General, 5 U.S.C. 801(a)(1), and indicate whether the rule is a ''major rule'' as defined in 5 U.S.C. 804(2). The CRA further states that the Office of Information and Regulatory Affairs (OIRA) determines whether a rule qualifies as a ''major rule.'' OIRA has determined that this rule is not a ''major rule'' under the CRA. To comply with the CRA, the Commission will submit the required information to each House of Congress and the Comptroller General.

List of Subjects in 16 CFR Part 1310

Administrative practice and procedure, Consumer protection, Infants and children.

■ For the reasons stated in the preamble, the Commission adds part 1310 to title 16 of the Code of Federal Regulations as follows:

PART 1310—BAN OF INCLINED SLEEPERS FOR INFANTS

Sec.
1310.1 Purpose and Scope.
1310.2 Definition.
1310.3 Banned Hazardous Product.
1310.4 Effective Date.

Authority: 15 U.S.C. 2057d.

§ 1310.1 Purpose and Scope.

The purpose of this rule is to prohibit the sale, offer for sale, manufacture for sale, distribution in commerce, or importation into the United States, of any inclined sleepers for infants, as defined in part 1310.2 and as set forth in the Safe Sleep for Babies Act of 2021 (15. U.S.C. 2057d).

§ 1310.2 Definition.

Inclined sleeper for infants means a product with an inclined sleep surface greater than ten degrees that is intended, marketed, or designed to provide sleeping accommodations for an infant up to 1 year old.

§ 1310.3 Banned Hazardous Product.

Any inclined sleeper for infants, as defined in section 1310.2, regardless of the date of manufacture, is a banned hazardous product under section 8 of the Consumer Product Safety Act (15 U.S.C. 2057).

§ 1310.4 Effective Date.

By statute, the effective date of this ban is November 12, 2022. The effective date of this rule is September 15, 2023.

Alberta E. Mills,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2023–17350 Filed 8–15–23; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 500, 510, 516, 520, 522, 524, 526, 529, 556 and 558

[Docket No. FDA–2023–N–0002]

New Animal Drugs; Approval of New Animal Drug Applications; Withdrawal of Approval of New Animal Drug Applications, Change of Sponsor, Change of Sponsor Address

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the animal drug regulations to reflect application-related actions for new animal drug applications (NADAs), abbreviated new animal drug applications (ANADAs), and conditionally approved new animal drug applications (cNADAs) during April, May, and June 2023. FDA is informing the public of the availability of summaries of the basis of approval and of environmental review documents, where applicable. The animal drug regulations are also being amended to improve their accuracy and readability.

DATES: This rule is effective August 16, 2023.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV–6), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–5689, *george.haibel@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Approvals

FDA is amending the animal drug regulations to reflect approval actions for NADAs, ANADAs, and cNADAs during April, May, and June 2023, as listed in table 1. In addition, FDA is informing the public of the availability, where applicable, of documentation of environmental review required under the National Environmental Policy Act (NEPA) and, for actions requiring review of safety or effectiveness data, summaries of the basis of approval (FOI Summaries) under the Freedom of Information Act (FOIA). These public documents may be seen in the office of the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500. Persons with access to the internet may obtain these documents at the CVM FOIA Electronic Reading Room: *https://www.fda.gov/about-fda/center-veterinary-medicine/cvm-foia-electronic-reading-room.* Marketing exclusivity and patent information may be accessed in FDA's publication, Approved Animal Drug Products Online (Green Book) at: *https://www.fda.gov/animal-veterinary/products/approved-animal-drug-products-green-book.*

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS, ANADAS, AND CNADAS APPROVED DURING APRIL, MAY, AND JUNE 2023 REQUIRING EVIDENCE OF SAFETY AND/OR EFFECTIVENESS

Approval date	File No.	Sponsor	Product name	Effect of the action	Public documents	21 CFR section
April 5, 2023	200–612	Bimeda Animal Health Ltd., 1B The Herbert Building, The Park, Carrickmines, Dublin 18, Ireland.	BIMASONE (flumethasone) Injectable Solution.	Original approval for the treatment of various inflammatory conditions in horses, dogs, and cats as a generic copy of NADA 030–414.	FOI Summary	522.960c
April 10, 2023	038–439	Phibro Animal Health Corp., GlenPointe Centre East, 3d Floor, 300 Frank W. Burr Blvd., Suite 21, Teaneck, NJ 07666.	TERRAMYCIN for Fish (oxytetracycline) Type A Medicated Article.	Supplemental approval for the control of mortality due to columnaris disease in catfish and freshwater-reared salmonids.	FOI Summary	558.450

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS, ANADAS, AND CNADAS APPROVED DURING APRIL, MAY, AND JUNE 2023 REQUIRING EVIDENCE OF SAFETY AND/OR EFFECTIVENESS—Continued

Approval date	File No.	Sponsor	Product name	Effect of the action	Public documents	21 CFR section
April 20, 2023	141–570	Boehringer Ingelheim Animal Health USA, Inc., 3239 Satellite Blvd., Duluth, GA 30096.	NEXGARD COMBO (esafoxolaner, eprinomectin, and praziquantel) Topical Solution.	Original approval for prevention of heartworm disease; for treatment and prevention of flea infestations, treatment and control of tick infestations, roundworms, hookworms, and tapeworms in cats and kittens.	FOI Summary	524.838
May 1, 2023	141–571	Elanco US Inc., 2500 Innovation Way, Greenfield, IN 46140.	VARENZIN–CA1 (molidustat oral suspension).	Conditional approval for the control of nonregenerative anemia associated with chronic kidney disease (CKD) in cats.	FOI Summary	516.1449
May 5, 2023	141–562	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.	LIBRELA (bedinvetmab injection) Injectable Solution.	Original approval for the control of pain associated with osteoarthritis in dogs.	FOI Summary	522.158
May 10, 2023	200–748	Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sofia, Bulgaria.	PENNCHLOR (chlortetracycline Type A medicated article) and MONOVET (monensin Type A medicated article) to be used in the manufacture of Type B and Type C medicated feeds.	Original approval for multiple indications in beef calves 2 months of age and older and in growing beef steers and heifers fed in confinement for slaughter as a generic copy of NADA 141–564.	FOI Summary	558.128
May 25, 2023	200–750	Cronus Pharma Specialities India Private Ltd., Sy No-99/1, M/s GMR Hyderabad Aviation SEZ Ltd., Mamidipalli Village, Shamshabad Mandal, Ranga Reddy, Hyderabad, Telangana, 501218, India.	DORAJECT (doramectin injection) Injectable Solution.	Original approval for treatment and control of internal and external parasites of cattle and swine as a generic copy of NADA 141–061.	FOI Summary	522.770
June 9, 2023	141–555	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.	APOQUEL CHEWABLE (oclacitinib tablet) Tablets.	Original approval for control of pruritus associated with allergic dermatitis and control of atopic dermatitis in dogs at least 12 months of age.	FOI Summary	520.1604
June 21, 2023	141–406	Boehringer Ingelheim Animal Health USA, Inc., 3239 Satellite Blvd., Duluth, GA 30096.	NEXGARD (afoxolaner) Chewable Tablet.	Supplemental approval for Asian longhorned tick.	FOI Summary	520.43
June 22, 2023	200–751	Pegasus Laboratories, Inc., 8809 Ely Rd., Pensacola, FL 32514.	Firocoxib Chewable Tablets for Dogs (firocoxib).	Original approval for the control of pain and inflammation associated with osteoarthritis and for the control of postoperative pain and inflammation associated with soft-tissue and orthopedic surgery in dogs as a generic copy of NADA 141–230.	FOI Summary	520.928

Also, FDA is amending the animal drug regulations to reflect approval of supplemental applications, as listed in table 2, to change the marketing status of dosage form antimicrobial animal drug products from over-the-counter (OTC) to by veterinary prescription (Rx). These applications were submitted in voluntary compliance with the goals of the FDA Center for Veterinary Medicine's Judicious Use Initiative as identified by guidance for industry #263, ''Recommendations for Sponsors of Medically Important Antimicrobial Drugs Approved for Use in Animals to Voluntarily Bring Under Veterinary Oversight All Products That Continue to be Available Over-the-Counter,'' June 11, 2021 (*https://www.fda.gov/media/130610/download*).

