DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520 and 529

[Docket No. FDA–2016–N–0002]

Oral Dosage Form New Animal Drugs; 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 43 supplemental new animal drug applications (NADAs) and 52 supplemental abbreviated new animal drug applications (ANADAs) for revised labeling reflecting a change in marketing status from over-the-counter (OTC) to prescription (Rx) for antimicrobial drugs of importance to human medicine administered to food-producing animals in medicated drinking water. These applications were submitted in voluntary compliance with the goals of the FDA Center for Veterinary Medicine's (CVM's) Judicious Use Initiative.

DATES: This rule is effective December 31, 2016.

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: FDA is amending the animal drug regulations to reflect approval of 43 supplemental NADAs and 52 supplemental ANADAs for revised labeling reflecting a change in marketing status from OTC to Rx for antimicrobial drugs of importance to human medicine administered to food-producing animals in medicated drinking water. 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 to Rx marketing status is consistent with the FDA CVM's initiative for the Judicious Use of Antimicrobials. The affected applications follow:

File No.	Animal drug product	Sponsor
006–084	SULMET (sulfamethazine) Drinking Water Solution	Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sophia, Bulgaria (Huvepharma EOOD).
006–677	S.Q. (sulfaquinoxaline) 20% Solution	Huvepharma EOOD.
006–707	SULQUIN 6–50 (Sulfaquinoxaline)	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007 (Zoetis Inc.).
006–891	SUL–Q–NO_X (sulfaquinoxaline) Solution	Huvepharma EOOD.
007–087	Sulfaquinoxaline Solubilized (Powder)	Huvepharma EOOD.
008–622	TERRAMYCIN (oxytetracycline) Soluble Powder	Zoetis Inc.
011–315	NEOMIX 325 (neomycin) Soluble Powder	Zoetis Inc.
015–160	Sodium Sulfachloropyrazine Solution	Zoetis Inc.
031–205	AGRIBON (sulfadimethoxine) 12.5% Drinking Water Solution	Zoetis Inc.
031–553	ESB 3 (sulfachloropyrazine) Soluble Powder/Solution	Zoetis Inc.
032–946	MAGNA TERRAMYCIN (oxytetracycline and carbomycin) Soluble Powder.	Zoetis Inc.
033–373	VETSULID SP (sulfachloropyridazine) Soluble Powder	Huvepharma EOOD.
035–157	GALLIMYCIN (erythromycin) Soluble Powder	Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland (Cross Vetpharm Group Ltd.).
038–200	MEDAMYCIN (oxytetracycline) Soluble Powder	Phibro Animal Health Corp., GlenPointe Centre East, 3d floor, 300 Frank W. Burr Blvd., suite 21, Teaneck, NJ 07666 (Phibro Animal Health Corp.).
038–661	SPECTOGARD (spectinomycin) Water Soluble Powder	Cross Vetpharm Group Ltd.
046–109	L–S 50 (lincomycin and spectinomycin) Water Soluble Powder	Zoetis Inc.
046–285	AGRIBON (sulfadimethoxine) Soluble Powder	Zoetis Inc.
055–012	CHLORONEX SULMET (chlortetracycline bisulfate and sulfamethazine) Soluble Powder.	Huvepharma EOOD.
055–020	AUREOMYCIN (chlortetracycline) Soluble Powder	Zoetis Inc.
055–060	Penicillin G Potassium, USP	Zoetis Inc.
065–071	AUREOMYCIN (chlortetracycline) Soluble Powder	Huvepharma EOOD.
065–123	Tetracycline Soluble Powder	Zoetis Inc.
065–140	TET–SOL 324 (tetracycline) Soluble Powder	Huvepharma EOOD.
065–178	FERMYCIN (chlortetracycline) Soluble	Phibro Animal Health Corp.
065–256	CHLORO–SOLUBLE–O (chlortetracycline) Soluble Powder	Pharmgate LLC, 1015 Ashes Dr., suite 102, Wilmington, NC 28405 (Pharmgate LLC).
065–269	POLYOTIC (tetracycline) Soluble Powder	Huvepharma EOOD.
065–410	TETRA–SAL (tetracycline) Soluble Powder	Zoetis Inc.
065–440	CHLORONEX (chlortetracycline) Soluble Powder	Huvepharma EOOD.
065–441	POLYOTIC (tetracycline) Soluble Powder Concentrate	Zoetis Inc.
065–480	Chlortetracycline Soluble Powder	Pharmgate LLC.
065–486	Chlortetracycline Bisulfate Soluble Powder	Strategic Veterinary Pharmaceuticals, Inc., 100 NW. Airport Rd., St. Joseph, MO 64503 (Strategic Vet. Pharm., Inc.).
065–496	Tetracycline Soluble Powder	Phibro Animal Health Corp.
091–191	GENTOCIN (gentamicin) Oral Solution	Intervet, Inc., 2 Giralda Farms, Madison, NJ 07940 (Intervet, Inc.).
100–094	POULTRY SULFA (sulfamerazine, sulfamethazine, and sulfaquinoxaline) Soluble Powder.	Huvepharma EOOD.
106–964	APRALAN (apramycin) Soluble Powder	Elanco US Inc.
111–636	LINCOMIX (lincomycin) Soluble Powder	Zoetis Inc.

