■ 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 *Clostridium perfringens* in broiler chickens; and as an aid in the prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*.	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.

[FR Doc. 2017–03677 Filed 2–23–17; 8:45 am]

BILLING CODE 4164–01–P

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.*

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CFR 514.116), notice is given that approval of ANADA 200–524, and all supplements and amendments thereto, is hereby withdrawn, effective March 6, 2017.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

[FR Doc. 2017–03678 Filed 2–23–17; 8:45 am]

BILLING CODE 4164–01–P

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.*

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.).

File No.	Product name	Sponsor
044–972	LINCOMIX (lincomycin)/COYDEN (clopidol)	Zoetis Inc.
047–261	LINCOMIX (lincomycin)/DECCOX (decoquinate)	Zoetis Inc.
047–262	LINCOMIX (lincomycin)/DECCOX (decoquinate)	Zoetis Inc.
048–954	LINCOMIX (lincomycin)/ZOAMIX (zoalene)	Zoetis Inc.
091–513	STAFAC (virginiamycin) Type A Medicated Article	Phibro Animal Health Corp., GlenPointe Centre East, 3d floor, 300 Frank W. Burr Blvd., Suite 21, Teaneck, NJ 07666 (Phibro Animal Health Corp.).
092–482	LINCOMIX (lincomycin)/COBAN (monensin)	Zoetis Inc.
093–106	LINCOMIX (lincomycin)/ROBENZ (robenidine)	Zoetis Inc.
101–689	LINCOMIX (lincomycin)/AVATEC (lasalocid)	Zoetis Inc.
122–481	STAFAC (virginiamycin)/COBAN (monensin)	Phibro Animal Health Corp.
122–608	STAFAC (virginiamycin)/AVATEC (lasalocid)	Phibro Animal Health Corp.
122–822	STAFAC (virginiamycin)/AMPROL PLUS (amprolium and ethopabate).	Phibro Animal Health Corp.
137–537	LINCOMIX (lincomycin)/BIO–COX (salinomycin)	Zoetis Inc.
138–792	TYLAN (tylosin)/RUMENSIN (monensin)/MGA (melengestrol acetate).	Zoetis Inc.
138–828	STAFAC (virginiamycin)/BIO–COX (salinomycin)	Phibro Animal Health Corp.
138–904	TYLAN (tylosin)/BOVATEC (lasalocid)/MGA (melengestrol acetate).	Zoetis Inc.
141–110	STAFAC (virginiamycin)/COBAN (monensin)	Phibro Animal Health Corp.
141–150	STAFAC (virginiamycin)/AVATEC (lasalocid)	Phibro Animal Health Corp.
200–092	STAFAC (virginiamycin)/SACOX (salinomycin)	Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sophia, Bulgaria (Huvepharma EOOD).
200–093	LINCOMIX (lincomycin)/SACOX (salinomycin)	Huvepharma EOOD.

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 044–820, 044–972, 047–261, 047–262, 048–954, 091–513, 092–482, 093–106, 101–689, 122–481, 122–608, 122–822, 137–537, 138–792, 138–828, 138–904, 141–110, 141–150, 200–092, and 200–093, and all supplements and amendments thereto, is hereby withdrawn, effective February 24, 2017.

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: February 17, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–03595 Filed 2–23–17; 8:45 am]

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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 for Use in Animal Feed; Approval of New Animal Drug Applications; Withdrawal of Approval of New Animal Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of eight supplemental new animal drug applications (NADAs). The effect of these supplemental applications will be to change the marketing status from over-the-counter (OTC) use to use by veterinary feed directive (VFD) for these antimicrobial drugs of importance to human medicine, administered to food-producing animals in medicated feed. Where applicable, FDA is also withdrawing approval of those parts of the NADAs that pertain to use of these antimicrobial drugs for production indications. These actions are being taken at the sponsors' requests because these particular medicated feeds will no longer be manufactured or marketed. These applications were submitted in voluntary compliance with the goals of FDA Center for Veterinary Medicine's (CVM's) Judicious Use Initiative. In addition, the animal drug regulations are being amended to reflect the voluntary withdrawal of approval of certain entire NADAs and abbreviated new animal drug applications (ANADAs) that were affected by this initiative.

DATES: This rule is effective February 24, 2017.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV–6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–5689, *george.haibel@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Supplemental Approval of Revised Labeling and Withdrawal of Approval of Portions of NADAs Pertaining to Production Indications

FDA is amending the animal drug regulations to reflect approval of eight supplemental NADAs for revised labeling reflecting a change in marketing status from OTC use to use by VFD for antimicrobial drugs of importance to human medicine administered to food-producing animals in medicated feed. Where applicable, FDA is also withdrawing approval of those parts of the NADAs that pertain to use of these antimicrobial drugs for production indications. These actions are being taken at the sponsors' requests because these particular medicated feeds will no longer be manufactured or marketed.

These applications were identified as being affected by guidance for industry (GFI) #213, ''New Animal Drugs and