will thereafter be continuously published in the Chart Supplement.

* * * * *

Paragraph 6002 Class E Airspace Areas Designated as Surface Areas.

* * * * *

ASW TX E2 Beaumont/Port Arthur, TX [Amended]

Jack Brooks Regional Airport, TX
(Lat. 29°57′03″ N, long. 94°01′15″ W)

Within a 5-mile radius of Jack Brooks Regional Airport. This Class E airspace area is effective during the specific dates and times established in advance by a Notice to Air Missions. The effective dates and times will thereafter be continuously published in the Chart Supplement.

* * * * *

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

ASW TX E5 Beaumont/Port Arthur, TX [Amended]

Jack Brooks Regional Airport, TX
(Lat. 29°57′03″ N, long. 94°01′15″ W)
Beaumont Municipal Airport, TX
(Lat. 30°04′13″ N, long. 94°12′54″ W)
Orange County Airport, TX
(Lat. 30°04′06″ N, long. 93°48′14″ W)

That airspace extending upward from 700 feet above the surface within a 7.5-mile radius of Jack Brooks Regional Airport; and within a 6.4-mile radius of Beaumont Municipal Airport; and within a 6.5-mile radius of Orange County Airport.

* * * * *

Issued in Fort Worth, Texas, on May 1, 2024.

Steven T. Phillips,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2024–09872 Filed 5–14–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF COMMERCE

International Trade Administration

15 CFR Part 326

[Docket No. 240226–0059]

RIN 0625–AB24

The U.S. and Foreign Commercial Service Pilot Fellowship Program; Correction

AGENCY: International Trade Administration, Department of Commerce.

ACTION: Final rule; correction.

SUMMARY: The International Trade Administration is correcting a final rule published in the **Federal Register** on May 7, 2024, regarding The U.S. and Foreign Commercial Service Pilot Fellowship Program. This correction applies to the effective date of final rule.

DATES: Effective May 15, 2024.

FOR FURTHER INFORMATION CONTACT: Wendy Thompson at *wendy.thompson@trade.gov* or 202–754–4075.

SUPPLEMENTARY INFORMATION: In FR Doc. 2024–09863, on page 37972 in the **Federal Register** of Tuesday, May 7, 2024, in the second column, correct the **DATES** caption by adding ‘‘, 2024’’ after ‘‘May 6’’.

Dated: May 8, 2024

Kimberly White-Bacon,

Program Manager.

[FR Doc. 2024–10561 Filed 5–14–24; 8:45 am]

BILLING CODE 3510–FP–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 522, 524, 529, and 558

[Docket No. FDA–2024–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) and abbreviated new animal drug applications (ANADAs) during January, February, and March 2024. The animal drug regulations are also being amended to improve their accuracy and readability.

DATES: This rule is effective May 15, 2024.

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

SUPPLEMENTARY INFORMATION:

I. Approvals

FDA is amending the animal drug regulations to reflect approval actions for NADAs and ANADAs during January, February, and March 2024, 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 *Animal Drugs @FDA: https://animaldrugsatfda.fda.gov/adafda/views/#/search.*

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS AND ANADAS APPROVED DURING JANUARY, FEBRUARY, AND MARCH 2024 REQUIRING EVIDENCE OF SAFETY AND/OR EFFECTIVENESS

Date of approval	File No.	Sponsor (drug labeler code)	Product name	Effect of the action	21 CFR section
January 11, 2024	200–766	Aurora Pharmaceutical, Inc., 1196 Highway 3 South, Northfield, MN 55057–3009 (051072).	EQUICOXIB (firocoxib) Oral Solution.	Original approval as a generic copy of NADA 141–253.	520.929

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS AND ANADAS APPROVED DURING JANUARY, FEBRUARY, AND MARCH 2024 REQUIRING EVIDENCE OF SAFETY AND/OR EFFECTIVENESS—Continued

