relevant facts concerning the issue, including copies of all pertinent documents. Except in unusual circumstances, such official interpretations will not be issued separately but will be incorporated in the official commentary to this part, which will be amended periodically. No official interpretations will be issued approving financial institutions' forms or statements. This restriction does not apply to forms or statements whose use is required or sanctioned by a government agency.

3. Unofficial oral interpretations. Unofficial oral interpretations may be provided at the discretion of Bureau staff. Written requests for such interpretations should be sent to the address set forth for official interpretations. Unofficial oral interpretations provide no protection under section 19(b) of RESPA. Ordinarily, staff will not issue unofficial oral interpretations on matters adequately covered by this part or the official Bureau interpretations.

4. Rules of construction. (a) Lists that appear in the commentary may be exhaustive or illustrative; the appropriate construction should be clear from the context. In most cases, illustrative lists are introduced by phrases such as ''including, but not limited to,'' ''among other things,'' ''for example,'' or ''such as.''

(b) Throughout the commentary, reference to ''this section'' or ''this paragraph'' means the section or paragraph in the regulation that is the subject of the comment.

5. Comment designations. Each comment in the commentary is identified by a number and the regulatory section or paragraph that the comment interprets. The comments are designated with as much specificity as possible according to the particular regulatory provision addressed. For example, some of the comments to § 1024.37(c)(1) are further divided by subparagraph, such as comment 37(c)(1)(i)–1. In other cases, comments have more general application and are designated, for example, as comment 40(a)–1. This introduction may be cited as comments I–1 through I–5.

* * * * *

PART 1026—TRUTH IN LENDING (REGULATION Z)

■ 18. The authority citation for part 1026 continues to read as follows:

Authority: 12 U.S.C. 2601, 2603–2605, 2607, 2609, 2617, 3353, 5511, 5512, 5532, 5581; 15 U.S.C. 1601 *et seq.*

Appendix A to Part 1026 [Amended]

■ 19. Appendix A to part 1026 is amended in the first sentence of the first paragraph immediately after the subheading *Request for Determination* by removing ''20006'' and adding ''20552'' in its place.

Appendix B to Part 1026 [Amended]

■ 20. Appendix B to part 1026 is amended in the ''Application'' section in the second sentence by removing ''20006'' and adding ''20552'' in its place.

Appendix C to Part 1026 [Amended]

■ 21. Appendix C to part 1026 is amended under ''Requests for Issuance of Official Interpretations'' by:
■ a. Removing ''Division of Research, Markets, and Regulations'' and adding ''Division of Research, Monitoring, and Regulations'' in its place; and
■ b. Removing ''20006'' and adding ''20552'' in its place.
■ 22. Supplement I is amended by revising paragraphs 1 and 2 under ''Appendix J—Annual Percentage Rate Computations for Closed-End Credit Transactions'' to read as follows:

Supplement I to Part 1026—Official Interpretations

* * * * *

Appendix J—Annual Percentage Rate Computations for Closed-End Credit Transactions

1. Use of appendix J. Appendix J sets forth the actuarial equations and instructions for calculating the annual percentage rate in closed-end credit transactions. While the formulas contained in this appendix may be directly applied to calculate the annual percentage rate for an individual transaction, they may also be utilized to program calculators and computers to perform the calculations.

2. Relation to Bureau tables. The Bureau's Annual Percentage Rate Tables also provide creditors with a calculation tool that applies the technical information in appendix J. An annual percentage rate computed in accordance with the instructions in the tables is deemed to comply with the regulation. Volume I of the tables may be used for credit transactions involving equal payment amounts and periods, as well as for transactions involving any of the following irregularities: odd first period, odd first payment and odd last payment. Volume II of the tables may be used for transactions that involve any type of irregularities. These tables may be obtained from the Bureau, 1700 G Street NW, Washington, DC 20552, upon request. The tables are also available on the Bureau's website at: *https://www.consumerfinance.gov//resources/applicable-requirements/annual-percentage-rate-tables/.*

* * * * *

PART 1030—TRUTH IN SAVINGS (REGULATION DD)

■ 23. The authority citation for part 1030 continues to read as follows:

Authority: 12 U.S.C. 4302–4304, 4308, 5512, 5581.