File No.	Animal drug product	Sponsor
122–272	SULMET (sulfamethazine) Soluble Powder	Huvepharma EOOD.
130–435	OXY–TET (oxytetracycline) Soluble Powder	Huvepharma EOOD.
133–836	GARACIN (gentamicin) Soluble Powder	Intervet, Inc.
140–578	SOLU–TET 324 (tetracycline) Soluble Powder	Zoetis Inc.
200–026	PENNOX 343 (oxytetracycline)	Pharmgate LLC.
200–030	Sulfadimethoxine 12.5% Oral Solution	Agri Laboratories, Ltd., P.O. Box 3103, St. Joseph, MO 64503 (Agri Laboratories, Ltd.).
200–031	Sulfadimethoxine Antibacterial Soluble Powder	Agri Laboratories, Ltd.
200–046	Neomycin Soluble Powder	Zoetis Inc.
200–049	Tetracycline Hydrochloride Soluble Powder-324	Agri Laboratories, Ltd.
200–050	NEOMED (neomycin) Soluble Powder	Cross Vetpharm Group Ltd.
200–066	AGRIMYCIN–343 (oxytetracycline) Soluble Powder	Agri Laboratories, Ltd.
200–103	PENAQUA SOL–G (penicillin G potassium) Soluble Powder	Cross Vetpharm Group Ltd.
200–106	R–PEN (penicillin G potassium) Soluble Powder	Huvepharma EOOD.
200–113	BIOSOL® (neomycin) Liquid	Zoetis Inc.
200–118	Neomycin Oral Solution	Huvepharma EOOD.
200–122	SOLU–PEN (penicillin G potassium) Soluble Powder	Zoetis Inc.
200–130	NEO–SOL 50 (neomycin) Soluble Powder	Zoetis Inc.
200–136	Tetracycline Hydrochloride Soluble Powder-324	Quo Vademus, LLC, 277 Faison McGowan Rd., Kenansville, NC 28349 (Quo Vademus, LLC).
200–144	Oxytetracycline HCl Soluble Powder	Cross Vetpharm Group Ltd.
200–146	TETROXY 25 (oxytetracycline)	Cross Vetpharm Group Ltd.
200–153	NEO 200 (neomycin) Oral Solution	Huvepharma EOOD.
200–165	SDM (sulfadimethoxine) 12.5% Oral Solution	Strategic Vet. Pharm., Inc.
200–185	GEN–GARD (Gentamicin sulfate) Soluble Powder	Agri Laboratories, Ltd.
200–189	Lincomycin Soluble	Huvepharma EOOD.
200–190	GENTORAL (gentamicin sulfate) Oral Solution	Med-Pharmex, Inc., 2727 Thompson Creek Rd., Pomona, CA 91767–1861 (Med-Pharmex, Inc.).
200–192	Sulfadimethoxine 12.5% Oral Solution	Huvepharma EOOD.
200–197	Streptomycin Oral Solution w/STREP SOL (RLNAD 065–252)	Huvepharma EOOD.
200–233	LINCO (lincomycin) Soluble Powder	Zoetis Inc.
200–234	TETRASOL (tetracycline) Soluble Powder	Med-Pharmex, Inc.
200–235	NEOSOL (neomycin) Soluble Powder	Med-Pharmex, Inc.
200–236	Chlortetracycline HCL Soluble Powder	Quo Vademus, LLC.
200–238	SULFASOL (sulfadimethoxine) Soluble Powder	Med-Pharmex, Inc.
200–241	LINCOSOL (lincomycin) Soluble Powder	Med-Pharmex, Inc.
200–247	TETROXY 343 (oxytetracycline) Soluble Powder	Cross Vetpharm Group Ltd.
200–251	SULFORAL (Sulfadimethoxine) Soluble Powder	Med-Pharmex, Inc.
200–258	Sulfadimethoxine Soluble Powder	Phibro Animal Health Corp.
200–289	NEOSOL–ORAL (neomycin) Soluble Powder	Med-Pharmex, Inc.
200–295	PENNCHLOR 64 (chlortetracycline) Soluble Powder	Pharmgate LLC.
200–303	Lincomycin Hydrochloride Soluble Powder	Quo Vademus, LLC.
200–345	Lincomycin-Spectinomycin Soluble Powder	Phibro Animal Health Corp.
200–347	Penicillin G Potassium USP	Quo Vademus, LLC.
200–372	HAN–PEN (penicillin G potassium) Soluble Powder	G.C. Hanford Manufacturing Co., P.O. Box 1017, Syracuse, NY 13201 (G.C. Hanford Mfg. Co.).
200–374	TETRAMED 324 HCA (tetracycline) Soluble Powder	Cross Vetpharm Group Ltd.
200–376	SULFAMED–G (sulfadimethoxine) Soluble Powder	Cross Vetpharm Group Ltd.
200–377	LINXMED–SP (lincomycin and spectinomycin) Soluble Powder	Cross Vetpharm Group Ltd.
200–378	Neomycin Sulfate 325 Soluble Powder	Sparhawk Laboratories, Inc., 12340 Santa Fe Trail Dr., Lenexa, KS 66215 (Sparhawk Laboratories, Inc.).
200–379	Neomycin Liquid	Sparhawk Laboratories, Inc.
200–380	SPECLINX–50 (lincomycin and spectinomycin) Soluble Powder	Cross Vetpharm Group Ltd.
200–407	Lincomycin-Spectinomycin Water Soluble Powder	Agri Laboratories, Ltd.
200–434	SMZ–MED 454 (sulfamethazine) Soluble Powder	Cross Vetpharm Group Ltd.
200–441	AUREOMYCIN (chlortetracycline) Soluble Powder	Huvepharma EOOD.
200–443	Sulfadimethoxine Soluble Powder	First Priority, Inc., 1590 Todd Farm Dr., Elgin, IL 60123.
200–460	TETROXY AQUATIC (oxytetracycline) Soluble Powder	Cross Vetpharm Group Ltd.
200–494	GENTAMED (gentamicin) Soluble Powder	Cross Vetpharm Group Ltd.

