



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-2020-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) and abbreviated new animal drug applications (ANADAs) during April, May, and June 2020. 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 [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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](mailto:george.haibel@fda.hhs.gov).

SUPPLEMENTARY INFORMATION:

### I. Approval Actions

FDA is amending the animal drug regulations to reflect approval actions for NADAs and ANADAs during April, May, and June 2020, 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 and ANADAs Approved During April, May, and June 2020

Approval date	File No.	Sponsor	Product name	Species	Effect of the action	Public documents
April 2, 2020	141-527	Bayer HealthCare LLC, Animal Health Division, P.O. Box 390, Shawnee Mission, KS 66201	BAYTRIL 100-CA1 (enrofloxacin) Injectable Solution	Cattle	Conditional approval for the treatment of clinical anaplasmosis in certain classes of cattle	FOI Summary
April 10, 2020	141-533	Boehringer Ingelheim Animal Health USA, Inc., 3239 Satellite Blvd., Duluth, GA 30096	ASERVO EQUIHALER (ciclesonide inhalation spray)	Horses	Original approval for the management of clinical signs associated with severe equine asthma in horses	FOI Summary
April 22, 2020	200-673	Aurora Pharmaceutical, Inc., 1196 Highway 3 South, Northfield, MN 55057-3009	REVOLT (selamectin) Topical Solution	Dogs and cats	Original approval as a generic copy of NADA 141-152	FOI Summary
April 27, 2020	200-674	Modern Veterinary Therapeutics, LLC, 14343 SW 119th Ave., Miami, FL 33186	Detomidine Hydrochloride (detomidine hydrochloride) Injectable Solution	Horses	Original approval as a generic copy of NADA 140-862	FOI Summary
May 14, 2020	200-679	Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sophia, Bulgaria	OPTIGRID (ractopamine HCl) Type A Medicated Article	Cattle	Original approval as a generic copy of NADA 141-221	FOI Summary
May 21, 2020	200-680	Felix Pharmaceuticals Pvt. Ltd., 25-28 North Wall Quay, Dublin 1, Ireland	Enrofloxacin flavored tablets	Dogs	Original approval as a generic copy of NADA 140-441	FOI Summary
May 27, 2020	200-638	Vétoquinol USA, Inc., 4250 N. Sylvania Ave., Fort Worth, TX 76137	IMOXI Topical Solution for Cats (imidacloprid and moxidectin)	Cats	Original approval as a generic copy of NADA 141-254	FOI Summary
May 28, 2020	200-510	Pharmgate, Inc. 1800 Sir Tyler Dr. Wilmington, NC 28405	Chlortetracycline Type B and Type C medicated feeds	Cattle	Supplemental approval for use of DERACIN (chlortetracycline) Type A medicated articles in the manufacture of Type B and Type C medicated feeds for control of bacterial pneumonia in beef cattle and replacement dairy heifers	N/A
June 1, 2020	200-134	Intervet, Inc., 2 Giralda Farms, Madison, NJ 07940	FERTAGYL (gonadorelin) Injectable Solution	Cattle	Supplemental approval for fixed-time artificial insemination in beef cows	FOI Summary
June 2, 2020	200-682	Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sophia, Bulgaria	VETMULIN 12.5% (tiamulin hydrogen fumarate) Liquid concentrate	Swine	Original approval as a generic copy of NADA 140-916	FOI Summary
June 4, 2020	200-399	Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sophia, Bulgaria	CYCLEGUARD (melengestrol acetate Type A liquid medicated article)	Cattle	Original approval as a generic copy of NADA 039-402	FOI Summary

June 15, 2020	141-534	Orion Corp., Orionintie 1, 02200 Espoo, Finland	CLEVOR (ropinirole ophthalmic solution)	Dogs	Original approval for the induction of vomiting in dogs	FOI Summary
June 18, 2020	141-535	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007	Chlortetracycline, sulfamethazine, and lasalocid Type B and Type C medicated feeds	Cattle	Original approval for use of AUREO S 700 (chlortetracycline and sulfamethazine) and BOVATEC (lasalocid) in the manufacture of Type B and Type C medicated feeds for beef steers and heifers fed in confinement for slaughter	FOI Summary

## II. Changes of Sponsor

Virbac AH, Inc., PO Box 162059, Fort Worth, TX 76161 has informed FDA that it has transferred ownership of, and all rights and interest in, NADA 141-084 for SENTINEL (lufenuron and milbemyacin oxime) Flavor Tabs, NADA 141-204 for the SENTINEL Flavor Tabs and CAPSTAR (nitenpyram) Flea Management System, and NADA 141-333 for SENTINEL SPECTRUM (lufenuron, milbemyacin oxime, and praziquantel) Chews to Intervet, Inc., 2 Giralda Farms, Madison, NJ 07940. Also, Sparhawk Laboratories, Inc., 12340 Santa Fe Trail Dr., Lenexa, KS 66215 has informed FDA that it has transferred ownership of, and all rights and interest in, A 200-348 for ECOMECTIN (ivermectin) Cattle Pour-On to Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sofia, Bulgaria. The animal drug regulations will be amended to reflect these changes of sponsor.

## III. Technical Amendments

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

- The entries in 21 CFR 510.600(c), 520.304, and 520.812 for Dechra Veterinary Products LLC are being amended to reflect the firm's current drug labeler code.
- The entries in 21 CFR 510.600(c) for Cronus Pharma Specialities India Private Ltd. are being amended to reflect the firm's current address.
- Conditions for use in 21 CFR 520.100 for use of amprolium crumbles in calves are being removed because no approved NADA exists for this dosage form product.
- The regulations in part 526 (21 CFR part 526) for intramammary dosage form drugs are being amended to reflect a current format and improve readability.
- The section in part 529 (21 CFR part 529) for sevofluorane anesthetic gas is being redesignated to reflect a current organizational scheme for dosage form new animal drugs.

