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Group.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**21 CFR Parts 510, 516, 520, 522, 524,  
and 558**

[Docket No. FDA–2023–N–0002]

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

**AGENCY:** Food and Drug Administration,  
HHS.

**ACTION:** Final rule; technical  
amendments.

**SUMMARY:** The Food and Drug  
Administration (FDA or we) is  
amending the animal drug regulations to  
reflect application-related actions for  
new animal drug applications (NADAs),  
abbreviated new animal drug  
applications (ANADAs), and  
conditionally approved new animal  
drug applications (CNADAs) during  
July, August, and September 2023. The  
animal drug regulations are also being  
amended to improve their accuracy and  
readability.

**DATES:** This rule is effective December 6,  
2023.

#### **FOR FURTHER INFORMATION CONTACT:**

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#### **SUPPLEMENTARY INFORMATION:**

##### **I. Approvals**

FDA is amending the animal drug  
regulations to reflect approval actions  
for NADAs, ANADAs, and CNADAs

during July, August, and September  
2023, as listed in table 1. In addition,  
FDA is informing the public of the  
availability, where applicable, of  
documentation of environmental review  
required under the National  
Environmental Policy Act (NEPA) and,  
for actions requiring review of safety or  
effectiveness data, summaries of the  
basis of approval (FOIA Summaries)  
under the Freedom of Information Act  
(FOIA). These documents, along with  
marketing exclusivity and patent  
information, may be obtained at  
[AnimalDrugs@FDA](mailto:AnimalDrugs@FDA): [https://  
animaldrugsatfda.fda.gov/adafda/  
views/#/search](https://animaldrugsatfda.fda.gov/adafda/views/#/search).

**TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAs, ANADAs, AND CNADAs APPROVED DURING JULY, AUGUST, AND  
SEPTEMBER 2023 REQUIRING EVIDENCE OF SAFETY AND/OR EFFECTIVENESS**

| Approval date        | File No. | Sponsor                                                                                                                                                                                  | Product name                                                          | Effect of the action                                                                                                                                                                                                                       | 21 CFR<br>section |
|----------------------|----------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| July 6, 2023 .....   | 200–752  | Cronus Pharma Specialties India Private Ltd., Sy No-99/1, M/s GMR Hyderabad Aviation SEZ Ltd., Mamidipalli Village, Shamshabad Mandal, Ranga Reddy, Hyderabad, Telangana, 501218, India. | DEXMEDVET (dexmedetomidine hydrochloride) Injectable Solution.        | Original approval as a sedative, analgesic, and preanesthetic in dogs and cats as a generic copy of NADA 141–267.                                                                                                                          | 522.558           |
| July 11, 2023 .....  | 200–753  | Do .....                                                                                                                                                                                 | CROPAMEZOLE (atipamezole hydrochloride) Injectable Solution.          | Original approval for reversal of sedation and analgesia in dogs as a generic copy of NADA 141–033.                                                                                                                                        | 522.147           |
| July 19, 2023 .....  | 141–554  | Boehringer Ingelheim Animal Health USA, Inc., 3239 Satellite Blvd., Duluth, GA30096.                                                                                                     | NEXGARD PLUS (afoxolaner, moxidectin, and pyrantel chewable tablets). | Original approval for the prevention, treatment, and control of internal and external parasites in dogs.                                                                                                                                   | 520.35            |
| August 3, 2023 ..... | 200–755  | Felix Pharmaceuticals Pvt. Ltd., 25–28 North Wall Quay, Dublin 1, Ireland.                                                                                                               | Firocoxib Chewable Tablets.                                           | Original approval for the control of pain and inflammation associated with osteoarthritis and for the control of postoperative pain and inflammation associated with soft-tissue and orthopedic surgery as a generic copy of NADA 141–230. | 520.928           |

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS, ANADAS, AND CNADAS APPROVED DURING JULY, AUGUST, AND SEPTEMBER 2023 REQUIRING EVIDENCE OF SAFETY AND/OR EFFECTIVENESS—Continued

| Approval date           | File No. | Sponsor                                                                                                 | Product name                                                 | Effect of the action                                                                                                                                                                                                                       | 21 CFR section |
|-------------------------|----------|---------------------------------------------------------------------------------------------------------|--------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|
| August 3, 2023 .....    | 200–756  | Ceva Sante Animale, 10 Avenue de la Ballastière, 33500 Libourne, France.                                | FIRODYL (firocoxib) Chewable Tablets.                        | Original approval for the control of pain and inflammation associated with osteoarthritis and for the control of postoperative pain and inflammation associated with soft-tissue and orthopedic surgery as a generic copy of NADA 141–230. | 520.928        |
| August 10, 2023 .....   | 141–568  | Boehringer Ingelheim Animal Health USA, Inc., 3239 Satellite Blvd., Duluth, GA30096.                    | SENVELGO (velagluflozin oral solution).                      | Original approval to improve glycemic control in otherwise healthy cats with diabetes mellitus not previously treated with insulin.                                                                                                        | 520.2654       |
| August 31, 2023 .....   | 200–757  | ZyVet Animal Health, Inc., 73 Route 31N, Pennington, NJ 08534.                                          | Acepromazine Maleate Tablets (acepromazine maleate tablets). | Original approval as an aid in tranquilization and as a preanesthetic agent in dogs as a generic copy of NADA 117–532.                                                                                                                     | 520.23         |
| September 6, 2023 ..... | 141–578  | Genus Lifesciences Inc., 700 N Fenwick St., Allentown, PA 18109.                                        | FIDOQUEL–CA1 (phenobarbital tablets).                        | Conditional approval for the control of seizures associated with idiopathic epilepsy in dogs.                                                                                                                                              | 516.1760       |
| September 20, 2023 ...  | 200–310  | Parnell Technologies Pty. Ltd., Unit 4, 476 Gardeners Rd., Alexandria, New South Wales 2015, Australia. | ESTROPLAN (cloprostenol injection) Injectable Solution.      | Supplemental approval for use with gonadorelin to synchronize estrous cycles to allow for fixed time artificial insemination (FTAI) in lactating dairy cows as a generic copy of NADA 113–645.                                             | 522.460        |