Date of approval	File No.	Sponsor (drug labeler code)	Product name	Effect of the action	21 CFR section
January 12, 2024	200–768	Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sofia, Bulgaria (016592).	RAVANTAGE 9 and RAVANTAGE 45 (ractopamine hydrochloride) Type A Medicated Articles.	Original approval as a generic copy of NADA 140–863.	558.500
January 12, 2024	200–767	Felix Pharmaceuticals Pvt. Ltd., 25–28 North Wall Quay, Dublin 1, Ireland (086101).	Carprofen Tablets	Original approval as a generic copy of NADA 141–053.	520.304
January 30, 2024	200–769	ZyVet Animal Health, Inc., 73 Route 31N, Pennington, NJ 08534 (086117).	SELAMECTIN Topical Solution	Original approval as a generic copy of NADA 141–152.	524.2098
February 13, 2024	141–575	Boehringer Ingelheim Animal Health USA, Inc., 3239 Satellite Blvd., Duluth, GA 30096 (000010).	VETMEDIN (pimobendan oral solution) Solution.	Original approval for management of the signs of mild, moderate, or severe congestive heart failure in dogs.	520.1782
February 22, 2024	200–749	Ceva Sante Animale, 10 Avenue de la Ballastière, 33500 Libourne, France (013744).	KESIUM (amoxicillin and clavulanate potassium tablets) Chewable Tablets.	Original approval as a generic copy of NADA 055–099.	520.88g
March 1, 2024	200–772	Parnell Technologies Pty. Ltd., unit 4, 476 Gardeners Rd., Alexandria, New South Wales 2015, Australia (068504).	CONTRASED (atipamezole hydrochloride) Injectable Solution.	Original approval as a generic copy of NADA 141–033.	522.147
March 15, 2024	141–579	Dechra Ltd. Snaygill Industrial Estate, Keighley Road, Skipton, North Yorkshire, BD23 2RW, United Kingdom (043264).	DUOTIC (terbinafine and betamethasone acetate otic gel) Otic Gel.	Original approval for treatment of otitis externa in dogs, associated with susceptible strains of yeast (*Malassezia pachydermatis*).	524.2338

II. Withdrawals of Approval

Boehringer Ingelheim Animal Health USA, Inc., 3239 Satellite Blvd., Duluth, GA 30096 (drug labeler code 000010) requested that FDA withdraw approval of the five NADAs 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 JANUARY, FEBRUARY, AND MARCH 2024

Date of withdrawal of approval	File No.	Product name	21 CFR section
March 4, 2024	141–015	ENACARD (enalapril maleate) Tablets	520.804
Do	141–096	DICURAL (difloxacin hydrochloride) Tablets	520.645
Do	141–108	ETOGESIC (etodolac) Tablets	520.870
Do	141–274	ETOGESIC (etodolac) Injectable Solution	522.870
Do	141–421	DUOCARE (ivermectin and praziquantel) Paste	520.1198

III. Changes 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. The regulations cited in table 3 are amended to reflect these actions.

TABLE 3—APPLICATIONS FOR WHICH OWNERSHIP WAS TRANSFERRED TO ANOTHER SPONSOR DURING JANUARY, FEBRUARY, AND MARCH 2024

File No.	Product name	Transferring sponsor (drug labeler code)	New sponsor (drug labeler code)	21 CFR section
200–141	ATTANE (isoflurane)	Piramal Critical Care, Inc., 3850 Schelden Circle, Bethlehem, PA 18017 (066794).	Piramal Pharma Ltd., Ground floor, Piramal Ananta, Agastya Corporate Park, Mumbai, Maharashtra—400070, India (065085).	529.1186
200–237	Isoflurane, USP	Do	Do	Do.
200–338	TRI–HEART (ivermectin and pyrantel pamoate) Tablets.	Heska Corp., 3760 Rocky Mountain Ave., Loveland, CO 80538–7084 (063604).	Diamond Animal Health, Inc., 2538 SE 43rd St., Des Moines, IA 50327 (053701).	510.600 520.1196
200–438	PETREM (sevoflurane)	Piramal Critical Care, Inc., 3850 Schelden Circle, Bethlehem, PA 18017 (066794).	Piramal Pharma Ltd., Ground floor, Piramal Ananta, Agastya Corporate Park, Mumbai, Maharashtra—400070, India (065085).	529.2110

IV. Change of Sponsor Address

ECO LLC, 344 Nassau St., Princeton, NJ 08540 (drug labeler code 066916 in 21 CFR 510.600(c)) has informed FDA that it has changed its address to 11224 Aurora Ave., Urbandale, IA 50322. 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 and readability of the animal drug regulations.