- Cross references in part 556 (21 CFR part 556) to related approved uses of new animal drugs are being amended as conforming changes to improve the accuracy of the regulations.
- The table in 21 CFR 558.4 is being amended to reflect the correct format for displaying assay limits for component drugs in fixed-ratio, combination drug Type A medicated articles and Type B and Type C medicated feeds.
- Three tabular entries in 21 CFR 558.68 are being amended to reflect the approved conditions of use of certain feed use combinations, which had been removed in error.
- Typographical errors are being corrected wherever they have been found.

#### IV. Legal Authority

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. This 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 the conditions of use of an approved or conditionally approved new animal drug and the name and address of the drug's sponsor in a "notice, which upon publication shall be effective as a regulation." A notice published pursuant to section 512(i) is not subject to the notice-and-comment rulemaking requirements of the Administrative Procedure Act, 5 U.S.C. 551 et seq. See section 512(i) of the FD&C Act (21 U.S.C. 360b(i)); 21 CFR 10.40(e)(3); S. Rep. 90-1308, at 5 (1968).

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, Food.

### 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—

a. In the table in paragraph (c)(1):

i. Revise the entries for "Cronus Pharma Specialities India Private Ltd." and "Dechra Veterinary Products LLC";

ii. Add an entry in alphabetical order for "Felix Pharmaceuticals Pvt. Ltd."; and

iii. Revise the entry for "Pharmgate, Inc."; and

b. In the table in paragraph (c)(2):

- i. Add an entry in numerical order for "017033";
- ii. Remove the entry for "026637";
- iii. Revise the entries for "069043" and "069254"; and
- iv. Add an entry in numerical order for "086101".

The additions and revisions 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
* * * * *	
Cronus Pharma Specialities India Private Ltd., Sy No-99/1, GMR Hyderabad Aviation SEZ Ltd., Mamidipalli Village, Shamshabad Mandal, Ranga Reddy, Hyderabad Telangana 501218, India	069043
* * * * *	
Dechra Veterinary Products LLC, 7015 College Blvd., suite 525, Overland Park, KS 66211	017033
* * * * *	
Felix Pharmaceuticals Pvt. Ltd., 25-28 North Wall Quay, Dublin 1, Ireland	086101
* * * * *	
Pharmgate Inc., 1800 Sir Tyler Dr., Wilmington, NC 28405	069254
* * * * *	

(2) \* \* \*

Drug labeler code	Firm name and address
* * * * *	
017033	Dechra Veterinary Products LLC, 7015 College Blvd., suite 525, Overland Park, KS 66211

* * * * *	
069043	Cronus Pharma Specialities India Private Ltd., Sy No-99/1, GMR Hyderabad Aviation SEZ Ltd., Mamidipalli Village, Shamshabad Mandal, Ranga Reddy, Hyderabad Telangana 501218, India
* * * * *	
069254	Pharmgate Inc., 1800 Sir Tyler Dr., Wilmington, NC 28405
* * * * *	
086101	Felix Pharmaceuticals Pvt. Ltd., 25-28 North Wall Quay, Dublin 1, Ireland
* * * * *	

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.

4. Add § 516.812 to subpart E to read as follows:

§ 516.812 Enrofloxacin.

(a) *Specifications.* Each milliliter (mL) of solution contains 100 milligrams (mg) enrofloxacin.

(b) *Sponsor.* See No. 000859 in § 510.600(c) of this chapter.

(c) *Conditions of use in cattle--(1) Amount.* Administer, by subcutaneous injection, a single dose of 12.5 mg/kilogram of body weight (5.7 mL/100 pounds of body weight).

Administered dose volume should not exceed 20 mL per injection site.

(2) *Indications for use.* For the treatment of clinical anaplasmosis associated with *Anaplasma marginale* in replacement dairy heifers under 20 months of age and all classes of beef cattle except beef calves less than 2 months of age and beef bulls intended for breeding (any age). Not for use in any other class of dairy cattle or in veal calves.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the extra-label use of this drug in food-producing animals. Cattle intended for human consumption must not be slaughtered within 28 days from the last

treatment. This product is not approved for use in female dairy cattle 20 months of age or older including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

PART 520--ORAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

6. In § 520.100, remove paragraph (a)(3), revise paragraph (b)(2), add paragraph (b)(3), and revise paragraph (d)(2) introductory text.

The revisions and addition read as follows:

§ 520.100 Amprolium.

\* \* \* \* \*

(b) \* \* \*

(2) No. 066104 for use of product described in paragraph (a)(1) of this section as in paragraph (d) of this section.

(3) No. 051072 for use of product described in paragraph (a)(1) of this section as in paragraph (d)(1) of this section.

\* \* \* \* \*

(d) \* \* \*

(2) *Calves*. Administer concentrate solution or soluble powder as a drench or in drinking water as follows:

\* \* \* \* \*

7. In § 520.304, revise paragraph (b), remove reserved paragraph (c), and redesignate paragraph (d) as paragraph (c).

The revision reads as follows:

§ 520.304 Carprofen.

\* \* \* \* \*

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

(1) Nos. 017033, 054771, 055529, and 062250 for use of products described in paragraph (a) as in paragraph (c) of this section.

(2) No. 000859 for use of product described in paragraph (a)(2) as in paragraph (c) of this section.

\* \* \* \* \*

8. In § 520.812, revise paragraphs (a) and (b) to read as follows:

§ 520.812 Enrofloxacin.

(a) *Specifications*--(1) Each tablet contains:

(i) 22.7, 68.0, or 136.0 milligrams (mg) enrofloxacin; or

(ii) 22.7, 68.0, 136.0, or 272 mg enrofloxacin.

(2) Each chewable tablet contains 22.7, 68.0, or 136.0 mg enrofloxacin.