**II. Withdrawals of Approval**

Oasmia Pharmaceutical AB, Vallongatan 1, Uppsala, 75228 Sweden requested that FDA withdraw conditional approval of CNADA 141–422 for PACCAL VET–CA1 (paclitaxel

for injection) because the product is no longer manufactured or marketed. Also, Med-Pharmex, Inc., 2727 Thompson Creek Rd., Pomona, CA 91767–1861 requested that FDA withdraw approval of the eight abbreviated applications

listed in table 2 because the products are no longer manufactured or marketed. As provided in the regulatory text of this document, the animal drug regulations are amended to reflect these actions.

TABLE 2—APPLICATIONS FOR WHICH APPROVAL WAS VOLUNTARILY WITHDRAWN DURING JULY, AUGUST, AND SEPTEMBER 2023

| File No.      | New animal drug                                                                           | 21 CFR section |
|---------------|-------------------------------------------------------------------------------------------|----------------|
| 200–190 ..... | GENTORAL (gentamicin sulfate) Concentrate Solution .....                                  | 520.1044a      |
| 200–241 ..... | LINCOSOL (lincomycin hydrochloride) Soluble Powder .....                                  | 520.1263b      |
| 200–245 ..... | DERMA–VET (neomycin sulfate, nystatin, thiostrepton, triamcinolone acetonide) Cream ..... | 524.1600a      |
| 200–275 ..... | MEDALONE (triamcinolone acetate) Cream .....                                              | 524.2483       |
| 200–289 ..... | NEOSOL–ORAL (neomycin sulfate) Concentrate Solution .....                                 | 520.1484       |
| 200–292 ..... | IVERSOL (ivermectin) Liquid for Horses .....                                              | 520.1195       |
| 200–299 ..... | IVER–ON (ivermectin) Topical Solution .....                                               | 524.1193       |
| 200–456 ..... | Dexamethasone Solution .....                                                              | 522.540        |

**III. Change of Sponsor**

The sponsors of the approved applications listed in table 3 have

informed FDA that they have transferred ownership of, and all rights and interest in, these applications to another sponsor. As provided in the regulatory

text of this document, the animal drug regulations are amended to reflect these actions.

TABLE 3—APPLICATIONS FOR WHICH OWNERSHIP WAS TRANSFERRED TO ANOTHER SPONSOR DURING JULY, AUGUST, AND SEPTEMBER 2023

| File No.      | Product name                                        | Transferring sponsor                                               | New sponsor                                        | 21 CFR section |
|---------------|-----------------------------------------------------|--------------------------------------------------------------------|----------------------------------------------------|----------------|
| 141–342 ..... | ALFAXAN Multidose (alfaxalone) injectable solution. | Jurox Pty. Ltd., 85 Gardiner St., Rutherford, NSW 2320, Australia. | Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007. | 522.52         |

TABLE 3—APPLICATIONS FOR WHICH OWNERSHIP WAS TRANSFERRED TO ANOTHER SPONSOR DURING JULY, AUGUST, AND SEPTEMBER 2023—Continued

| File No.      | Product name                                                   | Transferring sponsor                                                             | New sponsor                                                                                                       | 21 CFR section |
|---------------|----------------------------------------------------------------|----------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------|----------------|
| 200–699 ..... | Dexmedetomidine hydrochloride injection.                       | Akorn Operating Co. LLC, 5605 Centerpoint Ct., Suite A, Gurnee, IL 60031.        | Parnell Technologies Pty. Ltd., Unit 4, 476 Gardeners Rd., Alexandria, New South Wales 2015, Australia.           | 522.558        |
| 200–614 ..... | Pentobarbital sodium and phenytoin sodium injectable solution. | Do .....                                                                         | Noble Pharma, LLC, 4602 Domain Dr., Menomonie, WI 54751.                                                          | 522.1700       |
| 141–559 ..... | Pentosan polysulfate sodium injectable solution.               | Anzac Animal Health, LLC, 218 Millwell Dr., Suite B, Maryland Heights, MO 63043. | Dechra, Ltd., Snaygill Industrial Estate, Keighley Rd., Skipton, North Yorkshire, BD23 2RW, United Kingdom.       | 522.1704       |
| 200–553 ..... | Bacitracin, neomycin, polymyxin B ophthalmic ointment.         | Akorn Operating Co. LLC, 5605 Centerpoint Ct., Suite A, Gurnee, IL 60031.        | Domes Pharma S.A., ZAC de Champ Lamet, 3 rue Andre Citroen, Pont-du-Chateau, Auvergne-Rhône-Alpes, 63430, FRANCE. | 524.154        |

As provided in the regulatory text of this document, the animal drug regulations cited in table 3 are amended to reflect these actions.