- 21 CFR 510.600 is amended to remove entries for Heska Corp. and Piramal Critical Care, Inc. from the lists of sponsors of approved applications, to revise the entries for Cronus Pharma Specialities India Private Ltd. and ECO LLC; and to add entries for Diamond Animal Health, Inc.
- 21 CFR 522.840 is amended to reflect revisions to approved labeling for cattle implants containing estradiol.
- 21 CFR 522.1940 is amended to reflect the current format for regulations and revisions to approved labeling for cattle implants containing progesterone and estradiol benzoate.
- 21 CFR 522.2343 is amended to reflect revisions to approved labeling for cattle implants containing testosterone propionate and estradiol benzoate.
- 21 CFR 522.2477 is amended to reflect revisions to approved labeling for cattle implants containing trenbolone acetate and estradiol.
- 21 CFR 524.1193 is amended to reflect periods of persistent activity for an approved generic ivermectin topical solution used in cattle.
- 21 CFR 558.485 is amended to reflect an inclusion rate for pyrantel tartrate in medicated horse feeds.

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 Parts 520, 522, 524, and 529

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, 520, 522, 524, 529, 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. Add in alphabetical order an entry for ''Diamond Animal Health, Inc.'';

■ ii. Revise the entries for ''Cronus Pharma Specialities India Private Ltd.''; and ''ECO LLC''; and

■ iii. Remove the entries for ''Heska Corp.'' and ''Piramal Critical Care, Inc.'';

■ b. In the table in paragraph (c)(2), add an entry for ''053701''; remove the entries for ''063604'' and ''066794''; and revise the entries for ''066916'' and ''069043''.

The revisions and additions 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., Plot No.9(B), Survey No. 99/1, GMR Hyderabad Aviation SEZ Ltd., Mamidipalle Village, Balapur Mandal, Shamshabad, Rangareddy, Hyderabad, Telangana, 500108, India	069043
* * * * * * *	
Diamond Animal Health, Inc., 2538 SE 43rd St., Des Moines, IA 50327	053701
* * * * * * *	
ECO LLC, 11224 Aurora Ave., Urbandale, IA 50322	066916
* * * * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * * * *	
053701	Diamond Animal Health, Inc., 2538 SE 43rd St., Des Moines, IA 50327.
* * * * * * *	
066916	ECO LLC, 11224 Aurora Ave., Urbandale, IA 50322.
* * * * * * *	
069043	Cronus Pharma Specialities India Private Ltd., Plot No.9(B), Survey No. 99/1, GMR Hyderabad Aviation SEZ Ltd., Mamidipalle Village, Balapur Mandal, Shamshabad, Rangareddy, Hyderabad, Telangana, 500108, India.
* * * * * * *	

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

■ 4. In § 520.88g, revise the section heading and paragraph (a), and add paragraph (b)(3) to read as follows:

§ 520.88g Amoxicillin and clavulanate potassium tablets.

(a) *Specifications.* Each tablet or chewable tablet contains amoxicillin and clavulanate potassium equivalent to 50 milligrams (mg) amoxicillin and 12.5 mg clavulanic acid, 100 mg amoxicillin and 25 mg clavulanic acid, 200 mg amoxicillin and 50 mg clavulanic acid, or 300 mg amoxicillin and 75 mg clavulanic acid.

(b) * * *

(3) No. 013744 for use of chewable tablets as in paragraph (c) of this section.

* * * * *

■ 5. In § 520.304:
■ i. Add paragraph (a)(4);
■ ii. Revise paragraph (b)(1); and
■ iii. Add paragraph (b)(4).

The additions and revision read as follows:

§ 520.304 Carprofen.

(a) * * *

(4) Each flavored tablet contains 25, 75, or 100 mg carprofen.

(b) * * *

(1) Nos. 017033, 054771, 055529, and 062250 for use of products described in paragraphs (a)(1) and (a)(2) of this section as in paragraph (c) of this section.