(3) Each soft chewable tablet contains 22.7, 68.0, or 136.0 mg enrofloxacin.

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

(1) No. 000859 for use of products described in paragraphs (a)(1)(i), (a)(2), and (a)(3) of this section.

(2) No. 017033 for use of product described in paragraph (a)(1)(i) of this section.

(3) No. 058198 for use of product described in paragraph (a)(1)(ii) of this section.

(4) No. 086101 for use of product described in paragraph (a)(2) of this section.

\* \* \* \* \*

§ 520.1443 [Amended]

9. In § 520.1443, in paragraph (b), remove "051311" and in its place add "000061".

§ 520.1447 [Amended]

10. In § 520.1447, in paragraph (b), remove "051311" and in its place add "000061".

§ 520.1510 [Amended]

11. In § 520.1510, in paragraph (b)(2), remove "051311" and in its place add "000061".

§ 520.2455 [Amended]

12. In § 520.2455, in paragraph (b)(4), remove "No. 061133" and in its place add "Nos. 016592 and 061133".

#### PART 522--IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 522.536 [Amended]

14. In § 522.536, in paragraph (b), remove "No. 052483" and in its place add "Nos. 015914 and 052483".

15. In § 522.1077:

- a. Revise paragraphs (a)(3), (b), (d), and (e)(1)(i);
- b. Remove paragraph (e)(1)(ii);
- c. Redesignate paragraphs (e)(1)(iii) through (e)(1)(vii) as paragraphs (e)(1)(ii) through (e)(1)(vi);
- d. Revise newly redesignated paragraphs (e)(1)(ii) and (iii); and
- e. Remove and reserve paragraph (e)(2).

The revisions read as follows:

§ 522.1077 Gonadorelin.

(a) \* \* \*

(3) 50 µg of gonadorelin as gonadorelin diacetate tetrahydrate (equivalent to 43 µg gonadorelin); or

\* \* \* \* \*

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

(1) No. 000061 for use of the 43- $\mu$ g/mL product described in paragraph (a)(1) as in paragraphs (e)(1)(i) and (iii) of this section.

(2) No. 068504 for use of the 100- $\mu$ g/mL product described in paragraph (a)(2) as in paragraph (e)(1)(iv) of this section.

(3) No. 061133 for use of the 50- $\mu$ g/mL product described in paragraph (a)(3) as in paragraphs (e)(1)(i) of this section.

(4) No. 000010 for use of the 43- $\mu$ g/mL product described in paragraph (a)(3) as in paragraphs (e)(1)(i) and (v) of this section.

(5) No. 054771 for use of the 50- $\mu$ g/mL product described in paragraph (a)(4) as in paragraphs (e)(1)(ii) and (vi) of this section.

\* \* \* \* \*

(d) *Special considerations*--(1) Concurrent luteolytic drug use is approved as follows:

(i) Cloprostenol injection for use as in paragraph (e)(1)(iii) of this section as provided by No. 000061 in § 510.600(c) of this chapter.

(ii) Cloprostenol injection for use as in paragraph (e)(1)(iv) of this section as provided by No. 068504 in § 510.600(c) of this chapter.

(iii) Cloprostenol injection for use as in paragraph (e)(1)(v) of this section as provided by Nos. 000010 in § 510.600(c) of this chapter.

(iv) Dinoprost injection for use as in paragraphs (e)(1)(vi) of this section as provided by No. 054771 in § 510.600(c) of this chapter.

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

(e) \* \* \*

(1) *Indications for use and amounts*--(i) For the treatment of ovarian follicular cysts in dairy cattle: Administer 86  $\mu$ g gonadorelin (No. 000061) or 100  $\mu$ g gonadorelin diacetate tetrahydrate (Nos. 000010 and 061133) by intramuscular or intravenous injection.

(ii) For the treatment of ovarian follicular cysts in cattle: Administer 100 µg gonadorelin hydrochloride by intramuscular injection.

(iii) For use with cloprostenol sodium to synchronize estrous cycles to allow for fixed-time artificial insemination (FTAI) in beef cows and lactating dairy cows: Administer to each cow 86 µg gonadorelin by intramuscular injection, followed 6 to 8 days later by 500 µg cloprostenol by intramuscular injection, followed 30 to 72 hours later by 86 µg gonadorelin by intramuscular injection.

\* \* \* \* \*

#### PART 524--OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

17. In § 524.1146, revise paragraph (b)(2) and add paragraph (b)(3) to read as follows:

§ 524.1146 Imidacloprid and moxidectin.

\* \* \* \* \*

(b) \* \* \*

(2) Nos. 000859 and 017030 for use of product described in paragraph (a)(2) of this section as in paragraph (d)(2) of this section.

(3) No. 000859 for use of product described in paragraph (a)(2) of this section as in paragraph (d)(3) of this section.

\* \* \* \* \*

§ 524.1193 [Amended]

18. In § 524.1193, in paragraph (b)(2), remove "016592, 054925, and 058005" and in its place add "016592 and 054925".

19. Add § 524.2080 to read as follows:

§ 524.2080 Ropinirole.

(a) *Specifications*. Each milliliter of solution contains 30 milligrams (mg) ropinirole (equivalent to 34.2 mg ropinirole hydrochloride).

(b) *Sponsor*. See No. 052483 in § 510.600(c) of this chapter.

(c) *Conditions of use--(1) Amount*. Using the table provided in labeling, administer the number of eye drops topically, corresponding to body weight, that results in a target dose of 3.75 mg per square meter (mg/m<sup>2</sup>) (dose band 2.7 to 5.4 mg/m<sup>2</sup>). If the dog does not vomit within 20 minutes of the first dose, then a second dose may be administered.

(2) *Indications for use*. For the induction of vomiting in dogs.

