eimeria necatrix</i> , <i>E. tenella</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i> .	Feed as the sole ration for 21 consecutive days. To assure responsible antimicrobial drug use in broiler chickens, treatment administration must begin on or before 10 days of age. See § 558.355(d) of this chapter for additional required labeling.	058198

\* \* \* \* \*

Dated: February 21, 2017.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 524

[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 an abbreviated new animal drug application (ANADA) at the sponsor's request because the product is no longer manufactured or marketed.

**DATES:** Withdrawal of approval is effective March 6, 2017.

**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](mailto:sujaya.dessai@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Putney, Inc., One Monument Square, Suite 400, Portland, ME 04101 has requested that FDA withdraw approval of ANADA 200-524 for Mupirocin Ointment 2% because the product is no longer manufactured or marketed.

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(21 CFR 514.116), notice is given that approval of ANADA 200-524, and all supplements and amendments thereto, is hereby withdrawn, effective March 6, 2017.

Elsewhere in this issue of the **Federal Register**, FDA is amending the animal drug regulations to reflect the voluntary withdrawal of approval of this application.

Dated: February 21, 2017.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 558

[Docket No. FDA-2016-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 18 new animal drug applications (NADAs) and 2 abbreviated new animal drug applications (ANADAs). These withdrawals of

approval of NADAs and ANADAs for antimicrobial drugs of importance to human medicine that are administered to food-producing animals in medicated feed are being made because the products are no longer manufactured or marketed. These actions are consistent with the FDA Center for Veterinary Medicine's initiative for the Judicious Use of Antimicrobials.

**DATES:** Withdrawal of approval is effective February 24, 2017.

**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](mailto:sujaya.dessai@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** FDA is withdrawing approval of 18 NADAs and 2 ANADAs. These applications 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 (<http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM299624.pdf>). Their withdrawal of approval is consistent with the FDA Center for Veterinary Medicine's initiative for the Judicious Use of Antimicrobials.

Approval of the following applications for new animal drugs administered in medicated feed is being voluntarily withdrawn at the sponsors' requests because these products are no longer manufactured or marketed:

File No.	Product name	Sponsor
044-820 .....	LINCOMIX (lincomycin)/AMPROL PLUS (amprolium and ethopabate).	Zoetis Inc. 333 Portage St. Kalamazoo, MI 49007 (Zoetis Inc.).