The animal drug regulations are also being amended to reflect several non-substantive changes in format. These technical amendments are being made to improve the consistency and readability of the regulations.

Elsewhere in this issue of the **Federal Register**, FDA is amending the animal drug regulations to reflect approval of similar supplemental NADAs and ANADAs changing the marketing status of antimicrobial drugs administered to food-producing animals in medicated feed.

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 Parts 520 and 529

Animal drugs.

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 parts 520 and 529 are amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 520.110 [Amended]

■ 2. In § 520.110, in paragraph (d)(3), remove ''Prepare fresh medicated water daily.'' and as the last sentence add ''Federal law restricts this drug to use by or on the order of a licensed veterinarian.''

§ 520.441 [Amended]

■ 3. In § 520.441, in paragraphs (d)(1)(i)(A)(*2*), (d)(2)(i)(A)(*2*), (d)(4)(i)(A)(*2*), (d)(4)(i)(B)(*2*), (d)(4)(ii)(A)(*2*), (d)(4)(ii)(B)(*2*), (d)(4)(iii)(C), (d)(4)(iv)(C), (d)(5)(i)(A)(*2*), (d)(5)(ii)(A)(*2*), (d)(5)(iii)(C), and (d)(5)(iv)(C), as the last sentence add ''Federal law restricts this drug to use by or on the order of a licensed veterinarian.''

§ 520.445 [Amended]

■ 4. In § 520.445, in paragraph (d)(3), as the last sentence add ''Federal law restricts this drug to use by or on the order of a licensed veterinarian.''