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

§ 524.2098 [Amended]

20. In § 524.2098, in paragraph (b), remove "Nos. 054771, 055529, and 061651" and in its place add "Nos. 051072, 054771, 055529, and 061651".

#### PART 526--INTRAMAMMARY DOSAGE FORM NEW ANIMAL DRUGS

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

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

22. In § 526.88, revise the section heading, paragraph (a), the paragraph (d) subject heading, and paragraphs (d)(1) and (3) to read as follows:

§ 526.88 Amoxicillin.

(a) *Specifications*. Each single-dose, 10-milliliter syringe contains amoxicillin trihydrate equivalent to 62.5 milligrams (mg) amoxicillin.

\* \* \* \* \*

(d) *Conditions of use in lactating cows--(1) Amount*. Infuse the contents of one syringe (equivalent to 62.5 mg amoxicillin) into each infected quarter every 12 hours for a maximum of 3 doses.

\* \* \* \* \*

(3) *Limitations*. Milk taken from animals during treatment and for 60 hours (5 milkings) after the last treatment must not be used for food. Treated animals must not be slaughtered for food purposes within 12 days after the last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

23. In § 526.313, revise paragraphs (a) and (d) and add paragraph (e) to read as follows:  
§ 526.313 Ceftiofur.

(a) *Specifications*. Each single-dose, 10-milliliter syringe contains:

(1) 125 milligrams (mg) ceftiofur equivalents as the hydrochloride salt; or

(2) 500 mg ceftiofur equivalents as the hydrochloride salt.

\* \* \* \* \*

(d) *Conditions of use for syringe described in paragraph (a)(1) of this section in lactating cows*--(1) *Amount*. Infuse the contents of one syringe (125 mg ceftiofur equivalents) into each affected quarter. Repeat treatment in 24 hours. Once daily treatment may be repeated for up to 8 consecutive days.

(2) *Indications for use*. For the treatment of clinical mastitis associated with coagulase-negative staphylococci, *Streptococcus dysgalactiae*, and *Escherichia coli*; and the treatment of diagnosed subclinical mastitis associated with coagulase-negative staphylococci and *S. dysgalactiae*.

(3) *Limitations*. Milk taken from cows during treatment (a maximum of 8 daily infusions) and for 72 hours after the last treatment must not be used for human consumption. Following label use for up to 8 consecutive days, a 2-day preslaughter withdrawal period is required. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(4) *Special considerations*. Federal law prohibits extralabel use of this drug in lactating dairy cattle for disease prevention purposes; at unapproved doses; frequencies, durations, or routes of administration; and in unapproved major food-producing species/production classes.

(e) *Conditions of use for syringe described in paragraph (a)(2) of this section in dry cows--(1) Amount.* Infuse the contents of one syringe (500 mg ceftiofur equivalents) into each affected quarter at the time of dry off.

(2) *Indications for use.* For the treatment of subclinical mastitis in dairy cattle at the time of dry off associated with *Staphylococcus aureus*, *Streptococcus dysgalactiae*, and *Streptococcus uberis*.

(3) *Limitations.* Milk taken from cows completing a 30-day dry-off period may be used for food with no milk discard due to ceftiofur residues. Following intramammary infusion, a 16-day preslaughter withdrawal period is required for treated cows. No preslaughter withdrawal period is required for neonatal calves from treated cows regardless of colostrum consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(4) *Special considerations.* Federal law prohibits extralabel use of this drug in dry dairy cattle for disease prevention purposes; at unapproved doses; frequencies, durations, or routes of administration; and in unapproved major food-producing species/production classes.

24. In § 526.363, revise paragraphs (a) and (d) to read as follows:

§ 526.363 Cephapirin benzathine.

(a) *Specifications.* Each single-dose, 10-milliliter syringe contains 300 milligrams cephalosporin activity (as cephalosporin benzathine).

\* \* \* \* \*

(d) *Conditions of use in dry cows--(1) Amount.* Infuse the contents of one syringe (300 mg cephalosporin activity) into each quarter following last milking, but no later than 30 days before calving.

(2) *Indications for use.* For the treatment of mastitis caused by susceptible strains of *Streptococcus agalactiae* and *Staphylococcus aureus*, including penicillin-resistant strains.

(3) *Limitations.* For use in dry cows only. 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.

25. In § 526.365, revise paragraphs (a) and (d)(1) to read as follows:

§ 526.365 Cephapirin sodium.

(a) *Specifications.* Each single-dose, 10-milliliter syringe contains 200 milligrams (mg) cephapirin sodium activity.

\* \* \* \* \*

(d) \* \* \*

(1) *Amount.* Infuse the contents of one syringe (200 mg cephapirin activity) into each infected quarter immediately after the quarter has been completely milked out. Do not milk out for 12 hours. Repeat once only in 12 hours.

\* \* \* \* \*

26. Revise § 526.464 to read as follows:

§ 526.464 Cloxacillin benzathine.

(a) *Specifications.* Each single-dose, 7.5- or 10-milliliter syringe contains cloxacillin benzathine equivalent to 500 milligrams (mg) cloxacillin.

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

(c) *Related tolerances.* See § 556.165 of this chapter.

(d) *Conditions of use in dry cows--(1) Amount.* Infuse the contents of one syringe (equivalent to 500 mg cloxacillin) into each quarter immediately after last milking, but no later than 30 days before calving.

(2) *Indications for use.* For the treatment of mastitis caused by *Staphylococcus aureus* and *Streptococcus agalactiae* including penicillin resistant strains in dairy cows during the dry period.

(3) *Limitations*. Animals infused with this product must not be slaughtered for food until 30 days after the latest infusion. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 526.464a [Removed]

27. Remove § 526.464a.

§ 525.464b [Redesignated as § 526.464]

28. Redesignate § 526.464b as § 526.465 and revise the section heading and paragraphs (a) and (d) to read as follows:

§ 526.465 Cloxacillin sodium.