TABLE 2—SUPPLEMENTAL APPLICATIONS APPROVED DURING APRIL, MAY, AND JUNE 2023 TO CHANGE THE MARKETING STATUS OF ANTIMICROBIAL ANIMAL DRUG PRODUCTS FROM OTC TO RX

Approval date	File No.	Sponsor	Product name	21 CFR section
April 14, 2023	200–147	Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sofia, Bulgaria.	GENTAPOULT (gentamicin) Injectable Solution	522.1044
April 24, 2023	065–481	Cronus Pharma Specialities India Private Ltd., Sy No-99/1, M/s GMR Hyderabad Aviation SEZ Ltd., Mamidipalli Village, Shamshabad Mandal, Ranga Reddy, Hyderabad, Telangana, 501218, India.	Chlortetracycline Pneumonia/Calf Scour Bolus	520.443
April 24, 2023	200–128	Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sofia, Bulgaria.	AGRIMYCIN 200 (oxytetracycline HCl) Injectable Solution.	522.1660a

TABLE 2—SUPPLEMENTAL APPLICATIONS APPROVED DURING APRIL, MAY, AND JUNE 2023 TO CHANGE THE MARKETING STATUS OF ANTIMICROBIAL ANIMAL DRUG PRODUCTS FROM OTC TO RX—Continued

Approval date	File No.	Sponsor	Product name	21 CFR section
April 28, 2023	108–963	Cronus Pharma Specialities India Private Ltd., Sy No-99/1, M/s GMR Hyderabad Aviation SEZ Ltd., Mamidipalli Village, Shamshabad Mandal, Ranga Reddy, Hyderabad, Telangana, 501218, India.	MEDAMYCIN 100 (oxytetracycline HCl) Injectable Solution.	522.1662
April 28, 2023	097–452	Do	OXYJECT 100 (oxytetracycline HCl) Injectable Solution	522.1662
April 28, 2023	047–278	Do	OXY–TET 50 (oxytetracycline HCl) Injectable Solution	522.1662
April 28, 2023	045–143	Do	OXYJECT 50 (oxytetracycline HCl) Injectable Solution	522.1662
May 15, 2023	140–270	Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sofia, Bulgaria.	SULFATECH SR (sulfamethazine sustained release bolus).	520.2260b
May 15, 2023	200–306	Norbrook Laboratories Ltd., Carnbane Industrial Estate, Newry, County Down, BT35 6QQ, United Kingdom.	Oxytetracycline Injection 200	522.1660a
May 16, 2023	120–615	Bimeda Animal Health Ltd., 1B The Herbert Building, The Park, Carrickmines, Dublin 18, Ireland.	SUSTAIN III (sulfamethazine) Calf Bolus	520.2260b
May 17, 2023	200–224	Elanco US Inc., 2500 Innovation Way, Greenfield, IN 46140.	COMPONENT T–S with TYLAN; COMPONENT T–H with TYLAN (trenbolone acetate and tylosin tartrate) Implants.	522.2476
May 19, 2023	200–364	Bimeda Animal Health Ltd., 1B The Herbert Building, The Park, Carrickmines, Dublin 18, Ireland.	SPECTOGARD Scour-Chek (spectinomycin dihydrochloride pentahydrate) Oral Solution.	520.2123c
May 22, 2023	035–455	Do	ERYTHRO–36 Dry (erythromycin) IMM Infusion	526.820
May 22, 2023	200–452	Norbrook Laboratories Ltd., Carnbane Industrial Estate, Newry, County Down, BT35 6QQ, United Kingdom.	OXYTET 100 (oxytetracycline HCl) Injectable Solution	522.1662
May 26, 2023	200–068	Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sofia, Bulgaria.	Oxytetracycline Hydrochloride Injection, 100 mg/mL	522.1662
May 30, 2023	055–097	HQ Specialty Pharma Corp., 120 Rte. 17 North, Suite 130, Paramus, NJ 07652.	DRY–MAST (dihydrostreptomycin sulfate and penicillin G procaine).	526.1697
May 31, 2023	200–008	Boehringer Ingelheim Animal Health USA, Inc., 3239 Satellite Blvd., Duluth, GA 30096.	BIO–MYCIN 200 (oxytetracycline HCl) Injectable Solution.	522.1660a
June 2, 2023	065–383	Bimeda Animal Health Ltd., 1B The Herbert Building, The Park, Carrickmines, Dublin 18, Ireland.	FORMULA A–34; UNI BIOTIC (penicillin G procaine) 4 DOSE.	526.1696
June 2, 2023	200–537	Do	TETROXY–LA (oxytetracycline HCl) Injectable Solution	522.1660a
June 7, 2023	200–154	Pharmgate Inc., 1800 Sir Tyler Dr., Wilmington, NC 28405.	PENNO$_X$ 200 (oxytetracycline HCl) Injectable Solution	522.1660a
June 8, 2023	200–123	Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sofia, Bulgaria.	MAXIM–200 Injection (oxytetracycline HCl)	522.1660a
June 9, 2023	200–117	Bimeda Animal Health Ltd., 1B The Herbert Building, The Park, Carrickmines, Dublin 18, Ireland.	OXYSHOT LA (oxytetracycline HCl) Injectable Solution	522.1660a
June 15, 2023	135–906	Elanco US Inc., 2500 Innovation Way, Greenfield, IN 46140.	COMPONENT E–H with TYLAN (testosterone propionate and estradiol benzoate with tylosin tartrate) Implant.	522.2343
June 22, 2023	200–221	Do	COMPONENT TE–G with TYLAN; COMPONENT TE–ID with TYLAN; COMPONENT TE–IS with TYLAN; COMPONENT TE–S with TYLAN (trenbolone acetate, estradiol, and tylosin tartrate) Implants.	522.2477
June 30, 2023	200–346	Do	COMPONENT TE–200 with TYLAN; COMPONENT TE–H with TYLAN; COMPONENT TE–IH with TYLAN; (trenbolone acetate, estradiol, and tylosin tartrate) Implants.	522.2477
June 30, 2023	110–315	Do	COMPONENT E–C with TYLAN; COMPONENT E–S with TYLAN (progesterone, estradiol benzoate, and tylosin tartrate) Implants.	522.1940

II. Withdrawals of Approval

The sponsors of the following files have requested that FDA withdraw approval of the applications listed in table 3 because the products are no longer manufactured or marketed. As provided in the regulatory text of this document, the cited animal drug regulations are amended to reflect these actions.

TABLE 3—APPLICATIONS FOR WHICH APPROVAL WAS VOLUNTARILY WITHDRAWN DURING APRIL, MAY, AND JUNE 2023

File No.	Sponsor	Product name	21 CFR section
140–954	Intervet, Inc., 2 Giralda Farms, Madison, NJ 07940	Type C medicated swine feed containing fenbendazole and lincomycin.	558.325
141–002	Boehringer Ingelheim Animal Health USA, Inc., 3239 Satellite Blvd., Duluth, GA 30096.	OXY 1000 (oxytetracycline HCl) Calf Bolus; OXY 500 (oxytetracycline HCl) Calf Bolus.	520.1660c
200–191	Med-Pharmex, Inc., 2727 Thompson Creek Rd., Pomona, CA 91767–1861.	GENTASOL (gentamicin sulfate solution)	529.1044b

III. Change of Sponsor

Elanco US, Inc., 2500 Innovation Way, Greenfield, IN 46140 has informed FDA that it has transferred ownership of, and all rights and interest in, NADA 135–468 for CARBIGRAN 25 (nicarbazin) Type A Medicated Article to Pharmgate Inc., 1800 Sir Tyler Dr., Wilmington, NC 28405. As provided in the regulatory text of this document, 21 CFR 558.366 is amended to reflect this action.