#### IV. Change of Sponsor Address

Heska Corp., 1825 Sharp Point Dr., Fort Collins, CO 80525 has informed FDA that it has changed its address to 3760 Rocky Mountain Ave., Loveland, CO 80538–7084. The entries in § 510.600(c) are amended to reflect this action.

#### V. Technical Amendments

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

- 21 CFR 510.600 is amended to reflect sponsors of approved applications by adding entries for Domes Pharma S.A., Genus Lifesciences, Inc., and Noble Pharma, LLC, by revising the entry for Heska Corp., and by removing the entries for Jurox Pty. Ltd. and Oasmia Pharmaceutical AB.
- 21 CFR 520.23 is amended to reflect approved strengths of acepromazine maleate tablets for dogs and cats.
- 21 CFR 522.460 is amended to reflect current labeling for cloprostenol injectable solution for use in cattle.
- 21 CFR 522.2640 is amended to reflect the approved strengths of generic tylosin injectable solutions.
- 21 CFR 558.330 is amended to reflect the sponsors of drugs approved

for use in combination medicated feeds containing lubebegon and monensin.

- 21 CFR 558.355 is amended to reflect the classes of pasture cattle approved for use of a monensin free-choice block.
- 21 CFR 558.625 is amended to reflect the sponsors of drugs approved for use in combination medicated feeds containing lubebegon, monensin, and tylosin.

#### VI. Legal Authority

This final rule is issued under section 512(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360b(i)). Although deemed 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” and 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.

#### 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, and 524

Animal drugs.

##### 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, 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 for “Domes Pharma S.A.”, “Genus Lifesciences, Inc.”, and “Noble Pharma, LLC”; revise the entry for “Heska Corp.”; and remove the entries for “Jurox Pty. Ltd.” and “Oasmia Pharmaceutical AB”.

- 3. In the table in paragraph (c)(2), remove the entries for “049480” and “052818”, revise the entry for “063604”, and add entries for “064950”, “086119”, and “086189”.

The 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

\* \* \* \* \*

Domes Pharma S.A., ZAC de Champ Lamet, 3 rue Andre Citroen, Pont-du-Chateau, Auvergne-Rhône-Alpes, 63430, FRANCE .....

086189

| Firm name and address                                                 |   |   |   |   |   | Drug<br>labeler code |
|-----------------------------------------------------------------------|---|---|---|---|---|----------------------|
| *                                                                     | * | * | * | * | * | *                    |
| Genus Lifesciences Inc., 700 N Fenwick St., Allentown, PA 18109 ..... |   |   |   |   |   | 064950               |
| *                                                                     | * | * | * | * | * | *                    |
| Heska Corp., 3760 Rocky Mountain Ave., Loveland, CO 80538–7084 .....  |   |   |   |   |   | 063604               |
| *                                                                     | * | * | * | * | * | *                    |
| Noble Pharma, LLC, 4602 Domain Dr., Menomonie, WI 54751 .....         |   |   |   |   |   | 086119               |
| *                                                                     | * | * | * | * | * | *                    |

(2) \* \* \*

| Drug<br>labeler code | Firm name and address                                                                                             |   |   |   |   |   |
|----------------------|-------------------------------------------------------------------------------------------------------------------|---|---|---|---|---|
| *                    | *                                                                                                                 | * | * | * | * | * |
| 063604 .....         | Heska Corp., 3760 Rocky Mountain Ave., Loveland, CO 80538–7084.                                                   |   |   |   |   |   |
| *                    | *                                                                                                                 | * | * | * | * | * |
| 064950 .....         | Genus Lifesciences Inc., 700 N Fenwick St., Allentown, PA 18109.                                                  |   |   |   |   |   |
| *                    | *                                                                                                                 | * | * | * | * | * |
| 086119 .....         | Noble Pharma, LLC, 4602 Domain Dr., Menomonie, WI 54751.                                                          |   |   |   |   |   |
| *                    | *                                                                                                                 | * | * | * | * | * |
| 086189 .....         | Domes Pharma S.A., ZAC de Champ Lamet, 3 rue Andre Citroen, Pont-du-Chateau, Auvergne-Rhône-Alpes, 63430, FRANCE. |   |   |   |   |   |
| *                    | *                                                                                                                 | * | * | * | * | * |

**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.

**§ 516.1684 [Removed]**

■ 4. Remove § 516.1684.

■ 5. Add § 516.1760 to subchapter E to read as follows:

**§ 516.1760 Phenobarbital.**

(a) *Specifications.* Each tablet contains 16.2, 32.4, 64.8, or 97.2 milligrams (mg) phenobarbital.