* * * * *

(4) No. 086101 for use of product described in paragraphs (a)(1), (a)(2), and (a)(4) of this section as in paragraph (c) of this section.

* * * * *

§ 520.645 [Removed]

■ 6. Remove § 520.645.

§ 520.804 [Removed]

■ 7. Remove § 520.804.

§ 520.870 [Removed]

■ 8. Remove § 520.870.

■ 9. Amend § 520.928 by revising the section heading to read as follows:

§ 520.928 Firocoxib tablets.

■ 10. Add § 520.929 to read as follows:

§ 520.929 Firocoxib solution.

(a) *Specifications.* Each milliliter of solution contains 9 milligram (mg) firocoxib.

(b) *Sponsors.* See No. 051072 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Administer 0.1 mg per kilogram (0.045 mg per pound) of body weight once daily for up to 14 days.

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

(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.

■ 11. In § 520.1196, revise paragraph (b) to read as follows:

§ 520.1196 Ivermectin and pyrantel tablets.

* * * * *

(b) *Sponsors.* See Nos. 000010, 051311, and 053701 in § 510.600(c) of this chapter.

* * * * *

§ 520.1198 [Amended]

■ 12. In § 520.1198, remove paragraphs (a)(3) and (b)(3).

■ 13. Amend § 520.1780 by revising the section heading to read as follows:

§ 520.1780 Pimobendan tablets.

■ 14. Add § 520.1782 to read as follows:

§ 520.1782 Pimobendan solution.

(a) *Specifications.* Each milliliter of solution contains 1.5 milligrams (mg) pimobendan.

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

(c) *Conditions of use in dogs*—(1) *Amount.* Administer orally at a total daily dose of 0.23 mg/lb (0.5 mg/kg) body weight. The total daily dose should be divided into two equal portions administered approximately 12 hours apart (*i.e.,* morning and evening).

(2) *Indications for use.* For the management of the signs of mild, moderate, or severe congestive heart failure in dogs due to clinical myxomatous mitral valve disease (MMVD) or dilated cardiomyopathy (DCM); for use with concurrent therapy for congestive heart failure (*e.g.,* furosemide, etc.) as appropriate on a case-by-case basis.

(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.

■ 16. In § 522.147, revise paragraph (b) to read as follows:

§ 522.147 Atipamezole.

* * * * *

(b) *Sponsors.* See Nos. 015914, 052483, 068504, and 069043 in § 510.600(c) of this chapter.

* * * * *

■ 17. In § 522.840, revise paragraph (d) to read as follows:

§ 522.840 Estradiol.

* * * * *

(d) *Conditions of use*—(1) *Beef steer calves 2 months of age and older*—(i) *Amount and indications for use.* (A) An extended-release implant containing 25.7 mg estradiol for increased rate of weight gain for up to 200 days.

(B) An extended-release implant containing 43.9 mg estradiol for increased rate of weight gain for up to 400 days.

(ii) *Limitations.* For subcutaneous ear implantation only. Not approved for repeated implantation (reimplantation) with this or any other cattle ear implant in beef steer calves 2 months of age and older. Safety and effectiveness following reimplantation have not been evaluated. Do not use in beef calves less than 2 months of age, dairy calves, and veal calves. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in dairy cows or in animals intended for subsequent breeding. Use in these cattle may cause drug residues in milk and/or in calves born to these cows.

(2) *Growing beef steers and heifers on pasture (stocker, feeder, and slaughter)*—(i) *Amount and indications for use.* (A) An extended-release implant containing 25.7 mg estradiol for increased rate of weight gain for up to 200 days.

(B) An extended-release implant containing 43.9 mg estradiol for increased rate of weight gain for up to 400 days.

(ii) *Limitations.* For subcutaneous ear implantation only. Not approved for repeated implantation (reimplantation) with this or any other cattle ear implant in growing beef steers and heifers on pasture (stocker, feeder, and slaughter). Safety and effectiveness following reimplantation have not been evaluated. Do not use in beef calves less than 2 months of age, dairy calves, and veal calves. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in dairy cows or in animals intended for subsequent breeding. Use in these cattle may cause drug residues in milk and/or in calves born to these cows.