IV. Change of Sponsor Address

Intervet, Inc., 2 Giralda Farms, Madison, NJ 07940 has informed FDA that it has changed its address to 126 E. Lincoln Ave., Rahway, NJ 07065. As provided in the regulatory text of this document, the tabular listings in 21 CFR 510.600(c) are amended to reflect this action.

V. Technical Amendments

FDA is making the following amendments to improve the accuracy of the animal drug regulations.

- 21 CFR 500.1410 and 522.1660a are amended to reflect the use of N-methyl-2-pyrrolidone as an excipient in a formulation of oxytetracycline injectable solution.
- 21 CFR 520.1484 is being revised to include use of neomycin administered in drinking water of turkeys.
- 21 CFR 520.1660a is being redesignated as 21 CFR 520.1664 to reflect the drug as a fixed-ratio combination of oxytetracycline and carbomycin.
- 21 CFR 520.1660b is being revised to reflect the format and content of a prescription drug.
- 21 CFR 520.2220b is amended to reflect revised conditions of use for sulfadimethoxine oral suspension in dogs and cats.
- 21 CFR 520.2220c is amended to reflect revised conditions of use for sulfadimethoxine tablets in dogs and cats.
- 21 CFR 520.2260b is amended to reflect current sponsors of sulfamethazine sustained-release boluses for use in cattle.
- 21 CFR 522.2680 is amended to reflect revised conditions of use for zeranol implants in beef cattle.
- 21 CFR 529.1044a is amended to reflect sponsors of approved applications for use of gentamicin solution for uterine infusion in mares.
- 21 CFR 556.110 and 556.500 are being revised to reflect redesignation of a combination drug containing oxytetracycline and carbomycin used in the drinking water of chickens.
- 21 CFR 558.68 is being revised to reflect approved feeding instructions for avilamycin and monensin two-way, combination drug Type C medicated chicken feed.

VI. Legal Authority

This final rule is issued under section 512(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C.360b(i)), which requires **Federal Register** publication of ''notice[s] . . . effective as a regulation,'' of the conditions of use of approved new animal drugs. This rule sets forth technical amendments to the regulations to codify recent actions on approved new animal drug applications and corrections to improve the accuracy of the regulations, and as such does not impose any burden on regulated entities.

Although denominated a rule pursuant to the FD&C Act, this document 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. Likewise, this is not a rule subject to Executive Order 12866, which defines a rule as ''an agency statement of general applicability and future effect, which the agency intends to have the force and effect of law, that is designed to implement, interpret, or prescribe law or policy or to describe the procedure or practice requirements of an agency.''

List of Subjects

21 CFR Part 500

Animal drugs, Animal feeds, Cancer, Labeling, Packaging and containers, Polychlorinated biphenyls (PCBs).

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 516

Administrative practice and procedure, Animal drugs, Confidential business information, Reporting and recordkeeping requirements.

21 CFR Parts 520, 522, 524, 526, and 529

Animal drugs.

21 CFR Part 556

Animal drugs, Dairy products, Foods, Meat and meat products.

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, 21 CFR parts 500, 510, 516, 520, 522, 524, 526, 529, 556, and 558 are amended as follows:

PART 500—GENERAL

■ 1. The authority citation for part 500 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 342, 343, 348, 351, 352, 353, 360b, 371, 379e.

■ 2. In § 500.1410, revise paragraph (c) to read as follows:

§ 500.1410 N-methyl-2-pyrrolidone.

* * * * *

(c) *Related conditions of use.* See §§ 522.814, 522.955, and 522.1660a of this chapter.

PART 510—NEW ANIMAL DRUGS

■ 3. The authority citation for part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

■ 4. In § 510.600, in the table in paragraph (c)(1), revise the entry for ''Intervet, Inc.'' and in the table in paragraph (c)(2), revise the entry for ''000061'' to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * * * * *	
Intervet, Inc., 126 E Lincoln Ave., Rahway, NJ 07065	000061
* * * * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * * * *	
000061	Intervet, Inc., 126 E Lincoln Ave., Rahway, NJ 07065
* * * * * * *	

PART 516—NEW ANIMAL DRUGS FOR MINOR USE AND MINOR SPECIES

■ 5. The authority citation for part 516 continues to read as follows:

Authority: 21 U.S.C. 360ccc–1, 360ccc–2, 371.

■ 6. Add § 516.1449 to read as follows:

§ 516.1449 Molidustat oral suspension.

(a) *Specifications.* Each milliliter (mL) of suspension contains 25 milligrams (mg) molidustat sodium.

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Administer orally at a dosage of 5 mg/kg of body weight (2.3 mg/lb) daily for up to 28 consecutive days.

(2) *Indications for use.* For the control of nonregenerative anemia associated with chronic kidney disease in cats.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. It is a violation of Federal law to use this product other than as directed in the labeling.

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

■ 8. In § 520.43, revise paragraphs (c)(1) and (2) to read as follows:

§ 520.43 Afoxolaner.

* * * * *

(c) * * *

(1) *Amount.* Administer orally once a month at a minimum dosage of 1.14 mg/pound (2.5 mg/kilogram).

(2) *Indications for use.* Kills adult fleas and for the treatment and prevention of flea infestations (*Ctenocephalides felis*); and the treatment and control of *Ixodes scapularis* (black-legged tick), *Dermacentor variabilis* (American dog tick), *Amblyomma americanum* (lone star tick), *Rhipicephalus sanguineus* (brown dog tick), and *Haemaphysalis longicornis* (longhorned tick) infestations in dogs and puppies 8 weeks of age and older, weighing 4 pounds of body weight or greater, for 1 month; and for the prevention of *Borrelia burgdorferi* infections as a direct result of killing *Ixodes scapularis* vector ticks.

* * * * *

■ 9. In § 520.443, revise paragraph (d)(1)(ii) to read as follows:

§ 520.443 Chlortetracycline tablets and boluses.

* * * * *

(d) * * *

(1) * * *

(ii) *Limitations.* Administer bolus directly by mouth or crush and dissolve in milk or water for drenching or bucket feeding. Do not use for more than 5 days. Do not administer within 24 hours of slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

* * * * *

§ 520.928 [Amended]

■ 10. In § 520.928, in paragraph (b)(1), remove ''Nos. 000010 and 055529'' and add in its place ''Nos. 000010, 055246, and 055529''.

■ 11. In § 520.1484, revise paragraph (b)(3) and add paragraph (b)(4) to read as follows:

§ 520.1484 Neomycin.

* * * * *

(b) * * *

(3) Nos. 016592, 054771, and 058005 for use of product described in paragraph (a)(2) as in paragraph (e)(1) of this section.

(4) No. 054925 for use of product described in paragraph (a)(2) as in paragraphs (e)(1) and (2) of this section.

* * * * *

§ 520.1604 [Amended]

■ 12. In § 520.1604, in paragraph (a), remove ''Each tablet contains'' and add in its place ''Each tablet or chewable tablet contains''.

§ 520.1660a [Redesignated as § 520.1664]

■ 13. Redesignate § 520.1660a as § 520.1664.

§ 520.1660a [Reserved]

■ 14. Add reserved § 520.1660a.

■ 15. In § 520.1660b, revise the section heading and paragraphs (a) and (c) to read as follows:

§ 520.1660b Oxytetracycline capsules.

(a) *Specifications.* Each capsule contains 125 or 250 milligrams (mg) oxytetracycline hydrochloride.