Appendix C to Part 1030 [Amended]

■ 24. Appendix C to part 1030 is amended in the second sentence of paragraph (b) by removing ''20006'' and adding ''20552'' in its place.

Rohit Chopra,

Director, Consumer Financial Protection Bureau.

[FR Doc. 2023–05216 Filed 3–17–23; 8:45 am]

BILLING CODE 4810–AM–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

[Docket No. FDA–2022–N–0002]

New Animal Drugs; Approval of New Animal Drug Applications; Change of Sponsor

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 October, November, and December 2022. 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 the accuracy and readability of the regulations.

DATES: This rule is effective March 20, 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 October, November, and December 2022, 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.*

FDA has verified the website addresses as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS, ANADAS, AND CNADAS APPROVED DURING OCTOBER, NOVEMBER, AND DECEMBER 2022 REQUIRING EVIDENCE OF SAFETY AND/OR EFFECTIVENESS

Approval date	File No.	Sponsor	Product name	Effect of the action	Public documents	21 CFR section
November 4, 2022.	200–730	Parnell Technologies Pty. Ltd., Unit 4, 476 Gardeners Rd., Alexandria, New South Wales 2015, Australia.	RESPIRMYCIN (tulathromycin injection) Injectable Solution.	Original approval for the treatment of bovine respiratory disease, infectious bovine keratoconjunctivitis, and bovine foot rot as a generic copy of NADA 141–244.	FOI Summary	522.2630
November 14, 2022.	141–567	Ishihara Sangyo Kaisha, Ltd., 3–15, Edobori 1-chome, Nishi-ku, Osaka 550–0002, Japan.	PANOQUELL–CA1 (fuzapladib sodium for injection) Powder for injection.	Conditional approval for management of clinical signs associated with acute onset of pancreatitis in dogs.	FOI Summary	516.1012
December 2, 2022.	200–377	Bimeda Animal Health Ltd., 1B The Herbert Building, The Park, Carrickmines, Dublin 18, Ireland.	LINXMED (lincomycin hydrochloride) Soluble Powder.	Supplemental approval for control of American foulbrood in honey bees as a generic copy of NADA 111–636.	FOI Summary	520.1263b
December 2, 2022.	141–529	Pharmgate, Inc., 1800 Sir Tyler Dr., Wilmington, NC 28405.	PENNITRACIN (bacitracin methylenedisalicylate) and MAXIBAN (narasin and nicarbazin).	Original approval for the prevention of mortality caused by necrotic enteritis and coccidiosis in broiler chickens.	FOI Summary	558.364
December 8, 2022.	141–566	Increvet, Inc., 200 Portland St., Floor 3, Boston, MA 02114.	BEXACAT (bexagliflozin tablets) Tablets.	Original approval to improve glycemic control in otherwise healthy cats with diabetes mellitus not previously treated with insulin.	FOI Summary	520.170
December 15, 2022.	200–455	Bimeda Animal Health Ltd., 1B The Herbert Building, The Park, Carrickmines, Dublin 18, Ireland.	BILOVET (tylosin tartrate) Soluble Powder.	Original approval for the control of mortality caused by necrotic enteritis associated with *Clostridium perfringens* in broiler chickens as a generic copy of NADA 013–076.	FOI Summary	520.2640
December 20, 2022.	141–559	Anzac Animal Health, LLC, 218 Millwell Dr., Suite B, Maryland Heights, MO 63043.	ZYCOSAN (pentosan polysulfate sodium injection) Injectable Solution.	Original approval for the control of clinical signs associated with osteoarthritis in horses.	FOI Summary	522.1704
December 23, 2022.	141–450	Intervet, Inc., 2 Giralda Farms, Maison, NJ 07940.	BANAMINE Transdermal (flunixin transdermal solution) Transdermal Solution.	Supplemental approval for control of pyrexia associated with acute bovine mastitis, for addition of lactating dairy cows for all approved indications, and of a milk discard time.	FOI Summary	524.970

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 (CVM'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 OCTOBER, NOVEMBER, AND DECEMBER 2022 TO CHANGE THE MARKETING STATUS OF ANTIMICROBIAL ANIMAL DRUG PRODUCTS FROM OTC TO Rx