■ 5. In § 520.823, revise paragraphs (d)(1)(i), (d)(1)(iii), (d)(2)(i), (d)(2)(iii), (d)(3)(i), and (d)(3)(iii) to read as follows:

§ 520.823 Erythromycin.

* * * * *

(d) * * *

(1) * * *

(i) *Amount.* Administer 0.500 gram per gallon for 5 days.

* * * * *

(iii) *Limitations.* Do not use in replacement pullets over 16 weeks of age. Do not use in chickens producing eggs for human consumption. Withdraw 1 day before slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) * * *

(i) *Amount.* Administer 0.500 gram per gallon for 7 days.

* * * * *

(iii) *Limitations.* Do not use in replacement pullets over 16 weeks of age. Do not use in chickens producing eggs for human consumption. Withdraw 1 day before slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(3) * * *

(i) *Amount.* Administer 0.500 gram per gallon for 7 days.

* * * * *

(iii) *Limitations.* Do not use in turkeys producing eggs for human consumption. Withdraw 1 day before slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

■ 6. In § 520.1044a, revise paragraph (d)(3) to read as follows:

§ 520.1044a Gentamicin sulfate oral solution.

* * * * *

(d) * * *

(3) *Limitations.* Do not slaughter treated swine for food for at least 3 days following treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

■ 7. In § 520.1044c, remove paragraph (d)(4) and revise paragraph (d)(3) to read as follows:

§ 520.1044c Gentamicin sulfate powder.

* * * * *

(d) * * *

(3) *Limitations.* Withdrawal period: 10 days. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.1263c [Amended]

■ 8. In § 520.1263c, in paragraph (b)(1), remove ''No. 016592'' and in its place add ''Nos. 016592 and 054771''; in paragraph (d)(1)(iii), remove ''051259'' and in its place add ''054925'', and as the last sentence add ''Federal law restricts this drug to use by or on the order of a licensed veterinarian.''; and in paragraphs (d)(2)(iii) and (d)(3)(iii), add ''Federal law restricts this drug to use by or on the order of a licensed veterinarian.''

■ 9. In § 520.1265, add paragraph (d)(3) to read as follows:

§ 520.1265 Lincomycin and spectinomycin powder.

* * * * *

(d) * * *

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

■ 10. In § 520.1484, revise paragraphs (e)(1)(iii) and (e)(2)(iii) to read as follows:

§ 520.1484 Neomycin.

* * * * *

(e) * * **

(1) * * *

(iii) *Limitations.* Discontinue treatment prior to slaughter as follows: Cattle, 1 day; sheep, 2 days; swine and goats, 3 days. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) * * *

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

■ 11. In § 520.1660a, revise the section heading and paragraphs (e)(1) and (e)(3) to read as follows:

§ 520.1660a Oxytetracycline and carbomycin.

* * * * *

(e) * * *

(1) *Amount.* Administer 1.0 gram of oxytetracycline and 1.0 gram carbomycin per gallon for not more than 5 days.

* * * * *

(3) *Limitations.* Not for use in chickens producing eggs for human consumption. Withdraw 24 hours before slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

■ 12. In § 520.1660d, revise paragraphs (d)(1)(i)(A)(*1*), (d)(1)(i)(A)(*3*), (d)(1)(i)(B)(*1*), (d)(1)(i)(B)(*3*), (d)(1)(ii)(A)(*1*), (d)(1)(ii)(A)(*3*), (d)(1)(ii)(B)(*1*), (d)(1)(ii)(B)(*3*), (d)(1)(ii)(C)(*1*), (d)(1)(ii)(C)(*3*), (d)(1)(iii)(A), (d)(1)(iii)(C), (d)(1)(iv)(A), (d)(1)(iv)(C), (d)(1)(v)(A), (d)(1)(v)(C), (d)(2)(i), and (d)(2)(iii) to read as follows:

§ 520.1660d Oxytetracycline powder.

* * * * *

(d) * * *

(1) * * *

(i) * * *

(A) * * *

(*1*) *Amount.* Administer 200 to 400 milligrams/gallon for 7 to 14 days. Not to be used for more than 14 consecutive days.

* * * * *

(*3*) Do not use in birds producing eggs for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(B) * * *

(*1*) *Amount.* Administer 400 to 800 milligrams/gallon for 7 to 14 days. Not to be used for more than 14 consecutive days.