(b) *Sponsor.* See No. 064950 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Amount.*

Administer phenobarbital as tablets given orally twice a day at the minimum dosage of 2.5 mg per kilogram of body weight (mg/kg) and may be titrated to effect to a maximum dosage of 5 mg/kg. The dosage of phenobarbital tablets should be adjusted based on monitoring the clinical response of the individual patient.

(2) *Indications for use.* For the control of seizures associated with idiopathic epilepsy 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. In § 520.23, revise paragraphs (a) and (b) to read as follows:

**§ 520.23 Acepromazine.**

(a) *Specifications.* Each tablet contains 10 or 25 milligrams (mg) acepromazine maleate.

(b) *Sponsors.* See Nos. 000010 and 086117 in § 510.600(c) of this chapter.

\* \* \* \* \*

■ 8. Add § 520.35 to read as follows:

**§ 520.35 Afloxolaner, moxidectin, and pyrantel.**

(a) *Specifications.* Each chewable tablet contains 9.375 milligrams (mg) afloxolaner, 45 micrograms (mcg) moxidectin, and 18.75 mg pyrantel; 18.75 mg afloxolaner, 90 mcg moxidectin, and 37.5 mg pyrantel; 37.5 mg afloxolaner, 180 mcg moxidectin, and 75 mg pyrantel; 75 mg afloxolaner, 360 mcg moxidectin, and 150 mg pyrantel;

or 150 mg afloxolaner, 720 mcg moxidectin, and 300 mg pyrantel.

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

(c) *Conditions of use—(1) Amount.* Administer orally once a month at the minimum dose of 1.14 mg/lb (2.5 mg/kg) afloxolaner, 5.45 mcg/lb (12 mcg/kg) moxidectin, and 2.27 mg/lb (5.0 mg/kg) pyrantel. For heartworm disease prevention, give once monthly for at least 6 months after last exposure to mosquitoes.

(2) *Indications for use in dogs.* For the prevention of heartworm disease caused by *Dirofilaria immitis* and for the treatment and control of adult hookworm (*Ancylostoma caninum*, *Ancylostoma braziliense*, and *Uncinaria stenocephala*) and roundworm (*Toxocara canis* and *Toxascaris leonina*) infections. Kills adult fleas and is indicated for the treatment and prevention of flea infestations (*Ctenocephalides felis*) and the treatment and control of *Ixodes scapularis* (black-legged tick), *Rhipicephalus sanguineus* (brown dog tick), *Dermacentor variabilis* (American dog tick), and *Amblyomma americanum* (lone star tick) infestations for 1 month in dogs and puppies 8 weeks of age and older, weighing 4 pounds of body weight or greater.

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

#### § 520.928 [Amended]

■ 9. In § 520.928, in paragraph (b)(1), remove “Nos. 000010, 055246, and 055529” and in its place add “Nos. 000010, 013744, 055246, 055529, and 086101”.

#### § 520.1044a [Amended]

■ 10. In § 520.1044a, in paragraph (b), remove “Nos. 000061 and 054925” and in its place add “No. 000061”.

■ 11. In § 520.1195, revise paragraph (b)(1) to read as follows:

#### § 520.1195 Ivermectin liquid.

\* \* \* \* \*

(b) \* \* \*

(1) Nos. 058005 and 058198 for use of product described in paragraph (a)(1) of this section as in paragraphs (e)(1)(i), (e)(1)(ii)(A), and (e)(1)(iii) of this section.

\* \* \* \* \*

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

#### § 520.1263b Lincomycin powder.

\* \* \* \* \*

(b) \* \* \*

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

\* \* \* \* \*

(d) \* \* \*

(1) \* \* \*

(iii) *Limitations*. Discard medicated drinking water if not used within 2 days. Prepare fresh stock solution daily. Do not use for more than 10 days. If clinical signs of disease have not improved within 6 days, discontinue treatment and reevaluate diagnosis. The safety of lincomycin has not been demonstrated in pregnant swine or swine intended for breeding. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

\* \* \* \* \*

#### § 520.1484 [Amended]

■ 13. In § 520.1484, in paragraph (b)(1), remove “Nos. 054771 and 054925” and in its place add “No. 054771”; and remove paragraph (b)(4).

■ 14. Add § 520.2654 to read as follows:

#### § 520.2654 Velagliflozin.

(a) *Specifications*. Each milliliter of solution contains 15 milligrams (mg) velagliflozin.

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

(c) *Conditions of use*—(1) *Amount*. Administer orally 0.45 mg per pound of

body weight (1 mg per kilogram) velagliflozin once daily.

(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.

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

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

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

#### § 522.52 [Amended]

■ 16. In § 522.52, in paragraph (b), remove “049480” and in its place add “054771”.

■ 17. In § 522.147, revise paragraphs (b), (c)(1), and (2) to read as follows:

#### § 522.147 Atipamezole.

\* \* \* \* \*

(b) *Sponsors*. See Nos. 015914, 052483, and 069043 in § 510.600(c) of this chapter.