(a) *Specifications*. Each single-dose, 10-milliliter syringe contains cloxacillin sodium equivalent to 200 milligrams (mg) cloxacillin.

\* \* \* \* \*

(d) *Conditions of use in lactating cows*--(1) *Amount*. Infuse the contents of one syringe (equivalent to 200 mg cloxacillin) into each infected quarter. Treatment should be repeated at 12-hour intervals for a total of 3 doses.

(2) *Indications for use*. For the treatment of mastitis in lactating cows due to *Streptococcus agalactiae* and *Staphylococcus aureus*, nonpenicillinase-producing strains.

(3) *Limitations*. Milk taken from treated animals within 48 hours (4 milkings) after the latest treatment should not be used for food. Treated animals should not be slaughtered for food within 10 days after the latest treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

29. Revise § 526.820 to read as follows:

§ 526.820 Erythromycin.

(a) *Specifications*--(1) Each single-dose, 6-milliliter (mL) syringe contains 300 milligrams (mg) erythromycin (as the base).

(2) Each single-dose, 12-mL syringe contains 600 mg erythromycin (as the base).

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

(c) *Related tolerances*. See § 556.230 of this chapter.

(d) *Conditions of use for syringe described in paragraph (a)(1) of this section in lactating cows*--(1) *Amount*. Infuse the contents of one 6-mL syringe (300 mg erythromycin base) into each infected quarter. Repeat infusion at 12-hour intervals for a maximum of 3 infusions.

(2) *Indications for use*. For the treatment of mastitis due to *Staphylococcus aureus*, *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, and *Streptococcus uberis* in lactating cows.

(3) *Limitations*. Milk taken from animals during treatment and for 36 hours (3 milkings) after the latest treatment must not be used for food.

(e) *Conditions of use for syringe described in paragraph (a)(2) of this section in dry cows*--(1) *Amount*. Infuse the contents of one 12-mL syringe (600 mg erythromycin base) into each infected quarter at the time of drying off.

(2) *Indications for use*. For the treatment of mastitis due to *Staphylococcus aureus*, *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, and *Streptococcus uberis* in dry cows.

(3) *Limitations*. For use in dry cows only.

30. In § 526.1130, revise paragraph (a), the paragraph (d) subject heading, and paragraphs (d)(1) and (2) to read as follows:

§ 526.1130 Hetacillin.

(a) *Specifications*. Each single-dose, 10-milliliter syringe contains hetacillin potassium equivalent of 62.5 milligrams (mg) ampicillin.

\* \* \* \* \*

(d) *Conditions of use in lactating cows*--(1) *Amount*. Infuse the contents of one syringe (equivalent to 62.5 mg ampicillin) into each infected quarter. Repeat at 24-hour intervals for a maximum of 3 treatments.

(2) *Indications for use.* For the treatment of acute, chronic, or subclinical mastitis in lactating cows caused by susceptible strains of *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, *Staphylococcus aureus*, and *Escherichia coli*.

\* \* \* \* \*

31. Revise § 526.1590 to read as follows:

§ 526.1590 Novobiocin.

(a) *Specifications.* Each single-dose, 10-milliliter syringe contains:

(1) 150 milligrams (mg) of novobiocin equivalents as sodium novobiocin, or

(2) 400 mg of novobiocin equivalents as sodium novobiocin.

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

(c) *Related tolerances.* See § 556.460 of this chapter.

(d) *Conditions of use for syringe described in paragraph (a)(1) of this section in lactating cows--*(1) *Amount.* Infuse the contents of one syringe (equivalent to 150 mg novobiocin) into each infected quarter after milking. Repeat treatment once after 24 hours. Do not milk for at least 6 hours after treatment.

(2) *Indications for use.* For the treatment of mastitis caused by susceptible strains of *Staphylococcus aureus* in lactating cows.

(3) *Limitations.* Milk taken from treated animals within 72 hours (6 milkings) after latest treatment should not be used for food. Do not slaughter treated animals for food for 15 days following latest treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(e) *Conditions of use for syringe described in paragraph (a)(2) of this section in dry cows--*(1) *Amount.* Infuse the contents of one syringe (equivalent to 400 mg novobiocin) into each quarter at the time of drying off.

(2) *Indications for use.* For the treatment of mastitis caused by susceptible strains of *Staphylococcus aureus* and *Streptococcus agalactiae* in dry cows.

(3) *Limitations*. For udder installation for the treatment of mastitis in dry cows only. Infuse each quarter at the time of drying off, but not less than 30 days prior to calving. Do not slaughter treated animals for food for 30 days following udder infusion.

32. Revise § 526.1696 to read as follows:

§ 526.1696 Penicillin G procaine.

(a) *Specifications*. Each single-dose, 10-milliliter syringe contains penicillin G procaine equivalent to 100,000 units of penicillin G.

(b) *Sponsors*. See Nos. 010515 and 061133 in § 510.600(c) of this chapter.

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

(d) *Conditions of use in lactating cows*--(1) *Amount*. Infuse the contents of one 10-milliliter syringe (equivalent to 100,000 units penicillin G) into each infected quarter. Treatment may be repeated at 12-hour intervals for not more than 3 doses, as indicated by clinical response.

(2) *Indications for use*. For the treatment of mastitis caused by *Streptococcus agalactiae*, *S. dysgalactiae*, and *S. uberus* in lactating cows.

(3) *Limitations*. For intramammary infusion in lactating cows only. Discard all milk for 60 hours (5 milkings) after the latest treatment. Animals intended for human consumption must not be slaughtered within 3 days of latest treatment.

(e) *Conditions of use in dry cows*--(1) *Amount*. Infuse the contents of one 10-milliliter syringe (equivalent to 100,000 units penicillin G) into each infected quarter at time of drying-off.

(2) *Indications for use*. For the treatment of mastitis caused by *Streptococcus agalactiae* in dry cows.