* * * * *

(*3*) Do not use in birds producing eggs for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(ii) * * *

(A) * * *

(*1*) *Amount.* Administer 200 to 400 milligrams/gallon for 7 to 14 days. Not to be used for more than 14 consecutive days.

* * * * *

(*3*) Do not use in birds producing eggs for human consumption. Withdraw 5 days prior to slaughter those products sponsored by Nos. 054771 and 061623 in § 510.600(c) of this chapter. Withdraw 4 days prior to slaughter

those products sponsored by No. 054628. Zero-day withdrawal for those products sponsored by Nos. 057561 and 069254. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(B) * * *

(*1*) *Amount.* Administer 400 milligrams/gallon for 7 to 14 days. Not to be used for more than 14 consecutive days.

* * * * *

(*3*) Do not use in birds producing eggs for human consumption. Withdraw 5 days prior to slaughter those products sponsored by Nos. 054771 and 061623 in § 510.600(c) of this chapter. Withdraw 4 days prior to slaughter those products sponsored by No. 054628. Zero-day withdrawal for those products sponsored by Nos. 057561 and 069254. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(C) * * *

(*1*) *Amount.* Administer 25 milligrams per pound of body weight daily for 7 to 14 days. Not to be used for more than 14 consecutive days.

* * * * *

(*3*) Do not use in birds producing eggs for human consumption. Withdraw 5 days prior to slaughter those products sponsored by Nos. 054771 and 061623 in § 510.600(c) of this chapter. Withdraw 4 days prior to slaughter those products sponsored by No. 054628. Zero-day withdrawal for those products sponsored by Nos. 057561 and 069254. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(iii) * * *

(A) *Amount.* Administer 10 milligrams per pound of body weight daily for up to 14 days. Do not use for more than 14 consecutive days.

* * * * *

(C) Withdraw zero days prior to slaughter those products sponsored by Nos. 054771, 057561, 061623, and 069254 in § 510.600(c) of this chapter. Withdraw 4 days prior to slaughter those products sponsored by No. 054628. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(iv) * * *

(A) *Amount.* Administer 10 milligrams per pound of body weight daily for up to 14 days. Do not use for more than 14 consecutive days.

* * * * *

(C) Withdraw 5 days prior to slaughter. A milk discard period has not been established for this product in lactating dairy cattle. Do not use in female dairy cattle 20 months of age or older. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(v) * * *

(A) *Amount.* Administer 10 milligrams per pound of body weight daily for up to 14 days. Not to be used for more than 14 consecutive days.

* * * * *

(C) Withdraw 5 days prior to slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) * * *

(i) *Amount.* 200 milligrams per colony, administered via either a 1:1 sugar syrup (equal parts of sugar and water weight to weight) or dusting with a powdered sugar mixture. The drug is administered in 3 applications of sugar syrup or 3 dustings at 4- to 5-day intervals.

* * * * *

(iii) The drug should be fed early in the spring or fall and consumed by the bees before main honey flow begins to avoid contamination of production honey. Remove at least 6 weeks prior to main honey flow. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

■ 13. In § 520.1696b, redesignate paragraph (c) as paragraph (d) and add new paragraph (c), and revise redesignated paragraph (d)(3) to read as follows:

§ 520.1696b Penicillin G powder.

* * * * *

(c) *Related tolerances.* See § 556.510 of this chapter.

* * * * *

(d) * * *

(3) *Limitations.* Discontinue treatment at least 1 day prior to slaughter. Not for use in turkeys producing eggs for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.2123b [Amended]

■ 14. In § 520.2123b, remove paragraph (d)(1)(i); redesignate paragraphs (d)(1)(ii) and (iii) as paragraphs (d)(1)(i) and (ii); and in paragraph (d)(2), as the last sentence add ''Federal law restricts this drug to use by or on the order of a licensed veterinarian.''

§ 520.2184 [Amended]

■ 15. In § 520.2184, in paragraph (d)(3), remove the first sentence, and as the last sentence add ''Federal law restricts this drug to use by or on the order of a licensed veterinarian.''

§ 520.2200 [Amended]

■ 16. In § 520.2200, in paragraphs (d)(1)(iii) and (d)(2)(iii), as the last sentence add ''Federal law restricts this drug to use by or on the order of a licensed veterinarian.''

