

**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](mailto: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 <sub>x</sub> (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 .....	PENQUA 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](mailto: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.