* * * * *

(c) *Conditions of use in dogs and cats*—(1) *Amount.* Administer orally 25 to 50 mg per pound of body weight per day in divided doses at 12-hour intervals.

(2) *Indications for use.* For the treatment of bacterial pneumonia caused by *Brucella bronchiseptica,* tonsilitis caused by *Streptococcus hemolyticus,* bacterial enteritis caused by *Escherichia coli,* urinary tract infections caused by *Escherichia coli,* and wound infections caused by *Staphylococcus aureus.*

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

■ 16. In § 520.1660c, revise the section heading and paragraphs (a), (b), and (d) to read as follows:

§ 520.1660c Oxytetracycline tablets.

(a) *Specifications.* Each tablet contains 250 or 500 milligrams (mg) oxytetracycline hydrochloride.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

* * * * *

(d) *Conditions of use in beef and dairy cattle*—(1) *Amounts.* 10 mg per pound of body weight every 12 hours for treatment; 5 mg per pound of body weight every 12 hours for control.

(2) *Indications for use.* For treatment and control of bacterial enteritis caused by *Salmonella typhimurium* and *Escherichia coli* (colibacillosis) and bacterial pneumonia (shipping fever complex, pasteurellosis) caused by *Pasteurella multocida.*

(3) *Limitations.* Discontinue treatment 7 days prior to slaughter. Not for use in lactating dairy cattle. 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.

■ 17. In § 520.2220b, revise paragraphs (c)(1) and (2) to read as follows:

§ 520.2220b Sulfadimethoxine suspension.

* * * * *

(c) * * *

(1) *Amount.* Administer orally 25 mg per pound of body weight, followed by 12.5 mg per pound of body weight daily until the animal is free of clinical signs for 48 hours.

(2) *Indications for use.* For the treatment of sulfadimethoxine-susceptible bacterial infections in dogs and cats and enteritis associated with coccidiosis in dogs.

* * * * *

■ 18. In § 520.2220c, revise paragraphs (d)(1) and (2) to read as follows:

§ 520.2220c Sulfadimethoxine tablet.

* * * * *

(d) * * *

(1) *Amount.* Administer orally 25 mg per pound of body weight, followed by 12.5 mg per pound of body weight daily until the animal is free of clinical signs for 48 hours.

(2) *Indications for use.* For the treatment of sulfadimethoxine-susceptible bacterial infections in dogs and cats and enteritis associated with coccidiosis in dogs.

* * * * *

■ 19. In § 520.2260b, revise paragraphs (d)(2)(iii), (f)(2)(iii), and (g)(2)(iii) and remove paragraph (h).

The revisions read as follows:

§ 520.2260b Sulfamethazine sustained-release boluses.

* * * * *

(d) * * *

(2) * * *

(iii) *Limitations.* Do not use in female dairy cattle 20 months of age or older. Use of sulfamethazine in this class of cattle may cause milk residues. Do not treat animals within 12 days of slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

* * * * *

(f) * * *

(2) * * *

(iii) *Limitations.* For use in ruminating replacement calves only. Do not slaughter animals for food for at least 12 days after the last dose. Exceeding two consecutive doses may cause violative tissue residue to remain beyond the withdrawal time. Do not use in calves under 1 month of age or calves being fed an all milk diet. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(g) * * *

(2) * * *

(iii) *Limitations.* For use in beef cattle and nonlactating dairy cattle only. Do not slaughter animals for food for at least 8 days after the last dose. Do not use in lactating dairy cattle. Do not administer more than two consecutive doses. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 20. The authority citation for part 522 continues to read as follows:

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

■ 21. Add § 522.158 to read as follows:

§ 522.158 Bedinvetmab.

(a) *Specifications.* Each single-use vial contains 5, 10, 15, 20, or 30 milligrams (mg) bedinvetmab in an extractable volume of 1 milliliter.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Administer 0.23 mg/pound (0.5 mg/kilogram) body weight monthly by subcutaneous injection.

(2) *Indications for use.* For the control of pain associated with osteoarthritis in dogs.

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

■ 22. In § 522.770, revise paragraphs (b), (d)(1)(iii), and (d)(2)(iii) to read as follows:

§ 522.770 Doramectin.

* * * * *

(b) *Sponsors.* See Nos. 054771 and 069043 in § 510.600(c) of this chapter.

* * * * *

(d) * * *

(1) * * *

(iii) *Limitations.* Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. Administer as a single subcutaneous or intramuscular injection. Do not slaughter cattle for human consumption within 35 days of treatment. Not for use in female dairy cattle 20 months of age or older. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(2) * * *

(iii) *Limitations.* Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. Administer as a single intramuscular injection. Do not slaughter swine for human consumption within 24 days of treatment.

■ 23. In § 522.960c, revise paragraphs (b) and (c)(1)(iii) to read as follows:

§ 522.960c Flumethasone solution.

* * * * *

(b) *Sponsors.* See Nos. 054771 and 061133 in § 510.600(c) of this chapter.

(c) * * *

(1) * * *

(iii) *Limitations.* Not for use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

* * * * *

§ 522.1222 [Amended]

■ 24. In § 522.1222, in paragraph (b), remove ''063286,''.

■ 25. In § 522.1660a:

■ a. Revise paragraph (c);

■ b. Remove paragraph (d);

■ c. Redesignate paragraph (e) as paragraph (d); and

■ d. Revise newly redesignated paragraphs (d)(1)(ii) and (d)(2)(ii).

The revisions read as follows:

§ 522.1660a Oxytetracycline solution, 200 milligrams/milliliter.

* * * * *

(c) *Related tolerances.* See § 556.500 of this chapter; and for No. 061133, see also § 500.1410 of this chapter.

(d) * * *

(1) * * *

(ii) *Limitations.* Discontinue treatment at least 28 days prior to slaughter. Milk taken from animals during treatment and for 96 hours after the last treatment

must not be used for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) * * *

(ii) *Limitations.* Administer intramuscularly. Do not inject more than 5 mL per site in adult swine. Discontinue treatment at least 28 days prior to slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

■ 26. In § 522.1662, revise paragraphs (b), (c), (g), (h), and (j) to read as follows:

§ 522.1662 Oxytetracycline.

* * * * *

(b)(1) *Specifications.* Each milliliter (mL) of solution contains 50 milligrams (mg) oxytetracycline hydrochloride.

(2) *Sponsor.* See No. 069043 in § 510.600(c) of this chapter.

(3) *Conditions of use*—(i) *Amount.* Administer 3 to 5 mg per pound of body weight (mg/lb) per day by intramuscular injection. Leptospirosis, severe foot-rot, and severe forms of the indicated diseases should be treated with 5 mg/lb per day. Treatment should be continued for 24 to 48 hours following remission of clinical signs of disease, not to exceed 4 consecutive days. Not more than 10 mL should be injected per injection site in adult cattle, and only 2 mL per injection site in calves weighing 100 pounds or less.

(ii) *Indications for use.* Beef cattle, beef calves, nonlactating dairy cattle, and dairy calves; for treatment of diseases due to oxytetracycline-susceptible organisms as follows: Pneumonia and shipping fever complex (*Pasteurella* spp., *Haemophilus* spp., *Klebsiella* spp.), bacterial enteritis (scours) (*Escherichia coli*), foot-rot (*Spherophorus necrophorus*), diphtheria (*Spherophorus necrophorus*), wooden tongue (*Actinobacillus lignieresii*), leptospirosis (*Leptospira pomona*), and wound infections and acute metritis caused by *Staphylococcus* spp. and *Streptococcus* spp.

(iii) *Limitations.* Discontinue treatment at least 20 days prior to slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(c)(1) *Specifications.* Each milliliter (mL) of solution contains 50 or 100 milligrams (mg) oxytetracycline hydrochloride.