(3) *Limitations*. For intramammary infusion in dry cows only. Animals intended for human consumption must not be slaughtered within 14 days of last treatment. Discard all milk for 72 hours (6 milkings) following calving, or later as indicated by the marketable quality of the milk.

§ 526.1696a [Removed]

33. Remove § 526.1696a.

§ 526.1696b [Redesignated as § 526.1697]

34. Redesignate § 526.1696b as § 526.1697 and revise the section heading and paragraphs (a) and (d) and add paragraph (e).

The revisions and addition read as follows:

§ 526.1697 Penicillin G procaine and dihydrostreptomycin.

(a) *Specifications*. Each single-use, 10-milliliter syringe contains a suspension of:

(1) Penicillin G procaine equivalent to 200,000 units penicillin G and dihydrostreptomycin sulfate equivalent to 300 milligrams dihydrostreptomycin; or

(2) Penicillin G procaine equivalent to 1 million units penicillin G and dihydrostreptomycin sulfate equivalent to 1 gram dihydrostreptomycin.

\* \* \* \* \*

(d) *Conditions of use for syringe described in paragraph (a)(1) of this section in dry cows*--(1) *Amount*. Infuse the contents of one syringe (equivalent to 200,000 units penicillin G and 300 milligrams dihydrostreptomycin) into each quarter at the last milking prior to drying off.

(2) *Indications for use*. For the treatment of subclinical mastitis in dairy cows at the time of drying off, specifically against infections caused by *Staphylococcus aureus* and *Streptococcus agalactiae*.

(3) *Limitations*. For use in dry cows only. Not to be used within 6 weeks of calving. Milk taken from cows within 24 hours (2 milkings) after calving must not be used for food. Animals infused with this drug must not be slaughtered for food within 60 days of treatment or within 24 hours after calving.

(e) *Conditions of use for syringe described in paragraph (a)(2) of this section in dry cows*--(1) *Amount*. Infuse the contents of one syringe (equivalent to 1 million units penicillin G and 1 gram dihydrostreptomycin) into each quarter at the last milking prior to drying off.

(2) *Indications for use.* To reduce the frequency of existing infection and to prevent new infections with *Staphylococcus aureus* in dry cows.

(3) *Limitations.* Not for use in lactating cows. Not to be used within 6 weeks of calving. Milk taken from cows within 96 hours (8 milkings) after calving must not be used for food. Animals infused with this drug must not be slaughtered for food within 60 days from the time of infusion or within 96 hours after calving. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 526.1696c [Removed].

35. Remove § 526.1696c.

§ 526.1696d [Redesignated as § 526.1698]

36. Redesignate § 526.1696d as § 526.1698 and revise the section heading and paragraphs (a) and (d) and add paragraph (e).

The revisions and addition read as follows:

§ 526.1698 Penicillin G procaine and novobiocin.

(a) *Specifications.* Each single-use, 10-milliliter syringe contains a suspension of:

(1) Penicillin G procaine equivalent to 100,000 units penicillin G and 150 milligrams (mg) novobiocin as novobiocin sodium; or

(2) Penicillin G procaine equivalent to 200,000 units penicillin G and 400 mg novobiocin as novobiocin sodium.

\* \* \* \* \*

(d) *Conditions of use for syringe described in paragraph (a)(1) of this section in lactating cows--*(1) *Amount.* Infuse the contents of one syringe (equivalent to 100,000 units penicillin G and 150 mg novobiocin) into each infected quarter after milking. Repeat once after 24 hours.

(2) *Indications for use.* For the treatment of mastitis caused by susceptible strains of *Staphylococcus aureus*, *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, and *Streptococcus uberis* in lactating cows.

(3) *Limitations.* For udder instillation in lactating cows only. Do not milk for at least 6 hours after treatment; thereafter, milk at regular intervals. Milk taken from treated animals within 72 hours (6 milkings) after the latest treatment must not be used for food. Treated animals must not be slaughtered for food for 15 days following the latest treatment. If redness, swelling, or abnormal milk persists, discontinue use and consult a veterinarian.

(e) *Conditions of use for syringe described in paragraph (a)(2) of this section in lactating cows--(1) Amount.* Infuse the contents of one syringe (equivalent to 200,000 units penicillin G and 400 mg novobiocin) into each quarter at dry off.

(2) *Indications for use.* For the treatment of subclinical mastitis caused by susceptible strains of *Staphylococcus aureus* and *Streptococcus agalactiae* in dry cows.

(3) *Limitations.* For udder instillation in dry cows only. Do not use less than 30 days prior to calving. Milk from treated cows must not be used for food during the first 72 hours after calving. Treated animals must not be slaughtered for food for 30 days following udder infusion.

37. In § 526.1810, revise paragraph (a), the paragraph (d) subject heading, and the first sentence of paragraph (d)(1) to read as follows:

§ 526.1810 Pirlimycin.

(a) *Specifications.* Each single-dose, 10-milliliter syringe contains 50 milligrams (mg) of pirlimycin (as pirlimycin hydrochloride).

\* \* \* \* \*

(d) *Conditions of use in lactating cows--(1) Amount.* Infuse the contents of one syringe (50 mg pirlimycin) into each infected quarter. \* \* \*

\* \* \* \* \*

#### PART 529--CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

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

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

39. Add § 529.443 to read as follows:

§ 529.443 Ciclesonide.

(a) *Specifications.* A non-pressurized metered dose inhaler and drug cartridge combination containing a solution of 30 milligrams/milliliter of the prodrug ciclesonide. Each actuation releases 343 micrograms (mcg) of ciclesonide.

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

(c) *Conditions of use--(1) Amount.* Administer an initial dose of 8 actuations (2,744 mcg ciclesonide) twice daily for 5 days, followed by 12 actuations (4,116 mcg ciclesonide) once daily for 5 days.