Approval date	File No.	Sponsor	Product name	21 CFR section
October 11, 2022.	097–222	Boehringer Ingelheim Animal Health USA, Inc., 3239 Satellite Blvd., Duluth, GA 30096.	TODAY (cephapirin sodium) Intramammary Infusion.	526.365

TABLE 2—SUPPLEMENTAL APPLICATIONS APPROVED DURING OCTOBER, NOVEMBER, AND DECEMBER 2022 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
October 18, 2022.	055–039	Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sofia, Bulgaria.	Chlortetracycline Calf Oblets, 500 mg	520.443
October 31, 2022.	034–025	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007	LINCOMIX (lincomycin hydrochloride) Injectable Solution.	522.1260
November 2, 2022.	065–498	Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sofia, Bulgaria.	PEN BP–48 (penicillin G benzathine and penicillin G procaine) Injectable Suspension.	522.1696a
November 9, 2022.	108–114	Boehringer Ingelheim Animal Health USA, Inc., 3239 Satellite Blvd., Duluth, GA 30096.	TOMORROW (cephapirin benzathine) Intramammary Infusion.	526.363
November 15, 2022.	065–010	Norbrook Laboratories Ltd., Carnbane Industrial Estate, Newry, County Down, BT35 6QQ, United Kingdom.	NOROCILLIN (penicillin G procaine) Injectable Suspension.	522.1696b
November 16, 2022.	140–582	Bimeda Animal Health Ltd., 1B The Herbert Building, The Park, Carrickmines, Dublin 18, Ireland.	BIOCYL–50 (oxytetracycline hydrochloride) Injectable Solution; BIOCYL–100 (oxytetracycline hydrochloride) Injectable Solution.	522.1662
November 18, 2022.	141–143	Norbrook Laboratories Ltd., Carnbane Industrial Estate, Newry, County Down, BT35 6QQ, United Kingdom.	NOROMYCIN 300 LA (oxytetracycline) Injectable Solution.	522.1660b
November 30, 2022.	031–715	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007	ALBON (sulfadimethoxine) Boluses	520.2220d
November 30, 2022.	122–271	Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sofia, Bulgaria.	SULMET (sulfamethazine) Oblets	520.2260a
November 30, 2022.	200–038	Do	DI–METHOX (sulfadimethoxine) Injectable Solution.	522.2220
December 2, 2022.	101–862	Intervet, Inc., 2 Giralda Farms, Madison, NJ 07940	GARASOL (gentamicin sulfate) Injection	522.1044
December 7, 2022.	065–174	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007	CRYSTICILLIN 300 A.S. (penicillin G procaine) Injectable Suspension.	522.1696b
December 9, 2022.	113–232	Do	LIQUAMYCIN LA-200 (oxytetracycline) Injectable Solution.	522.1660a
December 9, 2022.	200–523	Bimeda Animal Health Ltd., 1B The Herbert Building, The Park, Carrickmines, Dublin 18, Ireland.	SULFAMED (sulfadimethoxine) Injectable Solution.	522.2220
December 12, 2022.	103–037	Intervet, Inc., 2 Giralda Farms, Madison, NJ 07940	GARACIN (gentamicin) Injectable Solution.	522.1044
December 15, 2022.	200–508	Bimeda Animal Health Ltd., 1B The Herbert Building, The Park, Carrickmines, Dublin 18, Ireland.	BILOVET (tylosin) Injectable Solution	522.2640
December 16, 2022.	138–955	Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sofia, Bulgaria.	TYLOVET (tylosin) Injectable Solution ...	522.2640
December 22, 2022.	092–523	Intervet, Inc., 2 Giralda Farms, Madison, NJ 07940	GARASOL (gentamicin sulfate) Solution	529.1044b

II. Changes of Sponsorship

Increvet, Inc., 200 Portland St., Floor 3, Boston, MA 02114 has informed FDA that it has transferred ownership of, and all rights and interest in, NADA 141–566 for BEXACAT (bexagliflozin tablets) Tablets, approved December 8, 2022, to Elanco US Inc., 2500 Innovation Way, Greenfield, IN 46140. The regulatory text for the original approval of this application reflects this change of sponsorship.