(3) *Growing beef steers and heifers fed in confinement for slaughter*—(i) *Amount and indications for use.* (A) An

extended-release implant containing 25.7 mg estradiol for increased rate of weight gain and improved feed efficiency for up to 200 days.

(B) An extended-release implant containing 43.9 mg estradiol for increased rate of weight gain and improved feed efficiency for up to 400 days.

(ii) *Limitations.* For subcutaneous ear implantation only. Not approved for repeated implantation (reimplantation) with this or any other cattle ear implant in growing beef steers and heifers fed in confinement for slaughter. Safety and effectiveness following reimplantation have not been evaluated. Do not use in beef calves less than 2 months of age, dairy calves, and veal calves. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in dairy cows or in animals intended for subsequent breeding. Use in these cattle may cause drug residues in milk and/or in calves born to these cows.

§ 522.870 [Removed]

■ 18. Remove § 522.870.

■ 19. Revise § 522.1940 to read as follows:

§ 522.1940 Progesterone and estradiol benzoate.

(a) *Specifications*—(1) *Each implant consists of progesterone and estradiol benzoate.* (i) 100 mg progesterone and 10 mg estradiol benzoate (one implant consisting of four pellets, each containing 25 mg progesterone and 2.5 mg estradiol benzoate).

(ii) 200 mg progesterone and 20 mg estradiol benzoate (one implant consisting of eight pellets, each containing 25 mg progesterone and 2.5 mg estradiol benzoate).

(2) *Each implant consists of progesterone and estradiol benzoate and tylosin tartrate.* (i) 100 mg progesterone, 10 mg estradiol benzoate, and 29 mg tylosin tartrate (one implant consisting of four pellets, each containing 25 mg progesterone and 2.5 mg estradiol benzoate, and one pellet containing 29 mg tylosin tartrate).

(ii) 200 mg progesterone, 20 mg estradiol benzoate, and 29 mg tylosin tartrate (one implant consisting of eight pellets, each containing 25 mg progesterone and 2.5 mg estradiol benzoate, and one pellet containing 29 mg tylosin tartrate).

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

(1) No. 054771 for use as in paragraphs (e)(1)(i)(A), (e)(1)(ii), (e)(2)(i)(A), (B), (C), and (e)(2)(ii) of this section.

(2) No. 058198 for use as in paragraphs (e)(1)(i)(A), (e)(1)(i)(B), (e)(1)(ii), and (e)(3) of this section.

(c) *Related tolerances.* See §§ 556.240 and 556.540 of this chapter.

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

(e) *Conditions of use*—(1) *Beef calves 45 days of age and older and weighing up to 400 lbs*—(i) *Amounts and indications for use.* (A) An implant containing 100 mg progesterone and 10 mg estradiol benzoate as described in paragraph (a)(1)(i) of this section for increased rate of weight gain.

(B) An implant containing 100 mg progesterone, 10 mg estradiol benzoate, and 29 mg tylosin tartrate as described in paragraph (a)(2)(i) of this section for increased rate of weight gain.

(ii) *Limitations.* Implant pellets subcutaneously in ear only. Other than when used as described in (e)(2)(i)(B) of this section, the implant as described in paragraph (a)(1)(i) of this section is not approved for repeated implantation (reimplantation). The implant as described in paragraph (a)(2)(i) of this section is not approved for repeated implantation (reimplantation) with this or any other cattle ear implant. Do not use in beef calves less than 45 days of age, dairy calves, and veal calves because effectiveness and safety have not been evaluated. Do not use in dairy cows or in animals intended for subsequent breeding. Use in these cattle may cause drug residues in milk and/or calves born to these cows.

(2) *Growing beef steers fed in confinement for slaughter*—(i) *Amounts and indications for use.* (A) An implant containing 200 mg progesterone and 20 mg estradiol benzoate as described in paragraph (a)(1)(ii) of this section for increased rate of weight gain and improved feed efficiency.