(2) *Indications for use.* For the management of clinical signs associated with severe equine asthma.

(3) *Limitations.* 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.

§ 529.2150 [Redesignated as § 529.2110]

40. Redesignate § 529.2150 as § 529.2110.

#### PART 556--TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

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

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

§ 556.38 [Amended]

42. In § 556.38, in paragraph (c), add "520.88e," after "520.88d,".

§ 556.165 [Amended]

43. In § 556.165, in paragraph (c), remove "§§ 526.464a and 526.464b" and in its place add "§§ 526.464 and 526.465".

§ 556.170 [Amended]

44. In § 556.170, in paragraph (c), remove "520.543" and in its place add "520.534".

§ 556.180 [Amended]

45. In § 556.180, in paragraph (c), remove "558.205" and in its place add "558.198".

§ 556.185 [Amended]

46. In § 556.185, in paragraph (c), remove "§ 558.198" and in its place add "§ 558.205".

§ 556.226 [Amended]

47. In § 556.226, in paragraph (c), remove "§ 522.812" and in its place add "§§ 516.812 and 522.812".

§ 556.300 [Amended]

48. In § 556.300, in paragraph (c), remove "§§ 522.1044a, 520.1044b, 520.1044c, and 524.1044e" and in its place add "§§ 520.1044a, 520.1044b, 520.1044c, 522.1044, 524.1044e, and 529.1044b".

§ 556.360 [Amended]

49. In § 556.360, in paragraph (c), add "520.1265," after "520.1260,".

§ 556.510 [Amended]

50. In § 556.510, in paragraph (c), remove "526.1696a, 526.1696b, 526.1696c, and 526.1696d" and in its place add "526.1696, 526.1697, and 526.1698".

§ 556.670 [Amended]

51. In § 556.670, in paragraph (c), remove "§§520.2218" and add "§§520.445, 520.2218" in its place.

PART 558--NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

53. In § 558.68, revise paragraphs (e)(1)(ii), (iii), and (v) to read as follows:

§ 558.68 Avilamycin.

\* \* \* \* \*

(e) \* \* \*

(1) \* \* \*

Avilamycin in	Combination	Indications for use	Limitations	Sponsor
---------------	-------------	---------------------	-------------	---------

grams/ton	in grams/ton			
*****				
(ii) 13.6 to 40.9	Monensin, 90 to 110	Broiler chickens: For the prevention of mortality caused by necrotic enteritis associated with <i>Clostridium perfringens</i> ; and as an aid in the prevention of coccidiosis caused by <i>Eimeria necatrix</i> , <i>E. tenella</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i> .	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
(iii) 13.6 to 40.9	Narasin, 54 to 90	Broiler chickens: For the prevention of mortality caused by necrotic enteritis associated with <i>Clostridium perfringens</i> ; and for the prevention of coccidiosis caused by <i>Eimeria necatrix</i> , <i>E. tenella</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i> .	Feed as the sole ration for 21 consecutive days to chickens that are at risk of developing, but not yet showing clinical signs of, necrotic enteritis associated with <i>Clostridium perfringens</i> . To assure responsible antimicrobial drug use in broiler chickens, treatment administration must begin on or before 18 days of age. Do not allow adult turkeys, horses, or other equines access to narasin formulations. Ingestion of narasin by these species has been fatal. Narasin as provided by No. 058198 in § 510.600(c) of this chapter.	058198
*****				

(v) 13.6 to 40.9	Salinomycin sodium, 40 to 60	Broiler chickens: For the prevention of mortality caused by necrotic enteritis associated with <i>Clostridium perfringens</i> ; and for the prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. maxima</i> , <i>E. brunetti</i> , and <i>E. mivati</i> .	Feed as the sole ration for 21 consecutive days. Feed to chickens that are at risk of developing, but not yet showing clinical signs of, necrotic enteritis associated with <i>Clostridium perfringens</i> . Not approved for use with pellet binders. To assure responsible antimicrobial drug use in broiler chickens, treatment administration must begin on or before 18 days of age. The safety of avilamycin has not been established in chickens intended for breeding purposes. Avilamycin has not been demonstrated to be effective in broiler chickens showing clinical signs of necrotic enteritis prior to the start of medication. Do not feed to laying hens producing eggs for human consumption. May be fatal if fed to adult turkeys or to horses. Salinomycin as provided by No. 016592 in § 510.600(c) of this chapter.	058198
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\* \* \* \* \*

54. In § 558.128, revise paragraphs (e)(4)(xv) and (xvi) to read as follows:

§ 558.128 Chlortetracycline.

\* \* \* \* \*

(e) \* \* \*

(4) \* \* \*

Chlortetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
*****				
(xv) 350 mg/head/day	.....	1. Beef cattle: For control of bacterial pneumonia associated with shipping fever complex caused by <i>Pasteurella</i> spp. susceptible to chlortetracycline.	To sponsor No. 054771 under NADAs 046-699 and 049-287, No. 066104 under NADA 092-286, and No. 069254 under NADA 048-480: withdraw 48 hours prior to slaughter. To sponsor No. 069254 under NADA 138-935 and ANADA 200-510: zero withdrawal period.	054771 069254
	.....	2. Beef cattle (under 700 lb): For control of active infection of anaplasmosis caused by <i>A. marginale</i> susceptible to chlortetracycline.	Withdraw 48 hours prior to slaughter. To sponsor No. 054771 under NADAs 046-699 and 049-287, No. 066104 under NADA 092-286, and No. 069254 under NADA 048-480: withdraw 48 hours prior to slaughter. To sponsor No. 054771 under NADA 048-761 and No. 069254 under NADA 138-935 and ANADA 200-510: zero withdrawal time.	054771 069254
(xvi) 20 to 350 g/ton	.....	Beef cattle and replacement dairy heifers: For control of bacterial pneumonia associated with shipping fever complex caused by <i>Pasteurella</i> spp. susceptible to chlortetracycline.	Feed to provide chlortetracycline at the rate of 350 mg per head per day. This drug is not approved for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. To sponsor No. 054771 under NADA 048-761 and No. 069254 under ANADA 200-510: zero withdrawal period.	054771 069254
*****				

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55. In § 558.140, revise paragraph (b)(1), redesignate paragraph (b)(2) as paragraph (b)(3), add new paragraph (b)(2), and revise paragraph (e)(1).