III. Technical Amendments

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

- 21 CFR 516.498 is removed from subpart C of part 516 and is added to subpart E.
- 21 CFR 520.370, 520.522, 522.246, 522.304, 522.2470, 524.1044c, 524.1044f, and 524.1484g are amended to reflect a sponsor's current drug labeler code.
- 21 CFR 520.441 is amended to revise the sponsor listings for uses of chlortetracycline in drinking water of various food-producing animals.
- 21 CFR 520.443 is amended to revise the sponsor listings for uses of chlortetracycline tablets and boluses in calves.
- 21 CFR 520.1196 is amended to revise the indication for uses of ivermectin and pyrantel tablets in dogs.
- 21 CFR 522. 1660a is amended to reflect the correct drug labeler code for a sponsor of an oxytetracycline injectable solution.
- 21 CFR 522.2471 is amended to add human food safety warnings for use of tilmicosin injectable solution in cattle and sheep.
- 21 CFR 524.1448 is amended to revise the indication for use of mirtazapine transdermal ointment in cats.
- 21 CFR 556.222 is amended to reflect a revised tolerance for residues of doramectin in liver of cattle.
- 21 CFR 556.500 is amended to reflect revised numbering of sections for oxytetracycline uses in food-producing animals.
- 21 CFR 558.76 is amended to add conditions of use previously approved under NADA 141–137 for use of bacitracin methylenedisalicylate in the manufacture of Type C medicated feeds for broiler and replacement chickens (87 FR 76418, December 14, 2022).
- 21 CFR 558.355 is amended to revise a caution statement on labeling of monensin Type A medicated articles for use in broiler breeder replacement chickens.

IV. 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 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 510, 516, 520, 522, 524, 526, 529, 556, and 558 are amended as follows:

PART 510—NEW ANIMAL DRUGS

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

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

■ 2. In § 510.600, in the table in paragraph (c)(1), add entries in alphabetical order for ''Ishihara Sangyo Kaisha, Ltd.'' and ''ZyVet Animal Health, Inc.'' and in the table in paragraph (c)(2), add entries in numerical order for ''064642'' and ''086117'' 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
* * * * * * *	
Ishihara Sangyo Kaisha, Ltd., 3–15, Edobori 1-chome, Nishi-ku, Osaka 550–0002, Japan	064642
* * * * * * *	
ZyVet Animal Health, Inc., 73 Route 31N, Pennington, NJ 08534	086117

(2) * * *

Drug labeler code	Firm name and address
* * * * * * *	
064642	Ishihara Sangyo Kaisha, Ltd., 3–15, Edobori 1-chome, Nishi-ku, Osaka 550–0002, Japan.
* * * * * * *	
086117	ZyVet Animal Health, Inc., 73 Route 31N, Pennington, NJ 08534.
* * * * * * *	

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

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

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

§ 516.498 [Transferred to Subpart E]

■ 4. Transfer § 516.498 from subpart C to subpart E.

■ 5. Add § 516.1012 to read as follows:

§ 516.1012 Fuzapladib.

(a) *Specifications.* The drug is provided as a powder for injection that is reconstituted with 3.5 milliliter (mL) of provided diluent to a final concentration of 4 milligrams (mg) fuzapladib sodium per mL.

(b) *Sponsor.* See No. 064642 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Administer at a dosage of 0.4 mg (0.1 mL) per kilogram of body weight once daily for 3 consecutive days by intravenous (IV) injection over 15 seconds to 1 minute.

(2) *Indications for use in dogs.* For the management of clinical signs associated with acute onset of pancreatitis in dogs.

(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

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

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

■ 7. Add § 520.170 to read as follows:

§ 520.170 Bexagliflozin.

(a) *Specifications.* Each tablet contains 15 milligrams bexagliflozin.

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

(c) *Conditions of use*—(1) *Amount.* Administer one tablet by mouth to cats 6.6 lb (3.0 kg) or greater once daily, at approximately the same time each day, with or without food, and regardless of blood glucose level.

(2) *Indications for use.* To improve glycemic control in otherwise healthy cats with diabetes mellitus not previously treated with insulin.

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

§ 520.370 [Amended]

■ 8. In § 520.370, in paragraph (b)(1), remove ''026637'' and add in its place ''017033''.