(B) An implant containing 200 mg progesterone and 20 mg estradiol benzoate as described in paragraph (a)(1)(ii) of this section for increased rate of weight gain in a reimplantation program where an implant as described in paragraph (a)(1)(i) of this section is the first implant and an implant as described in paragraph (a)(1)(ii) of this section is administered approximately 70 days later.

(C) An implant containing 200 mg progesterone and 20 mg estradiol benzoate as described in paragraph (a)(1)(ii) of this section for increased rate of weight gain in a reimplantation program where an implant as described in paragraph (a)(1)(ii) of this section is the first implant and an implant as described in paragraph (a)(1)(ii) of this section is administered approximately 70 days later.

(ii) *Limitations.* Implant pellets subcutaneously in ear only. Other than when used as described in paragraphs (e)(2)(i)(B) or (C) of this section, the implant described in paragraph (a)(1)(ii) of this section is not approved for repeated implantation (reimplantation) with any other cattle ear implant in growing beef steers and heifers fed in confinement for slaughter as safety and effectiveness have not been evaluated. Do not use in beef calves less than 2 months of age, dairy calves, and veal calves because effectiveness and safety have not been evaluated. Do not use in dairy cows or in animals intended for subsequent breeding. Use in these cattle may cause drug residues in milk and/or calves born to these cows.

(3) *Growing beef steers weighing 400 lbs or more*—(i) *Amounts and indications for use.* An implant containing 200 mg progesterone, 20 mg estradiol benzoate, and 29 mg tylosin tartrate as described in paragraph (a)(2)(ii) of this section for increased rate of weight gain and improved feed efficiency.

(ii) *Limitations.* The implant as described in paragraph (a)(2)(ii) of this section is not approved for repeated implantation (reimplantation) with this or any other cattle ear implant. Do not use in beef calves less than 2 months of age, dairy calves, and veal calves because effectiveness and safety have not been evaluated. Do not use in dairy cows or in animals intended for subsequent breeding. Use in these cattle may cause drug residues in milk and/or calves born to these cows.

■ 20. Revise § 522.2343 to read as follows:

§ 522.2343 Testosterone propionate and estradiol benzoate.

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

(1) No. 054771 for use as in paragraph (d)(1) of this section.

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

(b) *Related tolerances.* See §§ 556.240 and 556.710 of this chapter.

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

(d) *Conditions of use*—(1) *Growing beef heifers fed in confinement for*

slaughter—(i) *Amounts and indications for use.* An implant containing 200 mg testosterone propionate and 20 mg estradiol benzoate (one implant consisting of eight pellets, each containing 25 mg testosterone propionate and 2.5 mg estradiol benzoate) for increased rate of weight gain and improved feed efficiency.

(ii) *Limitations.* Implant pellets subcutaneously in ear only. Not approved for repeated implantation (reimplantation) with this or any other cattle ear implant. Do not use in beef calves less than 2 months of age, dairy calves, and veal calves because safety and effectiveness have not been evaluated. Do not use in dairy cows or in animals intended for subsequent breeding. Use in these cattle may cause drug residues in milk and/or in calves born to these cows.

(2) *Growing beef heifers weighing 400 lbs or more*—(i) *Amounts and indications for use.* An implant containing 200 mg testosterone propionate, 20 mg estradiol benzoate, and 29 mg tylosin tartrate (one implant consisting of eight pellets, each containing 25 mg testosterone propionate and 2.5 mg estradiol benzoate, and one pellet containing 29 mg tylosin tartrate) for increased rate of weight gain and improved feed efficiency.

(ii) *Limitations.* Implant pellets subcutaneously in ear only. Not approved for repeated implantation (reimplantation) with this or any other cattle ear implant. Do not use in beef calves less than 2 months of age, dairy calves, and veal calves because safety and effectiveness have not been evaluated. Do not use in dairy cows or in animals intended for subsequent breeding. Use in these cattle may cause drug residues in milk and/or in calves born to these cows.

■ 21. Revise § 522.2477 to read as follows:

§ 522.2477 Trenbolone acetate and estradiol.