(c) \* \* \*

(1) *Amount*. Administer 3,750 mcg/m<sup>2</sup> intramuscularly for the reversal of intravenous dexmedetomidine hydrochloride or medetomidine hydrochloride and 5,000 mcg/m<sup>2</sup> intramuscularly for the reversal of intramuscular dexmedetomidine hydrochloride or medetomidine hydrochloride.

(2) *Indications for use*. For the reversal of the sedative and analgesic effects of dexmedetomidine hydrochloride and medetomidine hydrochloride.

\* \* \* \* \*

■ 18. In § 522.460, revise paragraphs (b) and (c) to read as follows:

#### § 522.460 Cloprostenol.

\* \* \* \* \*

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

(1) No. 000061 for use of product described in paragraph (a)(1) of this section as in paragraphs (c)(1)(i) and (c)(2) of this section.

(2) No. 000061 for use of product described in paragraph (a)(2) as in paragraphs (c)(1)(ii) through (viii) and (c)(2) of this section.

(3) No. 068504 for use of product described in paragraph (a)(2) as in paragraphs (c)(1)(ii) through (vii), (c)(1)(ix), and (c)(2) of this section.

(c) *Conditions of use in cattle*—(1) *Amount and indications for use*.

(i) Administer 375 µg by intramuscular injection to induce

abortion in pregnant feedlot heifers from 1 week after mating until 4½ months of gestation.

(ii) Administer 500 µg by intramuscular injection for unobserved or non-detected estrus in beef cows, lactating dairy cows, and replacement beef and dairy heifers.

(iii) Administer 500 µg by intramuscular injection for treatment of pyometra or chronic endometritis in beef cows, lactating dairy cows, and replacement beef and dairy heifers.

(iv) Administer 500 µg by intramuscular injection for treatment of mummified fetus in beef cows, lactating dairy cows, and replacement beef and dairy heifers.

(v) Administer 500 µg by intramuscular injection for treatment of luteal cysts in beef cows, lactating dairy cows, and replacement beef and dairy heifers.

(vi) Administer 500 µg by intramuscular injection for abortion of beef cows, lactating dairy cows, and replacement beef and dairy heifers from 1 week after mating until 5 months of gestation. Not for use in heifers placed in feedlots.

(vii) Administer 500 µg by intramuscular injection as a single injection regimen or double injection regimen with a second injection 11 days after the first injection, for estrus synchronization in beef cows, lactating dairy cows, and replacement beef and dairy heifers.

(viii) For use with gonadorelin acetate to synchronize estrous cycles to allow for fixed time artificial insemination (FTAI) in 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. Gonadorelin acetate as provided in § 522.1077(a)(1) of this chapter.

(ix) For use with gonadorelin to synchronize estrous cycles to allow for FTAI in lactating dairy cows: administer to each cow by intramuscular injection, followed 6 to 8 days later by 500 µg cloprostenol by intramuscular injection, followed 30 to 72 hours later by gonadorelin by intramuscular injection. Gonadorelin as provided in § 522.1077(a)(1) through (3) of this chapter.

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

#### § 522.540 [Amended]

■ 19. In § 522.540, in paragraph (a)(2)(ii), remove “*Sponsors*. See Nos.

054925 and 058005” and in its place add “No. 058005”.

**§ 522.558 [Amended]**

■ 20. In § 522.558, in paragraph (b)(1), remove “Nos. 017033, 059399, and 086117” and in its place add “Nos. 017033, 068504, 069043, and 086117”.

**§ 522.1700 [Amended]**

■ 21. In § 522.1700, in paragraph (b), remove “059399” and in its place add “086119”.

**§ 522.1704 [Amended]**

■ 22. In § 522.1704, in paragraph (b), remove “086073” and in its place add “043264”.

■ 23. In § 522.2640, revise paragraphs (b)(1) and (2) to read as follows:

**§ 522.2640 Tylosin.**

\* \* \* \* \*

(b) \* \* \*

(1) Nos. 016592 and 058198 for use of 50- or 200-mg/mL solutions as in paragraph (e) of this section.

(2) No. 061133 for use of a 200-mg/mL solution as in paragraphs (e)(1) and (2) of this section.

\* \* \* \* \*

**PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS**

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

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

**§ 524.154 [Amended]**

■ 25. In § 524.154, in paragraph (b)(2), remove “059399” and in its place add “086189”.

**§ 524.1193 [Amended]**

■ 26. In § 524.1193, in paragraph (b)(2), remove “Nos. 016592 and 054925” and in its place add “No. 016592”.

■ 27. In § 524.1600a, revise paragraph (b) to read as follows:

**§ 524.1600a Nystatin, neomycin, thiostrepton, and triamcinolone ointment.**

\* \* \* \* \*

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

(1) For petrolatum base ointments: Nos. 025463 and 054771; or

(2) For vanishing cream base ointments: Nos. 025463 and 054771.

\* \* \* \* \*

**§ 524.2483 [Removed]**

■ 28. Remove § 524.2483.

**PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS**

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

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

■ 30. In § 558.330, revise paragraphs (d)(1)(ii) and (iii) and (d)(2)(i) and (ii) to read as follows:

**§ 558.330 Lubabegron.**

\* \* \* \* \*

(d) \* \* \*

(1) \* \* \*

| Lubabegron fumarate in grams/ton | Combination in grams/ton | Indications for use                                                                                                                                                                                                      | Limitations                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Sponsor        |
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| * * * * *                        | * * * * *                | * * * * *                                                                                                                                                                                                                | * * * * *                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | * * * * *      |
| (ii) 1.25 to 4.54 .....          | Monensin, 5 to 40        | Beef steers and heifers fed in confinement for slaughter: for reduction of ammonia gas emissions per pound of live weight and hot carcass weight and for improved feed efficiency during the last 14 to 91 days on feed. | Feed continuously as the sole ration to provide 13 to 90 mg lubabegron/head/day and 50 to 480 mg monensin/head/day during the last 14 to 91 days on feed. No additional improvement in feed efficiency has been shown from feeding monensin at levels greater than 30 g/ton (360 mg monensin/head/day). A decrease in dry matter intake may be noticed in some animals receiving lubabegron. Lubabegron has not been approved for use in breeding animals because safety and effectiveness have not been evaluated in these animals. Do not allow horses or other equines access to feed containing lubabegron and monensin. Ingestion of monensin by horses has been fatal. Monensin medicated cattle and goat feeds are safe for use in cattle and goats only. Consumption by unapproved species may result in toxic reactions. Feeding undiluted or mixing errors resulting in high concentrations of monensin has been fatal to cattle and could be fatal to goats. Must be thoroughly mixed in feeds before use. Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result. If feed refusals containing monensin are fed to other groups of cattle, the concentration of monensin in the refusals and amount of refusals fed should be taken into consideration to prevent monensin overdosing. A withdrawal period has not been established for this product for preparturient calves. Do not use in calves to be processed for veal. See special labeling considerations in § 558.355(d) of this chapter. Lubabegron fumarate as provided by No. 058198, monensin as provided by No. 016592 or 058198 in § 510.600(c) of this chapter. | 016592, 058198 |

| Lubabegron fumarate in grams/ton | Combination in grams/ton | Indications for use                                                                                                                                                                                                                                                                      | Limitations                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Sponsor        |
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| (iii) 1.25 to 4.54 .....         | Monensin, 10 to 40       | Beef steers and heifers fed in confinement for slaughter: for reduction of ammonia gas emissions per pound of live weight and hot carcass weight; and for prevention and control of coccidiosis due to <i>Eimeria bovis</i> and <i>E. zuernii</i> during the last 14 to 91 days on feed. | Feed continuously as the sole ration to provide 13 to 90 mg lubabegron/head/day and 0.14 to 0.42 mg monensin/lb body weight per day, depending upon severity of coccidiosis challenge, during the last 14 to 91 days on feed. A decrease in dry matter intake may be noticed in some animals receiving lubabegron. Lubabegron has not been approved for use in breeding animals because safety and effectiveness have not been evaluated in these animals. Do not allow horses or other equines access to feed containing lubabegron and monensin. Ingestion of monensin by horses has been fatal. Monensin medicated cattle and goat feeds are safe for use in cattle and goats only. Consumption by unapproved species may result in toxic reactions. Feeding undiluted or mixing errors resulting in high concentrations of monensin has been fatal to cattle and could be fatal to goats. Must be thoroughly mixed in feeds before use. Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result. If feed refusals containing monensin are fed to other groups of cattle, the concentration of monensin in the refusals and amount of refusals fed should be taken into consideration to prevent monensin overdosing. A withdrawal period has not been established for this product for pruruminating calves. Do not use in calves to be processed for veal. See special labeling considerations in § 558.355(d) of this chapter. Lubabegron fumarate as provided by No. 058198, monensin as provided by No. 016592 or 058198 in § 510.600(c) of this chapter. | 016592, 058198 |

(2) \* \* \*

(i) Monensin as in § 558.355.

(ii) Tylosin in § 558.625.

■ 31. In § 558.355, revise paragraph (f)(4)(iv) to read as follows:

§ 558.355 Monensin.

\* \* \* \* \*

(f) \* \* \*

(4) \* \* \*

| Monensin amount                | Indications for use                                                                                                                           | Limitations                                                                                                                                                                                                                                                                                                                                                     | Sponsor |
|--------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
| (iv) 400 mg per pound of block | Growing beef steers and heifers on pasture (stocker, feeder, and slaughter) and beef replacement heifers): for increased rate of weight gain. | Provide 50 to 200 mg of monensin (2 to 8 ounces of block) per head per day, in at least one block per five head of cattle. Feed blocks continuously. Do not feed salt of mineral supplements in addition to this block. Discontinue feeding if block consumption falls below 2 ounces or rises above 8 ounces daily. See paragraph (d)(10)(i) of this section.. | 086113  |

\* \* \* \* \*

■ 32. In § 558.625, revise paragraphs (e)(2)(vii) and (viii) to read as follows:

§ 558.625 Tylosin.