■ 9. In § 520.441, revise paragraphs (b)(1) and (3) and (d)(4)(iii)(C) to read as follows:

§ 520.441 Chlortetracycline powder.

* * * * *

(b) * * *

(1) No. 069254 for use as in paragraph (d) of this section.

* * * * *

(3) Nos. 069043 and 076475 for use as in paragraphs (d)(4)(i)(A), (d)(4)(i)(B), and (d)(4)(ii) and (iii) of this section.

* * * * *

(d) * * *

(4) * * *

(iii) * * *.

(C) *Limitations.* Prepare fresh solution daily as the sole source of chlortetracycline. Do not use for more than 5 days. For Nos. 066104, 069043, 069254, and 076475: Do not slaughter animals for food within 5 days of treatment. For No. 069254: Do not slaughter animals for food within 24 hours of treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

* * * * *

■ 10. In § 520.443, revise paragraphs (a), (b), and (d)(3)(ii) to read as follows:

§ 520.443 Chlortetracycline hydrochloride tablets and boluses.

(a) *Specifications.* Each tablet contains 25 milligrams (mg) chlortetracycline hydrochloride; each bolus contains 250 or 500 mg chlortetracycline hydrochloride.

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

(1) No. 069043 for use of a 250-mg bolus as in paragraph (d)(1) of this section.

(2) No. 016592 for use of a 25-mg tablet as in paragraph (d)(2) of this section.

(3) No. 016592 for use of a 500-mg bolus as in paragraph (d)(3) of this section.

* * * * *

(d) * * *

(3) * * *

(ii) *Limitations.* 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.

§ 520.522 [Amended]

■ 11. In § 520.522, in paragraph (b)(2), remove ''026637'' and add in its place ''017033''.

§ 520.1196 [Amended]

■ 12. In § 520.1196, in paragraph (c)(1)(ii), remove ''ascarids'' and add in its place ''roundworms''.

■ 13. In § 520.1263b, revise paragraphs (b)(1) and (2) to read as follows:

§ 520.1263b Lincomycin powder.

* * * * *

(b) * * *

(1) Nos. 054771 and 061133 for use as in paragraph (d) of this section.

(2) Nos. 016592, 054925, and 076475 for use as in paragraphs (d)(1) and (d)(2) of this section.

* * * * *

■ 14. In § 520.2220d, revise paragraph (d)(3) to read as follows:

§ 520.2220d Sulfadimethoxine bolus.

* * * * *

(d) * * *

(3) *Limitations.* Do not administer within 7 days of slaughter. Milk that has been taken from animals during treatment and 60 hours (five milkings) after the latest treatment must not be used for food. 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.

■ 15. In § 520.2260a, revise paragraph (d)(1)(iii) to read as follows:

§ 520.2260a Sulfamethazine oblets and boluses.

* * * * *

(d) * * *

(1) * * *

(iii) *Limitations.* Do not administer for more than 5 consecutive days. Do not treat cattle within 10 days of slaughter. 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. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

* * * * *

■ 16. In § 520.2640, add paragraph (b)(3) to read as follows:

§ 520.2640 Tylosin.

* * * * *

(b) * * *

(3) No. 061133 for use of a 100-g container as in paragraphs (e)(1)(i)(B) and (e)(1)(ii) of this section.

* * * * *

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

■ 18. In § 522.246, revise paragraph (b)(3) to read as follows:

§ 522.246 Butorphanol.

* * * * *

(b) * * *

(3) Nos. 000061, 017033, 043264, and 059399 for use of the product described in paragraph (a)(3) of this section as in paragraph (d)(3) of this section.

* * * * *

§ 522.304 [Amended]

■ 19. In § 522.304, in paragraph (b), remove ''026637'' and add in its place ''017033''.

■ 20. In § 522.1044, revise paragraphs (d)(2)(i) through (iii), (d)(3)(i) though (iii), and (d)(4)(i) through (iii) to read as follows:

§ 522.1044 Gentamicin.

* * * * *

(d) * * *

(2) * * *

(i) *Amount.* Administer subcutaneously in the neck 1 mg of gentamicin per 0.2 mL dose, using the 50- or 100-mg/mL product diluted with sterile saline to a concentration of 5 mg/mL.