(2) *Sponsor.* See No. 069043 in § 510.600(c) of this chapter.

(3) *Conditions of use*—(i) *Beef cattle and nonlactating dairy cattle*—(A) *Amount.* Administer 3 to 5 mg per pound of body weight (mg/lb) per day; 5 mg/lb per day for the treatment of anaplasmosis, severe foot-rot, and severe cases of other indicated diseases. For 50-mg/mL solution, administer intramuscularly or intravenously; for 100-mg/mL solution, administer intramuscularly only. Treatment should be continued for 24 to 48 hours following remission of clinical signs of disease, not to exceed 4 consecutive days.

(B) *Indications for use.* For treatment of diseases due to oxytetracycline-susceptible organisms as follows: Pneumonia and shipping fever complex associated with *Pasteurella* spp., *Haemophilus* spp., and *Klebsiella* spp., foot-rot and diphtheria caused by *Spherophorus necrophorus,* bacterial enteritis (scours) caused by *Escherichia coli,* wooden tongue caused by *Actinobacillus lignieresii,* leptospirosis caused by *Leptospira pomona,* anaplasmosis caused by *Anaplasma marginale;* and wound infections and acute metritis caused by *Staphylococcus* spp. and *Streptococcus* spp.

(C) *Limitations.* Exceeding the highest recommended dose of 5 mg/lb, administering at recommended levels for more than 4 consecutive days, and/or exceeding 10 mL intramuscularly per injection site may result in antibiotic residues beyond the withdrawal time. Discontinue treatment at least 18 days prior to slaughter. Not for use in lactating dairy cattle. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(ii) *Swine*—(A) *Amount.* Administer 3 to 5 mg/lb per day by intramuscular injection. Sows: Administer 3 mg/lb by intramuscular injection approximately 8 hours before farrowing or immediately after completion of farrowing.

(B) *Indications for use.* For treatment of bacterial enteritis (scours, colibacillosis) caused by *Escherichia coli,* pneumonia caused by *Pasteurella multocida,* and leptospirosis caused by *Leptospira pomona.* Sows: as an aid in control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *Escherichia coli.*

(C) *Limitations.* Do not inject more than 5 mL per injection site. Do not use for more than 4 consecutive days. Discontinue treatment at least 26 days before slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

* * * * *

(g)(1) *Specifications.* Each milliliter (mL) of solution contains 100 milligrams (mg) oxytetracycline hydrochloride.

(2) *Sponsor.* See No. 069043 in § 510.600(c) of this chapter.

(3) *Conditions of use.* For the treatment of diseases due to oxytetracycline-susceptible organisms as follows:

(i) *Beef cattle, beef calves, nonlactating dairy cattle, and dairy calves*—(A) *Amount.* Administer 3 to 5 mg/lb body weight per day by intramuscular, intravenous, or subcutaneous injection. In severe forms of the indicated diseases, administer 5 mg/lb body weight per day. Continue treatment 24 to 48 hours following remission of clinical signs of disease, not to exceed 4 consecutive days.

(B) *Indications for use.* For the treatment of pneumonia and shipping fever complex associated with *Pasteurella* spp., *Haemophilus* spp., or *Klebsiella* spp.

(C) *Limitations.* Do not inject more than 10 mL per intramuscular injection site in adult cattle, and no more than 1 mL per site in calves weighing 100 pounds or less. Do not slaughter cattle for 13 days after intramuscular or intravenous treatment, or 2 days after subcutaneous treatment. Exceeding the highest recommended dosage or duration of treatment (not more than 4 consecutive days) may result in residues beyond the withdrawal period. A withdrawal period has not been established for use of 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.

(ii) *Swine*—(A) *Amount.* Administer 3 to 5 mg/lb body weight per day by intramuscular injection. Sows: Administer 3 mg/lb body weight once, by intramuscular injection, approximately 8 hours before farrowing or immediately after completion of farrowing.

(B) *Indications for use.* For treatment of bacterial enteritis (scours, colibacillosis) caused by *Escherichia coli,* pneumonia caused by *Pasteurella multocida,* and leptospirosis caused by *Leptospira pomona.* Sows: As an aid in control of infectious enteritis (baby pig scours, colibacillosis) in suckling pigs caused by *Escherichia coli.*

(C) *Limitations.* Do not inject more than 5 mL per site. Discontinue treatment at least 20 days prior to slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(h)(1) *Specifications.* Each milliliter (mL) of solution contains 50 or 100 milligrams (mg) oxytetracycline hydrochloride.

(2) *Sponsors.* See No. 069043 in § 510.600(c) of this chapter for use of 50- and 100-mg/mL solution and Nos. 016592 and 055529 in § 510.600(c) of this chapter for use of 100-mg/mL solution.

(3) *Conditions of use in beef cattle, beef calves, nonlactating dairy cattle,*

and dairy calves—(i) *Amount.* Administer 3 to 5 mg/lb body weight per day by intramuscular injection; 5 mg/lb body weight per day for treatment of severe forms of the indicated diseases.

(ii) *Indications for use.* For treatment of bacterial pneumonia and shipping fever complex associated with *Pasteurella* spp., foot-rot and calf diphtheria caused by *Fusobacterium necrophorum,* bacterial enteritis (scours) caused by *Escherichia coli,* wooden tongue caused by *Actinobacillus lignieresii;* and wound infections and acute metritis caused by *Staphylococcus* spp. and *Streptococcus* spp.

(iii) *Limitations.* Do not inject more than 10 mL per site in adult cattle. Reduce the volume administered per injection site according to age and body size. In calves weighing 100 pounds or less, do not inject more than 2 mL per site. Discontinue treatment at least 22 days before slaughter. Not for use in lactating dairy animals. 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.

* * * * *

(j)(1) *Specifications.* Each milliliter (mL) of solution contains either 50 or 100 milligrams (mg) of oxytetracycline hydrochloride.

(2) *Sponsor.* See No. 061133 in § 510.600(c) of this chapter.

(3) *Conditions of use in beef cattle and nonlactating dairy cattle*—(i) *Amount.* Administer 3 to 5 mg/lb body weight daily by intravenous injection. Administer 5 mg/lb for anaplasmosis, severe foot rot, and severe forms of other diseases. Treatment should be continued 24 to 48 hours following remission of clinical signs of disease, but not to exceed 4 consecutive days.

(ii) *Indications for use.* For treatment of diseases due to oxytetracycline-susceptible organisms as follows: Pneumonia and shipping fever complex associated with *Pasteurella* spp. and *Haemophilus* spp., foot rot and diphtheria caused by *Fusobacterium necrophorum,* bacterial enteritis (scours) caused by *Escherichia coli,* wooden tongue caused by *Actinobacillus lignieresii,* leptospirosis caused by *Leptospira pomona,* anaplasmosis caused by *Anaplasma marginale* and anthrax caused by *Bacillus anthracis;* and acute metritis and wound infections caused by staphylococcal and streptococcal organisms.

(iii) *Limitations.* Not for use in lactating dairy cattle. Discontinue use at least 19 days prior to slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

■ 27. In § 522.1940, revise paragraph (a), redesignate paragraph (c) as paragraph (d), and add new paragraph (c).

The revision and addition read as follows:

§ 522.1940 Progesterone and estradiol benzoate.

(a) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(1) No. 054771 for use as in paragraphs (d)(1)(i)(A), (d)(1)(ii) and (iii), (d)(2)(i)(A), (d)(2)(ii) and (iii), and (d)(3) of this section.

(2) No. 058198 for use as in paragraphs (d)(1) and (2) of this section.

* * * * *

(c) *Special considerations.* Labeling of implants described in paragraphs (d)(1)(i)(B) and (d)(2)(i)(B) of this section shall bear the following: ''Federal law restricts this drug to use by or on the order of a licensed veterinarian.''.