\* \* \* \* \*

(e) \* \* \*

(2) \* \* \*

| Tylosin grams/ton    | Combination in grams/ton                                   | Indications for use                                                                                                                                                                                                                                                                                                                                                                                                         | Limitations                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Sponsor        |
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| *                    | *                                                          | *                                                                                                                                                                                                                                                                                                                                                                                                                           | *                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | *              |
| (vii) 8 to 10 .....  | Monensin, 5 to 40 plus lubabegron fumarate, 1.25 to 4.54.  | Beef steers and heifers fed in confinement for slaughter: for reduction of ammonia gas emissions per pound of live weight and hot carcass weight; for reduction of incidence of liver abscesses associated with <i>Fusobacterium necrophorum</i> and <i>Arcanobacterium pyogenes</i> and for improved feed efficiency during the last 14 to 91 days on feed.                                                                | Feed continuously as sole ration to provide 13 to 90 mg lubabegron/head/day, 50 to 480 mg monensin/head/day, and 60 to 90 mg tylosin/head/day during the last 14 to 91 days on feed. No additional improvement in feed efficiency has been shown from feeding monensin at levels greater than 30 g/ton (360 mg monensin/head/day). A decrease in dry matter intake may be noticed in some animals receiving lubabegron. Lubabegron has not been approved for use in breeding animals because safety and effectiveness have not been evaluated in these animals. Do not allow horses or other equines access to feed containing lubabegron and monensin. Ingestion of monensin by horses has been fatal. Monensin medicated cattle and goat feeds are safe for use in cattle and goats only. Consumption by unapproved species may result in toxic reactions. Feeding undiluted or mixing errors resulting in high concentrations of monensin has been fatal to cattle and could be fatal to goats. Must be thoroughly mixed in feeds before use. Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result. If feed refusals containing monensin are fed to other groups of cattle, the concentration of monensin in the refusals and amount of refusals fed should be taken into consideration to prevent monensin overdosing. A withdrawal period has not been established for this product for prurminating calves. Do not use in calves to be processed for veal. See special labeling considerations in § 558.355(d) of this chapter. Tylosin as provided by No. 016592 or 058198, monensin as provided by No. 016592 or 058198, lubabegron fumarate as provided by No. 058198 in § 510.600(c) of this chapter. | 016592, 058198 |
| (viii) 8 to 10 ..... | Monensin, 10 to 40 plus lubabegron fumarate, 1.25 to 4.54. | Beef steers and heifers fed in confinement for slaughter: for reduction of ammonia gas emissions per pound of live weight and hot carcass weight, for reduction of incidence of liver abscesses associated with <i>Fusobacterium necrophorum</i> and <i>Arcanobacterium pyogenes</i> and for prevention and control of coccidiosis due to <i>Eimeria bovis</i> and <i>E. zuernii</i> during the last 14 to 91 days on feed. | Feed continuously as sole ration to provide 13 to 90 mg lubabegron/head/day, 0.14 to 0.42 mg monensin/lb body weight per day, depending upon severity of coccidiosis challenge, up to 480 mg/head/day, and 60 to 90 mg tylosin/head/day during the last 14 to 91 days on feed. A decrease in dry matter intake may be noticed in some animals receiving lubabegron. Lubabegron has not been approved for use in breeding animals because safety and effectiveness have not been evaluated in these animals. Do not allow horses or other equines access to feed containing lubabegron and monensin. Ingestion of monensin by horses has been fatal. Monensin medicated cattle and goat feeds are safe for use in cattle and goats only. Consumption by unapproved species may result in toxic reactions. Feeding undiluted or mixing errors resulting in high concentrations of monensin has been fatal to cattle and could be fatal to goats. Must be thoroughly mixed in feeds before use. Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result. If feed refusals containing monensin are fed to other groups of cattle, the concentration of monensin in the refusals and amount of refusals fed should be taken into consideration to prevent monensin overdosing. A withdrawal period has not been established for this product for prurminating calves. Do not use in calves to be processed for veal. See special labeling considerations in § 558.355(d) of this chapter. Tylosin as provided by No. 016592 or 058198, monensin as provided by No. 016592 or 058198, lubabegron fumarate as provided by No. 058198 in § 510.600(c) of this chapter.                                                     | 016592, 058198 |
| *                    | *                                                          | *                                                                                                                                                                                                                                                                                                                                                                                                                           | *                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | *              |

\* \* \* \* \*

Dated: November 29, 2023.

**Lauren K. Roth,***Associate Commissioner for Policy.*

[FR Doc. 2023–26545 Filed 12–5–23; 8:45 am]

BILLING CODE 4164–01–P

**DEPARTMENT OF AGRICULTURE****Forest Service****36 CFR Parts 212, 214, and 251**

RIN 0596–AD54

**Travel Management; Administration of the Forest Transportation System; Postdecisional Administrative Review Process for Occupancy or Use of National Forest System Lands and Resources; Land Uses; Special Uses****AGENCY:** Forest Service, USDA.**ACTION:** Final rule.

**SUMMARY:** The United States Department of Agriculture, Forest Service (Forest Service or Agency) is making purely technical, clarifying revisions to its existing regulations governing administration of the forest transportation system, administrative appeal of certain written decisions pertaining to written authorizations for occupancy or use of National Forest System (NFS) lands and resources, and issuance and administration of special use authorizations for use and occupancy of NFS lands. The purely technical, clarifying revisions update citations and enhance consistency of the existing regulations with governing statutes.