(ii) *Indications for use.* As an aid in the prevention of early mortality in 1- to 3-day old turkey poults due to *Arizona*

paracolon infections susceptible to gentamicin.

(iii) *Limitations.* Injected poults must not be slaughtered for food for at least 9 weeks after treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(3) * * *

(i) *Amount.* Administer subcutaneously in the neck 0.2 mg of gentamicin per 0.2 mL dose, using the 50- or 100-mg/mL product diluted with sterile saline to a concentration of 1.0 mg/mL.

(ii) *Indications for use.* For prevention of early mortality in day-old chickens caused by *Escherichia coli, Salmonella typhimurium,* and *Pseudomonas aeruginosa* susceptible to gentamicin.

(iii) *Limitations.* Injected chicks must not be slaughtered for food for at least 5 weeks after treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(4) * * *

(i) *Amount.* Administer 5 mg of gentamicin as a single intramuscular dose using the 5 mg/mL solution.

(ii) *Indications for use.* For treatment of porcine colibacillosis in piglets up to 3 days old caused by strains of *Escherichia coli* sensitive to gentamicin.

(iii) *Limitations.* For single intramuscular dose in pigs up to 3 days of age only. Do not slaughter treated animals for food for at least 40 days following treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

* * * * *

■ 21. In § 522.1260, revise paragraph (e)(2)(iii) to read as follows:

§ 522.1260 Lincomycin.

* * * * *

(e) * * *

(2) * * *

(iii) *Limitations.* Do not treat within 48 hours of slaughter. For No 054771: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

■ 22. In § 522.1660a, revise paragraph (b) and add a sentence to the end of paragraphs (e)(1)(ii) and (e)(2)(ii) to read as follows:

§ 522.1660a Oxytetracycline solution, 200 milligrams/milliliter.

* * * * *

(b) *Sponsors.* See Nos. 000010, 016592, 054771, 055529, 061133, and 069254 in § 510.600(c) of this chapter.

* * * * *

(e) * * *

(1) * * *

(ii) * * * For No. 054771: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) * * *

(ii) * * * For No. 054771: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

■ 23. In § 522.1660b, add a sentence to the end of paragraphs (e)(1)(ii) and (e)(2)(ii) to read as follows:

§ 522.1660b Oxytetracycline solution, 300 milligrams/milliliter.

* * * * *

(e) * * *

(1) * * *

(ii) * * * For No. 055529: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) * * *

(ii) * * * For No. 055529: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

■ 24. In § 522.1662, revise paragraphs (j)(3)(i) and (iii) to read as follows:

§ 522.1662 Oxytetracycline.

* * * * *

(j) * * *

(3) * * *

(i) *Amount.* Administer by intravenous injection 3 to 5 milligrams per pound of body weight daily. Administer 5 milligrams per pound for anaplasmosis, severe foot rot, and severe forms of other diseases. Treatment should be continued 24 to 48 hours following remission of disease symptoms, but not to exceed a total of 4 consecutive days.

* * * * *

(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.

■ 25. In § 522.1696a, revise paragraph (d)(2)(iii) to read as follows:

§ 522.1696a Penicillin G benzathine and penicillin G procaine suspension.

* * * * *

(d) * * *

(2) * * *

(iii) *Limitations.* Not for use within 30 days of slaughter. For No. 016592: A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. For No. 016592: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

■ 26. In § 522.1696b, revise paragraph (d)(2)(iii)(C) to read as follows:

§ 522.1696b Penicillin G procaine aqueous suspension.

* * * * *

(d) * * *

(2) * * *

(iii) * * *

(C) For Nos. 054771 and 055529: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

■ 27. Add § 522.1704 to read as follows:

§ 522.1704 Pentosan polysulfate sodium.

(a) *Specifications.* Each milliliter of solution contains 250 milligrams (mg) of pentosan polysulfate sodium.

(b) *Sponsor.* See No. 086073 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Administer 3 mg per kilogram of body weight (1.4 mg per pound) by intramuscular injection once weekly for 4 weeks for a total of four doses.

(2) *Indications for use.* For the control of clinical signs associated with osteoarthritis in horses.

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

■ 28. In § 522.2470, revise paragraphs (b) introductory text and (b)(1) to read as follows:

§ 522.2470 Tiletamine and zolazepam for injection.