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

(1) No. 058198 for use in paragraphs (d)(1)(i)(B), (d)(1)(ii), (d)(2)(i)(B), (d)(2)(i)(D), (d)(2)(ii), (d)(3)(i)(B), (d)(3)(i)(D), (d)(3)(ii), (d)(4)(i)(A), (d)(4)(i)(B), and (d)(4)(ii) of this section.

(2) No. 000061 for use in paragraphs (d)(1)(i)(A), (d)(1)(i)(C), (d)(1)(ii), (d)(2)(i)(A), (d)(2)(i)(C), (d)(2)(i)(E), (d)(2)(ii), (d)(3)(i)(A), (d)(3)(i)(C), (d)(3)(i)(E), (d)(3)(ii), (d)(4)(i)(A), and (d)(4)(ii) of this section.

(3) No. 054771 for use in paragraphs (d)(2)(i)(A), (C), (d)(2)(ii), (d)(4)(i)(A), and (d)(4)(ii) of this section.

(b) *Related tolerances.* See §§ 556.240 and 556.739 of this chapter.

(c) *Special considerations.* Labeling of implants described in paragraphs (d)(1)(i)(B), (d)(2)(i)(B), (d)(2)(i)(D), (d)(3)(i)(B), (d)(3)(i)(D), and (d)(4)(i)(B) of this section shall bear the following: ''Federal law restricts this drug to use by or on the order of a licensed veterinarian.''

(d) *Conditions of use*—(1) G*rowing beef steers and heifers fed in confinement for slaughter*—(i) *Amounts and indications.* (A) An implant containing 200 mg trenbolone acetate and 20 mg estradiol (one implant consisting of 10 pellets each containing 20 mg trenbolone acetate and 2 mg estradiol) for increased rate of weight gain and improved feed efficiency.

(B) An implant containing 200 mg trenbolone acetate, 20 mg estradiol, and 29 mg tylosin tartrate (one implant consisting of 10 pellets, each containing 20 mg trenbolone acetate and 2 mg estradiol, and 1 pellet containing 29 mg tylosin tartrate) for increased rate of weight gain and improved feed efficiency.

(C) An extended- and delayed-release implant containing 200 mg trenbolone acetate and 20 mg estradiol (1 implant consisting of 10 coated pellets, each containing 20 mg trenbolone acetate and 2 mg estradiol) for increased rate of weight gain and improved feed efficiency during 70 to 200 days after implantation.

(ii) *Limitations.* Implant pellets subcutaneously in ear only. Not approved for repeated implantation (reimplantation) with this or any other cattle ear implant in growing beef steers and heifers fed in confinement for slaughter. Do not use in beef calves less than 2 months of age, dairy calves, and veal calves because safety and effectiveness have not been evaluated. Do not use in dairy cows or in animals intended for subsequent breeding. Use in these cattle may cause drug residues in milk and/or calves born to these cows.

(2) *Growing beef steers fed in confinement for slaughter*—(i) *Amounts and indications.* (A) An implant containing 80 mg trenbolone acetate and 16 mg estradiol (one implant consisting of four pellets, each containing 20 mg trenbolone acetate and 4 mg estradiol) for increased rate of weight gain and improved feed efficiency.

(B) An implant containing 80 mg trenbolone acetate, 16 mg estradiol, and 29 mg tylosin tartrate (one implant consisting of four pellets, each containing 20 mg trenbolone acetate and 4 mg estradiol, and one pellet containing 29 mg tylosin tartrate) for increased rate of weight gain and improved feed efficiency.

(C) An implant containing 120 mg trenbolone acetate and 24 mg estradiol (one implant consisting of six pellets, each containing 20 mg trenbolone acetate and 4 mg estradiol) for increased rate of weight gain and improved feed efficiency.

(D) An implant containing 120 mg trenbolone acetate, 24 mg estradiol, and 29 mg tylosin tartrate (one implant consisting of six pellets, each containing 20 mg trenbolone acetate and 4 mg estradiol, and one pellet containing 29 mg tylosin tartrate) for increased rate of weight gain and improved feed efficiency.

(E) An extended-release implant containing 200 mg trenbolone acetate and 40 mg estradiol (one implant consisting of six coated pellets and four uncoated pellets, each containing 20 mg trenbolone acetate and 4 mg estradiol) for increased rate of weight gain and improved feed efficiency for up to 200 days after implantation.