* * * * *

■ 28. In § 522.2343, revise paragraph (a), redesignate paragraph (c) as paragraph (d), and add new paragraph (c).

The revision and addition read as follows:

§ 522.2343 Testosterone propionate and estradiol benzoate.

(a) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(1) No. 054771 for use as in paragraphs (d)(1)(i) and (d)(2) and (3) of this section.

(2) No. 058198 for use as in paragraph (d) of this section.

* * * * *

(c) *Special considerations.* Labeling of implants described in paragraph (d)(1)(ii) of this section shall bear the following: ''Federal law restricts this drug to use by or on the order of a licensed veterinarian.''

* * * * *

■ 29. In § 522.2476, revise paragraph (a), redesignate paragraph (c) as paragraph (d), and add new paragraph (c).

The revision and addition read as follows:

§ 522.2476 Trenbolone acetate.

(a) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(1) No. 000061 for use as in paragraphs (d)(1)(i)(A), (d)(1)(ii) and (iii), (d)(2)(i)(A), and (d)(2)(ii) and (iii) of this section.

(2) No. 058198 for use as in paragraph (d) of this section.

* * * * *

(c) *Special considerations.* Labeling of implants described in paragraph (d)(1)(i)(B) and (d)(2)(i)(B) of this section shall bear the following: ''Federal law restricts this drug to use by or on the order of a licensed veterinarian.''.

* * * * *

■ 30. In § 522.2477, redesignate paragraphs (b) and (c) as paragraphs (a) and (b) and add new paragraph (c) to read as follows:

§ 522.2477 Trenbolone acetate and estradiol.

* * * * *

(c) *Special considerations.* Labeling of implants described in paragraphs (d)(1)(i)(B), (E), and (F), (d)(2)(i)(B), (E), and (F), and (d)(3)(i)(B) of this section shall bear the following: ''Federal law restricts this drug to use by or on the order of a licensed veterinarian.''.

* * * * *

■ 31. In § 522.2680, revise paragraphs (d)(1)(ii)(A) and (B) and (d)(1)(iii) to read as follows:

§ 522.2680 Zeranol.

* * * * *

(d) * * *

(1) * * *

(ii) * * *

(A) Weaned beef calves, growing beef cattle, feedlot steers, and feedlot heifers: For increased rate of weight gain and improved feed conversion.

(B) Suckling calves: For increased rate of weight gain.

(iii) *Limitations.* Implant pellets subcutaneously only. Not approved for repeated implantation (reimplantation) with this or any other cattle ear implant within a single production phase as safety and effectiveness have not been evaluated. Do not use in beef calves less than 2 months of age, dairy calves, and veal calves because effectiveness and safety have not been evaluated. A withdrawal period has not been established for this product in preruminating calves. Do not use in replacement beef heifers after weaning or in bulls, dairy cows, or replacement dairy heifers.

* * * * *

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

■ 32. The authority citation for part 524 continues to read as follows:

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

■ 33. Add § 524.838 to read as follows:

§ 524.838 Esafoxolaner, eprinomectin, and praziquantel.

(a) *Specifications.* Each milliliter (mL) of topical solution contains 12

milligrams (mg) esafoxolaner, 4 mg eprinomectin, and 83 mg praziquantel.

(b) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Administer the entire contents of a provided unit applicator topically once a month at a minimum dose of 0.055 mL/lb (0.12 mL/kg), which delivers a minimum dose of 0.66 mg/lb (1.45 mg/kg) esafoxolaner, 0.23 mg/lb (0.51 mg/kg) eprinomectin, and 4.55 mg/lb (10.0 mg/kg) praziquantel.

(2) *Indications for use.* For the prevention of heartworm disease caused by *Dirofilaria immitis.* Kills adult fleas (*Ctenocephalides felis*) and is indicated for the treatment and prevention of flea infestations, the treatment and control of *Ixodes scapularis* (black-legged tick) and *Amblyomma americanum* (lone star tick) infestations, and the treatment and control of roundworms (fourth-stage larval and adult *Toxocara cati*), hookworms (fourth-stage larval and adult *Ancylostoma tubaeforme;* adult *Ancylostoma braziliense*), and tapeworms (*Dipylidium caninum*) in cats and kittens 8 weeks of age and older, and weighing 1.8 lbs or greater.

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

PART 526—INTRAMAMMARY DOSAGE FORM NEW ANIMAL DRUGS

■ 34. The authority citation for part 526 continues to read as follows:

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

§ 526.1696 [Amended]

■ 35. In § 526.1696, in paragraphs (d)(3) and (e)(3), in the last sentence, remove ''For No. 042791:''.

■ 36. In § 526.1697, add a sentence to the end of paragraph (d)(3) to read as follows:

§ 526.1697 Penicillin G procaine and dihydrostreptomycin.

(d) * * *

(3) * * * 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

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

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

■ 38. In § 529.1044a, revise paragraph (b) to read as follows:

§ 529.1044a Gentamicin solution for infusion.

* * * * *

(b) *Sponsors.* See Nos. 000061, 016592, 054771, 058005, 058198, 061133, and 069043 in § 510.600(c) of this chapter.

* * * * *

■ 39. In 529.1044b, revise paragraph (c)(3) to read as follows:

§ 529.1044b Gentamicin solution for dipping eggs.

* * * * *

(c) * * *

(3) *Limitations.* Eggs which have been dipped in the drug shall not be used for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

■ 40. The authority citation for part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

■ 41. In § 556.110, revise paragraph (c) to read as follows:

§ 556.110 Carbomycin.

* * * * *

(c) *Related conditions of use.* See § 520.1664 of this chapter.

■ 42. In § 556.500, revise paragraph (c) to read as follows:

§ 556.500 Oxytetracycline.

* * * * *

(c) *Related conditions of use.* See §§ 520.1660c, 520.1660d, 520.1664, 522.1660a, 522.1660b, 522.1662, 522.1664, 529.1660, 558.450, and 558.455 of this chapter.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

■ 44. 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 ..	Broiler chickens: For the prevention of mortality caused by necrotic enteritis associated with *Clostridium perfringens;* 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 this complete Type C medicated 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 18 days of age. See § 558.355(d) of this chapter. Monensin as provided by No. 058198 in § 510.600(c) of this chapter.	058198
*	*	*	*	*

* * * * *

■ 45. In § 558.128, revise paragraphs (e)(4)(iii) and (iv), (e)(4)(ix) through (xiv), and (e)(4)(xviii) through (xx) to read as follows:

§ 558.128 Chlortetracycline.