* * * * *

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter.

(1) Nos. 017033 and 054771 for use as in paragraph (c) of this section.

* * * * *

■ 29. In § 522.2471, remove paragraph (d), redesignate paragraph (e) as paragraph (d), and revise newly redesignated paragraphs (d)(1)(iii) and (d)(2)(iii).

The revisions read as follows:

§ 522.2471 Tilmicosin.

* * * * *

(d) * * *

(1) * * *

(iii) *Limitations.* Animals intended for human consumption must not be slaughtered within 42 days of last treatment. Do not use in lactating dairy cattle 20 months of age or older. Use of tilmicosin in this class of cattle may cause milk residues. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) * * *

(iii) *Limitations.* Not for use in lactating ewes producing milk for human consumption. Animals intended for human consumption must not be slaughtered within 42 days of last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

■ 30. In 522.2630, revise paragraph (b)(1) to read as follows:

§ 522.2630 Tulathromycin.

* * * * *

(b) * * *

(1) Nos. 000061, 013744, 051311, 054771, 055529, 058198, 061133, and 068504 for use of product described in paragraph (a)(1) as in paragraphs (d)(1)(i), (d)(1)(ii), (d)(1)(iii)(A), and (d)(2) of this section.

* * * * *

§ 522.2640 [Amended]

■ 31. In § 522.2640, in paragraph (b)(2), remove ''000010'' and add in its place ''016592'' and in paragraphs (e)(1)(iii) and (e)(2)(iii), in the last sentence of each paragraph, remove ''For No. 058198:''.

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. In § 524.970, revise paragraphs (d)(2) and (3) to read as follows:

§ 524.970 Flunixin.

* * * * *

(d) * * *

(2) *Indications for use.* For the control of pyrexia associated with bovine respiratory disease and acute bovine mastitis, and the control of pain associated with foot rot in beef cattle 2 months of age and older and dairy cattle.

(3) *Limitations.* Not for use in beef and dairy bulls intended for breeding over 1 year of age. Milk that has been taken during treatment and for 48 hours after treatment must not be used for human consumption. Cattle must not be slaughtered for human consumption within 8 days of treatment. Not for use in replacement dairy heifers 20 months of age or older or dry dairy cows; use in these cattle may cause drug residues in calves born to these cows or heifers. Not for use in beef calves less than 2 months of age, dairy calves, and veal calves. A withdrawal period has not been established for this product in pre-ruminating calves. Approved only as a single topical dose in cattle. Repeated treatments may result in violative residues in milk or in edible tissues. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 524.1044c [Amended]

■ 34. In § 524.1044c, in paragraph (b), remove ''026637'' and add in its place ''017033''.

■ 35. In § 524.1044f, revise paragraph (b) to read as follows:

§ 524.1044f Gentamicin and betamethasone spray.

* * * * *

(b) *Sponsors.* See Nos. 000061, 017033, 054925, 058005, and 058829 in § 510.600(c) of this chapter.

* * * * *

■ 36. In § 524.1448, revise paragraph (c)(2) to read as follows:

§ 524.1448 Mirtazapine transdermal ointment.

* * * * *

(c) * * *

(2) *Indications for use.* For body weight gain in cats with a history of weight loss.

* * * * *

§ 524.1484g [Amended]

■ 37. In § 524.1484g, in paragraph (b), remove ''026637'' and add in its place ''017033''.

PART 526—INTRAMAMMARY DOSAGE FORM NEW ANIMAL DRUGS

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

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

■ 39. In § 526.363, revise paragraph (d)(3) to read as follows:

§ 526.363 Cephapirin benzathine.

* * * * *

(d) * * *

(3) *Limitations.* For use in dry cows only. Not to be used within 30 days of calving. Milk from treated cows must not be used for food during the first 72 hours after calving. Animals infused with this product must not be slaughtered for food until 42 days after the latest infusion. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

■ 40. In § 526.365, revise paragraph (d)(3) to read as follows:

§ 526.365 Cephapirin sodium.

* * * * *

(d) * * *

(3) *Limitations.* Milk that has been taken from animals during treatment and for 96 hours after the last treatment must not be used for food. Treated animals must not be slaughtered for food until 4 days after the last treatment. 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

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

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

■ 42. In § 529.1044b, add a sentence to the end of paragraph (c)(3) to read as follows:

§ 529.1044b Gentamicin solution for dipping eggs.

