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138–828, 138–904, 141–110, 141–150, 200–092, and 200–093, and all supplements and amendments thereto, is hereby withdrawn, effective February 24, 2017.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]

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 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

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 change from OTC to VFD marketing status is consistent with FDA CVM's initiative for the Judicious Use of Antimicrobials.

The affected applications for Type A medicated articles for which supplemental applications with revised labeling were approved are as follows:

File No.	Animal drug product	Sponsor
091–467	STAFAC 500 (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.).
140–998	V–MAX (virginiamycin) Type A Medicated Article	Phibro Animal Health Corp.

The affected applications for manufacturing combination drug medicated feeds follow:

File No.	Animal drug product	Sponsor
046–718	TERRAMYCIN (oxytetracycline)/MGA (melengestrol acetate)	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007 (Zoetis Inc.).
046–719	TERRAMYCIN (oxytetracycline)/MGA (melengestrol acetate)	Zoetis Inc.
140–579	TERRAMYCIN (oxytetracycline)/BOVATEC (lasalocid)	Zoetis Inc.
141–114	STAFAC (virginiamycin)/AVIAX (semduramicin)	Phibro Animal Health Corp.
141–289	STAFAC (virginiamycin)/AVIAX II (semduramicin) (biomass)	Phibro Animal Health Corp.
141–430	STAFAC (virginiamycin)/COBAN (monensin)	Phibro Animal Health Corp.

II. Withdrawals of Approval

At the sponsors' requests, approval of applications is being withdrawn for medicated feeds containing antimicrobial drugs of importance to human medicine administered to food-producing animals because these products are no longer manufactured or marketed. The applications being withdrawn are as follows:

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

Elsewhere in this issue of the **Federal Register**, FDA gave notice 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, and 141–150, and ANADAs 200–092 and 200–093, and all supplements and amendments thereto, is withdrawn, effective February 24, 2017. As provided in the regulatory text of this document, the animal drug

regulations are amended to reflect these voluntary withdrawals of approval.

A similar rule published in the **Federal Register** of December 27, 2016 (81 FR 94991), amended the approved conditions of use in 21 CFR part 558 to reflect approval of an additional 106 supplemental NADAs and supplemental ANADAs for the manufacture of medicated feeds for administration of antimicrobial drugs to food-producing animals and the voluntary withdrawal of approval of 11 NADAs and 4 ANADAs.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 1. The authority citation for part 558 continues to read as follows:

Authority: 21 U.S.C. 354, 360b, 360ccc, 360ccc–1, 371.

■ 2. In § 558.450, redesignate paragraph (e)(4)(iii) as paragraph (e)(4)(v) and add paragraphs (e)(4)(iii) and (iv) to read as follows:

§ 558.450 Oxytetracycline.

* * * * *

(e) * * *

(4) *Cattle*—

Oxytetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
* *	*	* *	*	*
(iii) 75 mg/head/day	Lasalocid 25 to 30	Heifers fed in confinement for slaughter (over 400 lb): For reduction of incidence of liver abscesses; and for increased rate of weight gain and improved feed efficiency.	Feed continuously to provide 250 to 360 mg lasalocid and 75 mg of oxytetracycline per head per day. Lasalocid as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(iv) 75 mg/head/day	Melengestrol acetate, 0.25 to 2.0.	Heifers fed in confinement for slaughter (over 400 lb): For reduction of incidence of liver abscesses; and for increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat).	Feed continuously to provide 0.25 to 0.5 mg of melengestrol acetate and 75 mg of oxytetracycline per head per day. Melengestrol as provided by No. 054771 in § 510.600(c) of this chapter.	054771
* *	*	* *	*	*

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■ 3. In § 558.635, revise paragraphs (a) and (e) and add paragraphs (d)(1) and (2) to read as follows:

§ 558.635 Virginiamycin.

(a) *Specifications.* Type A medicated articles containing 10, 20, 50, or 227 grams virginiamycin per pound.

* * * * *

(d) *Special considerations.* (1) Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian. See § 558.6 for additional requirements.

(2) The expiration date of VFDs for virginiamycin medicated feeds must not exceed 6 months from the date of issuance. VFDs for virginiamycin shall not be refilled.

* * * * *

(e) *Conditions of use*—(1) *Chickens*—

Virginiamycin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 20		Broiler chickens: For prevention of necrotic enteritis caused by *Clostridium* spp. susceptible to virginiamycin.	Not for use in layers	066104
(ii)–(vi) [Reserved]				
(vii) 20	Monensin, 90 to 110	Broiler chickens: For prevention of necrotic enteritis caused by *Clostridium* spp. susceptible to virginiamycin; and as an aid in the prevention of coccidiosis caused by *Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. maxima,* and *E. mivati*.	Feed continuously as the sole ration. Do not feed to laying chickens. Monensin as provided by No. 058198 in § 510.600(c) of this chapter.	066104
(viii) [Reserved]				

Virginiamycin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(ix) 20	Semduramicin, 22.7	Broiler chickens: For prevention of necrotic enteritis caused by *Clostridium* spp. susceptible to virginiamycin; for the prevention of coccidiosis caused by *Eimeria acervulina, E. brunetti, E. maxima, E mivati/mitis, E. necatrix,* and *E. tenella*.	Feed continuously as the sole ration. Do not feed to laying hens. Semduramicin as provided by No. 066104 in § 510.600(c) of this chapter.	066104
(x) 20	Semduramicin (biomass), 22.7	Broiler chickens: For prevention of necrotic enteritis caused by *Clostridium* spp. susceptible to virginiamycin; for the prevention of coccidiosis caused by *Eimeria acervulina, E. brunetti, E. maxima, E mivati/mitis, E. necatrix,* and *E. tenella*.	Feed continuously as the sole ration. Withdraw 1 day before slaughter. Do not feed to laying hens. Semduramicin as provided by No. 066104 in § 510.600(c) of this chapter.	066104

(2) *Swine*—

Virginiamycin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 25		Growing-finishing swine: As an aid in control of dysentery in swine up to 120 pounds in animals or on premises with a history of swine dysentery but where symptoms have not yet occurred.		066104
(ii) 50 or 100		Growing-finishing swine: For treatment and control of swine dysentery in swine up to 120 pounds.	Feed 100 grams per ton for 2 weeks, 50 grams per ton thereafter.	066104
(iii) 100		Growing-finishing swine: For treatment of swine dysentery in nonbreeding swine over 120 pounds.	Feed for 2 weeks	066104

(3) *Cattle*—

Virginiamycin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 13.5 to 16.0		Cattle fed in confinement for slaughter: For reduction of incidence of liver abscesses.	Feed continuously as the sole ration to provide 85 to 240 milligrams per head per day. Not for use in animals intended for breeding.	066104
(ii) [Reserved]				

Dated: February 17, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–03596 Filed 2–23–17; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 174

[EPA–HQ–OPP–2014–0457; FRL–9957–97]

VNT1 Protein in Potato; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of VNT1 protein in potato when used as a plant-incorporated protectant. J.R. Simplot Company submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting a permanent exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of VNT1 protein in potato under FFDCA.

DATES: This regulation is effective February 24, 2017. Objections and requests for hearings must be received on or before April 25, 2017 and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also