§ 520.2218 [Amended]

■ 17. In § 520.2218, in paragraphs (d)(1)(ii) and (d)(2)(ii), remove the first sentence, and as the last sentence add ''Federal law restricts this drug to use by or on the order of a licensed veterinarian.''

■ 18. In § 520.2220a, revise the section heading and paragraphs (d)(1)(iii), (d)(2)(iii), and (d)(3)(iii) to read as follows:

§ 520.2220a Sulfadimethoxine oral solution and soluble powder.

* * * * *

(d) * * *

(1) * * *

(iii) *Limitations.* Withdraw 5 days before slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) * * *

(iii) *Limitations.* Withdraw 5 days before slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(3) * * *

(iii) *Limitations.* Withdraw 7 days before slaughter. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the extralabel use of this product in lactating dairy cattle.

§ 520.2261a [Amended]

■ 19. In § 520.2261a, in paragraph (d)(3), as the last sentence add ''Federal law restricts this drug to use by or on the order of a licensed veterinarian.''

§ 520.2261b [Amended]

■ 20. In § 520.2261b, in paragraphs (d)(1)(iii), (d)(2)(iii), (d)(3)(iii), and (d)(4)(iii), as the last sentence add ''Federal law restricts this drug to use by or on the order of a licensed veterinarian.''

§ 520.2325a [Amended]

■ 21. In § 520.2325a, in paragraph (d), remove the first sentence, and as the last sentence add ''Federal law restricts this drug to use by or on the order of a licensed veterinarian.''

§ 520.2345d [Amended]

■ 22. In § 520.2345d, in paragraphs (d)(1)(iii), (d)(2)(iii), (d)(3)(iii), and (d)(4)(iii), as the last sentence add ''Federal law restricts this drug to use by or on the order of a licensed veterinarian.''

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

■ 23. The authority citation for part 529 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 24. In § 529.1660, add paragraph (d)(3) to read as follows:

§ 529.1660 Oxytetracycline.

* * * * *

(d) * * *

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: December 20, 2016.

Tracey H. Forfa,

Deputy Director, Center for Veterinary Medicine.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 556 and 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 71 supplemental new animal drug applications (NADAs) and 35 supplemental abbreviated new animal drug applications (ANADAs) for revised labeling reflecting a change in marketing status from over-the-counter (OTC) use to use by veterinary feed directive (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 growth promotion 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 ANADAs that were affected by this initiative. The animal drug regulations are also being amended to reflect several non-substantive changes in format. These technical amendments are being made to improve the consistency and readability of the regulations.

DATES: This rule is effective December 30, 2016.

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 71 supplemental NADAs and 35 supplemental ANADAs 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 growth promotion 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 to VFD marketing status is consistent with FDA CVM's initiative for the Judicious Use of Antimicrobials.

The animal drug regulations for medicated feeds are also being amended to reflect several non-substantive changes in format. These technical amendments are being made to improve the consistency and readability of the regulations.

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

File No.	Animal drug product	Sponsor
006–391	S.Q. 40% (sulfaquinoxaline) Type A Medicated Article	Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sophia, Bulgaria (Huvepharma EOOD).
008–804	TM–50 or TM–100 (oxytetracycline) 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.).
010–092	GALLIMYCIN–100P (erythromycin) Type A Medicated Article	Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland (Cross Vetpharm Group Ltd.).
010–918	HYGROMIX 8 (hygromycin B) Type A Medicated Article	Elanco US Inc., 2500 Innovation Way, Greenfield, IN 46140 (Elanco US Inc.).
012–491	TYLAN (tylosin) Type A Medicated Article	Elanco US Inc.
033–950	Sulfamerazine In Fish Grade	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007 (Zoetis Inc.).
035–688	AUREOMIX S 40/40 (chlortetracycline and sulfamethazine) Granular Type A Medicated Article.	Zoetis Inc.
035–805	AUREO S 700 (chlortetracycline and sulfamethazine) Granular Type A Medicated Article.	Zoetis Inc.
038–439	TERRAMYCIN 200 (oxytetracycline) for Fish Type A Medicated Article.	Phibro Animal Health Corp.
040–209	ROFENAID 40 (sulfadimethoxine and ormetoprim) Type A Medicated Article.	Zoetis Inc.