* * * * *

(c) * * *

(3) * * * For No. 000061: 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

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

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

■ 44. In § 556.222, revise paragraphs (b)(1)(i) and (c) to read as follows:

§ 556.222 Doramectin.

* * * * *

(b) * * *

(1) * * *

(i) Liver (target tissue): 300 ppb.

* * * * *

(c) *Related conditions of use.* See §§ 522.770, 522.772, and 524.770 of this chapter.

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

§ 556.500 Oxytetracycline.

* * * * *

(c) *Related conditions of use.* See §§ 520.1660a, 520.1660c, 520.1660d, 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

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

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

■ 47. In § 558.76, redesignate paragraph (d)(1)(iv) as paragraph (d)(1)(v) and add new paragraph (d)(1)(iv) to read as follows:

§ 558.76 Bacitracin methylenedisalicylate.

* * * * *

(d) * * *

(1) * * *

Bacitracin in grams per ton	Indications for use	Limitations	Sponsor
*	* * * * * * *		
(iv) 50	Broiler and replacement chickens: For the prevention of mortality caused by necrotic enteritis associated with *Clostridium perfringens*.	Feed as the sole ration for 28 to 35 days, starting from the time chicks are placed for brooding.	069254
*	* * * * * * *		

* * * * *

■ 48. In § 558.355, revise paragraph (d)(8)(vi) to read as follows:

§ 558.355 Monensin.

* * * * *

(d) * * *

(8) * * *

(vi) Not for broiler breeder replacement chickens.

* * * * *

■ 49. In § 558.364:

■ a. Revise paragraphs (d)(1)(ii) and (iii);

■ b. Redesignate paragraphs (d)(1)(iv) and (v) as paragraphs (d)(1)(vi) and (vii); and

■ c. Add new paragraphs (d)(1)(iv) and (v).

The revisions and additions read as follows:

§ 558.364 Narasin and nicarbazin.

* * * * *

(d) * * *

(1) * * *

Narasin and nicarbazin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
* *	* *	* * *		
(ii) 27 to 45 of each drug.	Bacitracin methylenedisalicylate, 4 to 50.	Broiler chickens: For the prevention of coccidiosis caused by *Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima,* and for increased rate of weight gain and improved feed efficiency.	Feed continuously as the sole ration. Do not feed to laying hens. Do not allow adult turkeys, horses, or other equines access to formulations containing narasin. Ingestion of narasin by these species has been fatal. Withdraw 5 days before slaughter. Bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) of this chapter.	058198
(iii) 27 to 45 of each drug.	Bacitracin methylenedisalicylate, 4 to 50.	Broiler chickens: For the prevention of coccidiosis caused by *Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima,* and for increased rate of weight gain and improved feed efficiency.	Feed as the sole ration throughout the feeding period. For broiler chickens only. Do not feed to laying hens. Do not allow adult turkeys, horses, or other equines access to formulations containing narasin. Ingestion of narasin by these species has been fatal. Bacitracin methylenedisalicylate as provided by No. 069254 in § 510.600(c) of this chapter.	069254
(iv) 27 to 45 of each drug.	Bacitracin methylenedisalicylate, 50.	Broiler chickens: For the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati,* and as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.	Feed continuously as the sole ration. Do not feed to laying hens. Do not allow adult turkeys, horses, or other equines access to formulations containing narasin. Ingestion of narasin by these species has been fatal. Withdraw 5 days before slaughter. Bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(v) 27 to 45 of each drug.	Bacitracin methylenedisalicylate, 50.	Broiler chickens: For the prevention of coccidiosis caused by *Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima,* and for the prevention of mortality caused by necrotic enteritis associated with *Clostridium perfringens*.	Feed as the sole ration for 28 to 35 days, starting from the time chicks are placed for brooding. For broiler chickens only. Do not feed to laying hens. Do not allow adult turkeys, horses, or other equines access to formulations containing narasin. Ingestion of narasin by these species has been fatal. Bacitracin methylenedisalicylate as provided by No. 069254 in § 510.600(c) of this chapter.	069254
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Dated: March 13, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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