**DATES:** This rule is effective December 6, 2023.

**ADDRESSES:** Information on this final rule may be obtained via written request addressed to the Director, Lands, Minerals, and Geology Management, USDA Forest Service, 201 14th Street NW, Washington, DC 20250–1124 or by email to [SM.FS.WO\\_LandStaff@usda.gov](mailto:SM.FS.WO_LandStaff@usda.gov).

**FOR FURTHER INFORMATION CONTACT:** Mark Chandler, Realty Specialist, (202) 205–1117 or [mark.chandler@usda.gov](mailto:mark.chandler@usda.gov). Individuals who use telecommunication devices for the hearing impaired may call the Federal Relay Service at (800) 877–8339 between 8:00 a.m. and 5:00 p.m., Eastern Time, Monday through Friday.

**SUPPLEMENTARY INFORMATION:** This final rule makes purely technical, clarifying revisions to the Agency's existing regulations at 36 CFR 212.8, 214.4, 251.50, 251.51, 251.53, 251.54, 251.55,

251.57, 251.58, 251.59, 251.60, 251.64, and 251.124 governing administration of the forest transportation system, administrative appeal of certain written decisions pertaining to written authorizations for occupancy or use of NFS lands and resources, and issuance and administration of special use authorizations for use and occupancy of NFS lands. The purely technical, clarifying revisions update citations and enhance consistency of the existing regulations with governing statutes. These purely technical, clarifying revisions do not formulate standards, criteria, or guidelines applicable to Forest Service programs and therefore do not require public notice and opportunity to comment under section 14(a) of the Forest and Rangeland Renewable Resources Planning Act of 1974 (16 U.S.C. 1612(a)).

**36 CFR Part 212, Subpart A**

The Department is revising text in § 212.8(d)(5)(i) to track revisions being made to § 251.60(a)(2)(i) and to provide that a formal adjudicatory hearing is required for revocation for nonuse of an easement issued under the National Forest Roads and Trails Act (FRTA).

**36 CFR Part 214**

The Department is revising § 214.4(c)(1)(i) to provide that suspension or revocation of permits as well as easements issued under the Mineral Leasing Act (MLA) and revocation for nonuse of an easement issued under FRTA are not subject to administrative appeal under 36 CFR part 214. In contrast to the Federal Land Policy and Management Act (FLPMA) addressed in 36 CFR 251.53(l), the MLA addressed in 36 CFR 251.53(e) requires a formal adjudicatory proceeding for suspension or revocation of permits as well as easements (30 U.S.C. 185(o)(1)(C)). Therefore, suspension or revocation of permits as well as easements issued under the MLA must be exempt from the informal administrative appeal process under 36 CFR part 214. FRTA provides for a formal hearing for revocation of an easement for nonuse (16 U.S.C. 534).

**36 CFR Part 251, Subpart B****§ 251.50**

The Department is removing paragraph (c)(3) of § 251.50, which requires a special use authorization for a noncommercial recreational activity if required by an order issued under 36 CFR part 261, subpart B, or by a regulation issued under 36 CFR part 261, subpart C. There is no basis for issuance of such an order under 36 CFR

part 261, subpart B. Moreover, there is no need for issuance of such an order or regulation because the Forest Service has the authority to require a noncommercial special recreation permit under the Federal Lands Recreation Enhancement Act and its implementing directives in Forest Service Handbook (FSH) 2309.13, Chapter 30.

**§ 251.51**

The Department is revising the definitions for “outfitting” and “guiding” by replacing the phrase “pecuniary remuneration” with the word “monetary.” The revised language is more contemporary and easier to understand.

**§ 251.53**

The Department is revising § 251.53(a) by changing the phrase “group events” to “noncommercial group use” and deleting the phrase “and distribution of noncommercial printed materials” for authorizations issued under the Organic Administration Act (16 U.S.C. 551). The term of art per the definitions for special uses in 36 CFR 251.51 is

“noncommercial group use.” The distribution of noncommercial printed materials does not require a special use authorization under 36 CFR 251.50(c).

The Department is adding paragraph (o) to § 251.53 to include the Forest Service's authority under section 111 of the National Historic Preservation Act of 1966 (54 U.S.C. 306121) to issue leases for Federally owned historic properties on NFS lands.

**§ 251.54**

The Department is revising § 251.54(d) through (g) to use appropriate terminology when referring to a proponent or a proposal and to enhance clarity.

The Department is revising § 251.54(e)(1)(iv), which precludes consideration of proposals for a permanent use and occupancy of NFS lands, to add an exception for permanent easements issued under FRTA (16 U.S.C. 533).

The Department is revising § 251.54(f)(1)(i) regarding who may apply for an oil or gas pipeline right-of-way authorization for greater consistency with the MLA (30 U.S.C. 181).

The Department is revising § 251.54(g)(3)(iii) to replace the citation to 36 CFR part 215 with a citation to 36 CFR part 218. The postdecisional administrative appeal process in 36 CFR part 215 has been replaced with the predecisional objection process in 36 CFR part 218.