The revisions and addition read as follows:

§ 558.140 Chlortetracycline and sulfamethazine.

\*\*\*\*\*

(b) \*\*\*

(1) No. 054771 for use of product described in paragraph (a)(1) as in paragraph (e)(1) of this section.

(2) No. 069254 for use of product described in paragraph (a)(1) as in paragraph (e)(1)(i) of this section.

\* \* \* \* \*

(e) \* \* \*

(1) Cattle--

Chlortetracycline and sulfamethazine amount each	Combination in grams/ton	Indications for use	Limitations	Sponsors
(i) To provide 350 milligrams per head per day	.....	Beef cattle: As an aid in the maintenance of weight gains in the presence of respiratory disease such as shipping fever.	Feed for 28 days. Withdraw 7 days prior to slaughter. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.	054771 069254
(ii) 35 to 105 g/ton, each	Lasalocid, 10 to 30	Beef steers and heifers fed in confinement for slaughter: As an aid in the maintenance of weight gains in the presence of respiratory disease such as shipping fever, and for improved feed efficiency.	Feed continuously for 28 days to provide 350 mg chlortetracycline, 350 mg sulfamethazine, and 100 to 300 mg lasalocid per head per day. Do not allow horses or other equines access to Type C feeds containing lasalocid as ingestion may be fatal. Safety of lasalocid for use in unapproved species has not been established. Withdraw 7 days prior to slaughter. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Lasalocid as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(iii) 35 to 42.2 g/ton, each	Lasalocid, 25 to 30	Beef steers and heifers fed in confinement for slaughter: As an aid in the maintenance of weight gains in the presence of respiratory disease such as shipping	Feed continuously for 28 days to provide 350 mg chlortetracycline, 350 mg sulfamethazine, and 250 to 300 mg lasalocid per head per day. Do not allow horses or other equines access to Type C feeds containing lasalocid as ingestion may be fatal. Safety of lasalocid for use in unapproved species has not been established. Withdraw 7 days prior to	054771

		fever, and for improved feed efficiency and increased rate of weight gain.	slaughter. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Lasalocid as provided by No. 054771 in § 510.600(c) of this chapter.	
(iv) 35 to 700 g/ton, each	Lasalocid, 30 to 181.8	Beef cattle up to 800 lb: As an aid in the maintenance of weight gains in the presence of respiratory disease such as shipping fever, and for control of coccidiosis caused by <i>Eimeria bovis</i> and <i>E. zuernii</i> .	Hand feed continuously for 28 days to provide 350 mg chlortetracycline, 350 mg sulfamethazine, and 1 mg lasalocid per 2.2 lb body weight per day up to a maximum of 360 mg lasalocid per head per day. Do not allow horses or other equines access to Type C feeds containing lasalocid as ingestion may be fatal. Safety of lasalocid for use in unapproved species has not been established. Withdraw 7 days prior to slaughter. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Lasalocid as provided by No. 054771 in § 510.600(c) of this chapter.	054771

\* \* \* \* \*

56. In § 558.311, redesignate paragraphs (e)(5)(ii) through (vi) as paragraphs (e)(5)(iii) through (vii) and add new paragraph (e)(5)(ii) to read as follows:

§ 558.311 Lasalocid.

\* \* \* \* \*

(e) \* \* \*

(5) \* \* \*

(ii) Chlortetracycline and sulfamethazine as in §558.140.

\* \* \* \* \*

57. In § 558.342, in paragraph (b)(2), remove "No. 058198" and in its place add "Nos. 016592 and 058198" and revise paragraph (e)(1)(i).

The revision reads as follows:

§ 558.342 Melengestrol.

\* \* \* \* \*

(e) \* \* \*

(1) \* \* \*

Melengestrol acetate in mg/head/day	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 0.25 to 0.5	.....	Heifers fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat).	Administer 0.5 to 2.0 pounds (lb)/head/day of medicated feed containing 0.125 to 1.0 mg melengestrol acetate/lb to provide 0.25 to 0.5 mg melengestrol acetate/head/day.	016592, 054771, 058198
* * * * *				

\* \* \* \* \*

58. In § 558.500, in paragraph (b), remove "Nos. 054771 and 058198" and in its place add "Nos. 016592, 054771, and 058198" and revise paragraphs (e)(2)(i), (iii), and (vi).

The revisions read as follows:

§ 558.500 Ractopamine.

\* \* \* \* \*

(e) \* \* \*

(2) \* \* \*

Ractopamine in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 8.2 to 24.6	.....	Cattle fed in confinement for slaughter: For increased rate of weight gain and improved feed efficiency during the last 28 to 42 days on feed	Feed continuously as sole ration during the last 28 to 42 days on feed	016592 054771 058198
* * * * *				
(iii) 9.8 to 24.6	.....,	Cattle fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and increased carcass leanness during the last 28 to 42 days on feed	Feed continuously as sole ration during the last 28 to 42 days on feed	016592 054771 058198
* * * * *				

(vi) Not to exceed 800; to provide 70 to 400 mg/head/day	.....	Cattle fed in confinement for slaughter: For increased rate of weight gain and improved feed efficiency during the last 28 to 42 days on feed	Top dress in a minimum of 1 lb of medicated feed	016592 054771 058198
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Dated: February 26, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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