* * * * *

(e) * * *

(4) * * *

Chlortetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
*	*	*	* * * *	
(iii) 7 to 17.5 g/ton	Monensin, 5 to 40	Growing beef steers and heifers fed in confinement for slaughter over 400 lb: For reduction of the incidence of liver abscesses and for improved feed efficiency.	Feed as the sole ration to provide 70 mg chlortetracycline per head per day and 50 to 480 mg monensin per head per day. No additional improvement in feed efficiency has been shown from feeding monensin at levels greater than 30 grams per ton (360 mg monensin per head per day). For use in dry feeds only. Not for use in liquid feed supplements. Do not allow horses or other equines access to feed containing monensin. Ingestion of monensin by horses has been fatal. Monensin medicated cattle and goat feeds are safe for use in cattle and goats only. Consumption by unapproved species may result in toxic reactions. Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result. If feed refusals containing monensin are fed to other groups of cattle, the concentration of monensin in the refusals and amount of refusals fed should be taken into consideration to prevent monensin overdosing. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Monensin as provided by Nos. 016592 and 058198, chlortetracycline by No. 069254 in §510.600(c) of this chapter.	016592 069254
(iv) 7 to 17.5 g/ton	Monensin, 10 to 40	Growing beef steers and heifers fed in confinement for slaughter over 400 lb: For reduction of the incidence of liver abscesses and for prevention and control of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii*.	Feed as the sole ration to provide 70 mg chlortetracycline per head per day and 0.14 to 0.42 mg monensin per lb. body weight per day to provide, depending upon severity of coccidiosis challenge, up to 480 mg monensin per head per day. For use in dry feeds only. Not for use in liquid feed supplements. Do not allow horses or other equines access to feed containing monensin. Ingestion of monensin by horses has been fatal. Monensin medicated cattle and goat feeds are safe for use in cattle and goats only. Consumption by unapproved species may result in toxic reactions. Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result. If feed refusals containing monensin are fed to other groups of cattle, the concentration of monensin in the refusals and amount of refusals fed should be taken into consideration to prevent monensin overdosing. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Monensin as provided by Nos. 016592 and 058198, chlortetracycline by No. 069254 in §510.600(c) of this chapter.	016592 069254
*	*	*	* * * *	
(ix) 33.33 to 66.67 g/ton.	Monensin, 5 to 40	Growing beef steers and heifers fed in confinement for slaughter over 700 lbs: For control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline and for improved feed efficiency.	Feed as the sole ration to provide 0.5 mg chlortetracycline per lb. body weight per day and 50 to 480 mg monensin per head per day. No additional improvement in feed efficiency has been shown from feeding monensin at levels greater than 30 grams per ton (360 mg monensin per head per day). For use in dry feeds only. Not for use in liquid feed supplements. Do not allow horses or other equines access to feed containing monensin. Ingestion of monensin by horses has been fatal. Monensin medicated cattle and goat feeds are safe for use in cattle and goats only. Consumption by unapproved species may result in toxic reactions. Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result. If feed refusals containing monensin are fed to other groups of cattle, the concentration of monensin in the refusals and amount of refusals fed should be taken into consideration to prevent monensin overdosing. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Monensin as provided by Nos. 016592 and 058198, chlortetracycline by No. 069254 in §510.600(c) of this chapter.	016592 069254
(x) 33.33 to 66.67 g/ton.	Monensin, 10 to 40	Growing beef steers and heifers fed in confinement for slaughter over 700 lbs: For control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline and for the prevention and control of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii*.	Feed as the sole ration to provide 0.5 mg chlortetracycline per lb. body weight per day and 0.14 to 0.42 mg monensin per lb. body weight per day to provide, depending upon severity of coccidiosis challenge, up to 480 mg monensin per head per day. For use in dry feeds only. Not for use in liquid feed supplements. Do not allow horses or other equines access to feed containing monensin. Ingestion of monensin by horses has been fatal. Monensin medicated cattle and goat feeds are safe for use in cattle and goats only. Consumption by unapproved species may result in toxic reactions. Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result. If feed refusals containing monensin are fed to other groups of cattle, the concentration of monensin in the refusals and amount of refusals fed should be taken into consideration to prevent monensin overdosing. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Monensin as provided by Nos. 016592 and 058198, chlortetracycline by No. 069254 in §510.600(c) of this chapter.	016592 069254

Chlortetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
(xi) 50 to 117 g/ton	Monensin, 7.14 to 40	Growing beef steers and heifers fed in confinement for slaughter under 700 lbs: For control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline and for improved feed efficiency.	Feed as the sole ration to provide 350 mg chlortetracycline per head per day and 50 to 480 mg monensin per head per day. No additional improvement in feed efficiency has been shown from feeding monensin at levels greater than 30 grams per ton (360 mg monensin per head per day). For use in dry feeds only. Not for use in liquid feed supplements. Do not allow horses or other equines access to feed containing monensin. Ingestion of monensin by horses has been fatal. Monensin medicated cattle and goat feeds are safe for use in cattle and goats only. Consumption by unapproved species may result in toxic reactions. Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result. If feed refusals containing monensin are fed to other groups of cattle, the concentration of monensin in the refusals and amount of refusals fed should be taken into consideration to prevent monensin overdosing. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Monensin as provided by Nos. 016592 and 058198, chlortetracycline by No. 069254 in § 510.600(c) of this chapter.	016592 069254
(xii) 50 to 117 g/ton	Monensin, 10 to 40	Growing beef steers and heifers fed in confinement for slaughter under 700 lbs: For control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline and for the prevention and control of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii*.	Feed as the sole ration to provide 350 mg chlortetracycline per head per day and 0.14 to 0.42 mg monensin per lb. body weight per day to provide, depending upon severity of coccidiosis challenge, up to 480 mg monensin per head per day. For use in dry feeds only. Not for use in liquid feed supplements. Do not allow horses or other equines access to feed containing monensin. Ingestion of monensin by horses has been fatal. Monensin medicated cattle and goat feeds are safe for use in cattle and goats only. Consumption by unapproved species may result in toxic reactions. Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result. If feed refusals containing monensin are fed to other groups of cattle, the concentration of monensin in the refusals and amount of refusals fed should be taken into consideration to prevent monensin overdosing. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Monensin as provided by Nos. 016592 and 058198, chlortetracycline by No. 069254 in § 510.600(c) of this chapter.	016592 069254
(xiii) 50 to 117 g/ton ...	Monensin, 7.14 to 40	Growing beef steers and heifers fed in confinement for slaughter: For the control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline and for improved feed efficiency.	Feed as the sole ration to provide 350 mg chlortetracycline per head per day and 50 to 480 mg monensin per head per day. No additional improvement in feed efficiency has been shown from feeding monensin at levels greater than 30 grams per ton (360 mg monensin per head per day). For use in dry feeds only. Not for use in liquid feed supplements. Do not allow horses or other equines access to feed containing monensin. Ingestion of monensin by horses has been fatal. Monensin medicated cattle and goat feeds are safe for use in cattle and goats only. Consumption by unapproved species may result in toxic reactions. Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result. If feed refusals containing monensin are fed to other groups of cattle, the concentration of monensin in the refusals and amount of refusals fed should be taken into consideration to prevent monensin overdosing. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Monensin as provided by Nos. 016592 and 058198, chlortetracycline by No. 069254 in § 510.600(c) of this chapter.	016592 069254
(xiv) 50 to 117 g/ton ...	Monensin, ≤10 to 40	Growing beef steers and heifers fed in confinement for slaughter: For the control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline and for the prevention and control of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii*.	Feed as the sole ration to provide 350 mg chlortetracycline per head per day and 0.14 to 0.42 mg monensin per lb. body weight per day to provide, depending upon severity of coccidiosis challenge, up to 480 mg monensin per head per day. For use in dry feeds only. Not for use in liquid feed supplements. Do not allow horses or other equines access to feed containing monensin. Ingestion of monensin by horses has been fatal. Monensin medicated cattle and goat feeds are safe for use in cattle and goats only. Consumption by unapproved species may result in toxic reactions. Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result. If feed refusals containing monensin are fed to other groups of cattle, the concentration of monensin in the refusals and amount of refusals fed should be taken into consideration to prevent monensin overdosing. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Monensin as provided by Nos. 016592 and 058198, chlortetracycline by No. 069254 in § 510.600(c) of this chapter.	016592 069254

Chlortetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
*	*	*	* * * *	
(xviii) 400 to 2,000 g/ton.	Monensin, 5 to 40	Growing beef steers and heifers fed in confinement for slaughter: For treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to chlortetracycline; for improved feed efficiency.	Feed as the sole ration to provide 10 mg chlortetracycline per lb. body weight per day and 50 to 480 mg monensin per head per day. Feed for not more than 5 days, then continue feeding monensin Type C medicated feed alone. No additional improvement in feed efficiency has been shown from feeding monensin at levels greater than 30 grams per ton (360 mg monensin per head per day). For use in dry feeds only. Not for use in liquid feed supplements. Do not allow horses or other equines access to feed containing monensin. Ingestion of monensin by horses has been fatal. Monensin medicated cattle and goat feeds are safe for use in cattle and goats only. Consumption by unapproved species may result in toxic reactions. Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result. If feed refusals containing monensin are fed to other groups of cattle, the concentration of monensin in the refusals and amount of refusals fed should be taken into consideration to prevent monensin overdosing. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Monensin as provided by Nos. 016592 and 058198, chlortetracycline by No. 069254 in § 510.600(c) of this chapter.	016592 069254
(xix) 400 to 2,000 g/ton.	Monensin, 10 to 40	Growing beef steers and heifers: For treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to chlortetracycline; and for the prevention and control of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii*.	Feed as the sole ration to provide 10 mg chlortetracycline per lb. body weight per day and 0.14 to 0.42 mg monensin per lb. body weight per day to provide, depending upon severity of the coccidiosis challenge, up to 480 mg monensin per head per day. Feed for not more than 5 days, then continue feeding monensin Type C medicated feed alone. For use in dry feeds only. Not for use in liquid feed supplements. Do not allow horses or other equines access to feed containing monensin. Ingestion of monensin by horses has been fatal. Monensin medicated cattle and goat feeds are safe for use in cattle and goats only. Consumption by unapproved species may result in toxic reactions. Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result. If feed refusals containing monensin are fed to other groups of cattle, the concentration of monensin in the refusals and amount of refusals fed should be taken into consideration to prevent monensin overdosing. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Monensin as provided by Nos. 016592 and 058198, chlortetracycline by No. 069254 in § 510.600(c) of this chapter.	016592 069254
(xx) 400 to 2,000 g/ton	Monensin, 10 to 200	Beef calves 2 months of age and older: For treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to chlortetracycline; and for the prevention and control of coccidiosis due to *Eimeria bovis* and *Eimeria zuernii*.	Feed as the sole ration to provide 10 mg chlortetracycline per lb. body weight per day and 0.14 to 1.00 mg monensin per lb. body weight per day to provide, depending upon severity of coccidiosis challenge, up to 200 mg of monensin per head per day. Feed for not more than 5 days, then continue to feed monensin Type C medicated feed alone. For use in dry feeds only. Not for use in liquid feed supplements. Do not allow horses or other equines access to feed containing monensin. Ingestion of monensin by horses has been fatal. Monensin medicated cattle and goat feeds are safe for use in cattle and goats only. Consumption by unapproved species may result in toxic reactions. Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result. If feed refusals containing monensin are fed to other groups of cattle, the concentration of monensin in the refusals and amount of refusals fed should be taken into consideration to prevent monensin overdosing. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Monensin as provided by Nos. 016592 and 058198, chlortetracycline by No. 069254 in § 510.600(c) of this chapter.	016592 069254
*	*	*	* * * *	

§ 558.325 [Amended]

■ 46. In § 558.325, remove and reserve paragraphs (e)(2)(ii), (viii), and (xiii).

■ 47. In § 558.366, revise paragraphs (b) and (d)(1)(v) to read as follows:

§ 558.366 Nicarbazin.

* * * * *

(b) *Sponsors.* See Nos. 060728, 066104, and 069254 in § 510.600(c) of this chapter.

* * * * *

(d) * * *

(1) * * *

Nicarbazin in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
*	*	* *	* * *	
(v) 113.5		Chickens: As an aid in preventing outbreaks of cecal (*Eimeria tenella*) and intestinal (*E. acervulina, E. maxima, E. necatrix,* and *E. brunetti*) coccidiosis.	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard. Do not use as a treatment for coccidiosis. Do not use in flushing mashes. Do not feed to laying hens. Withdraw 4 days before slaughter.	060728 069254
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■ 48. In § 558.450, revise paragraphs (e)(5)(iv) and (v) to read as follows:

§ 558.450 Oxytetracycline.

* * * * *

(e) * * *

(5) * * *

Oxytetracycline amount	Indications for use	Limitations	Sponsor
*	* *	* * *	
(iv) 2.5 to 3.75 g/100 lb of fish/day.	1. Freshwater-reared salmonids: For control of ulcer disease caused by *Haemophilus piscium,* furunculosis caused by *Aeromonas salmonicida,* bacterial hemorrhagic septicemia caused by *A. hydrophila,* and pseudomonas disease.	Administer in mixed ration for 10 days. Do not liberate fish or slaughter fish for food for 21 days following the last administration of medicated feed.	066104
	2. Catfish: For control of bacterial hemorrhagic septicemia caused by *A. hydrophila* and pseudomonas disease.	Administer in mixed ration for 10 days. Do not liberate fish or slaughter fish for food for 21 days following the last administration of medicated feed. Do not administer when water temperature is below 16.7 °C (62 F).	066104
(v) 3.75 g/100 lb of fish/day.	1. Freshwater-reared salmonids: For control of mortality due to coldwater disease associated with *Flavobacterium psychrophilum* or for control of mortality due to columnaris disease associated with *Flavobacterium columnare*.	Administer in mixed ration for 10 days. Do not liberate fish or slaughter fish for food for 21 days following the last administration of medicated feed.	066104
	2. Freshwater-reared salmonids weighing up to 55 grams: For marking the skeletal tissue.	Feed for 10 days. Immediate release is permitted following last feeding of medicated feed.	066104
	3. Catfish: For control of mortality due to columnaris disease associated with *Flavobacterium columnare*.	Administer in mixed ration for 10 days. Do not liberate fish or slaughter fish for food for 21 days following the last administration of medicated feed. Do not administer when water temperature is below 16.7 °C (62 F).	066104
*	* *	* * *	

Dated: August 9, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–17454 Filed 8–15–23; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Office of Natural Resources Revenue

30 CFR Part 1217

[Docket No. ONRR–2022–0001; DS63644000 DRT000000.CH7000 223D1113RT]

RIN 1012–AA32

Electronic Provision of Records During an Audit; Correction

AGENCY: Office of Natural Resources Revenue (''ONRR''), Interior.

ACTION: Final rule; correction.

SUMMARY: On August 9, 2023, ONRR published a final rule amending its regulations to allow ONRR and other authorized Department of the Interior (''Department'') representatives the option to require that an auditee use electronic means to provide records requested during an audit of an auditee's royalty reporting and payment. The final rule used a subpart that was designated reserved. This document corrects the final regulations by adding the subpart.

DATES: Effective on September 8, 2023.

FOR FURTHER INFORMATION CONTACT: For questions concerning this final rulemaking, contact Ginger Hensley, Regulatory Specialist, by phone at 303–231–3171, or by email at *ONRR_RegulationsMailbox@onrr.gov.*

SUPPLEMENTARY INFORMATION: ONRR published a final rule in the **Federal Register** on August 9, 2023 (88 FR 53790). ONRR amended a reserved subpart under part 1217, subpart A, without including instructions to add the subpart. Accordingly, the final rule is corrected by making the following correcting amendments.

Federal Register Correction

Effective September 8, 2023, in rule document 2023–17059 at 88 FR 53790 in the issue of August 9, 2023, on page 53793, in the first column, amendatory instruction 8 and the accompanying regulatory text are corrected to read as follows:

§ 1217.10 [Corrected]

■ 8. Add subpart A, consisting of § 1217.10, to read as follows:

Subpart A—General Provisions

§ 1217.10 Providing records during an audit.

(a) ONRR or an authorized State or Tribe may specify the method an auditee must use to provide records for all audits conducted under this chapter, statute, or agreement. The methods may include one or more of the following:

(1) Inspect records at an auditee's place of business during normal business hours;

(2) Send records using secure electronic means. When requesting that records be provided electronically, ONRR or the authorized State or Tribe will specify the format in which the records shall be produced, directions for electronic transmission, and instructions to ensure secure transmission; or