(ii) *Limitations.* Implant pellets subcutaneously in ear only. Not approved for repeated implantation (reimplantation) with this or any other cattle ear implant in growing beef steers fed in confinement for slaughter. Do not use in beef calves less than 2 months of age, dairy calves, and veal calves because safety and effectiveness have not been evaluated. Do not use in dairy cows or in animals intended for subsequent breeding. Use in these cattle may cause drug residues in milk and/or calves born to these cows.

(3) *Growing beef heifers fed in confinement for slaughter*—(i) *Amounts and indications.* (A) An implant containing 80 mg trenbolone acetate and 8 mg estradiol (one implant consisting of four pellets, each containing 20 mg trenbolone acetate and 2 mg estradiol) for increased rate of weight gain.

(B) An implant containing 80 mg trenbolone acetate, 8 mg estradiol, and 29 mg tylosin tartrate (one implant consisting of four pellets, each containing 20 mg trenbolone acetate and 2 mg estradiol, and one pellet containing 29 mg tylosin tartrate) for increased rate of weight gain and improved feed efficiency.

(C) An implant containing 140 mg trenbolone acetate and 14 mg estradiol (one implant consisting of seven pellets, each containing 20 mg trenbolone acetate and 2 mg estradiol) for increased rate of weight gain and improved feed efficiency.

(D) An implant containing 140 mg trenbolone acetate, 14 mg estradiol, and 29 mg tylosin tartrate (one implant consisting of seven pellets, each containing 20 mg trenbolone acetate and 2 mg estradiol, and one pellet containing 29 mg tylosin tartrate) for increased rate of weight gain and improved feed efficiency.

(E) An extended-release implant containing 200 mg trenbolone acetate and 20 mg estradiol (one implant consisting of six coated pellets and four uncoated pellets, each containing 20 mg trenbolone acetate and 2 mg estradiol) for increased rate of weight gain and improved feed efficiency for up to 200 days after implantation.

(ii) *Limitations.* Implant pellets subcutaneously in ear only. Not approved for repeated implantation (reimplantation) with this or any other cattle ear implant in growing beef heifers fed in confinement for slaughter. Do not use in beef calves less than 2 months of age, dairy calves, and veal calves because safety and effectiveness have not been evaluated. Do not use in dairy cows or in animals intended for subsequent breeding. Use in these cattle may cause drug residues in milk and/or calves born to these cows.

(4) *Growing beef steers and heifers on pasture (stocker, feeder, and slaughter)*—(i) *Amounts and indications for use.* (A) An implant containing 40 mg trenbolone acetate and 8 mg estradiol (one implant consisting of two pellets, each containing 20 mg trenbolone acetate and 4 mg estradiol) for increased rate of weight gain.

(B) An implant containing 40 mg trenbolone acetate, 8 mg estradiol, and 29 mg tylosin tartrate (one implant consisting of two pellets, each containing 20 mg trenbolone acetate and 4 mg estradiol, and one pellet containing 29 mg tylosin tartrate) for increased rate of weight gain.

(ii) *Limitations.* Implant pellets subcutaneously in ear only. Not approved for repeated implantation (reimplantation) with this or any other cattle ear implant in growing beef steers and heifers on pasture (stocker, feeder, and slaughter). Do not use in beef calves less than 2 months of age, dairy calves, and veal calves because safety and effectiveness have not been evaluated. Do not use in dairy cows or in animals intended for subsequent breeding. Use in these cattle may cause drug residues in milk and/or calves born to these cows.

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

■ 23. In § 524.1193:
■ a. Revise paragraph (b);
■ b. Remove paragraph (d);
■ c. Redesignate paragraph (e) as paragraph (d) and revise newly redesignated paragraphs (d)(2) and (d)(3).

The revisions read as follows:

§ 524.1193 Ivermectin topical solution.

* * * * *

(b) *Sponsors.* See Nos. 000010, 016592, 055529, 058829, and 061133 in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

* * * * *

(d) * * *

(2) *Indications for use.* It is used for the treatment and control of: Gastrointestinal roundworms (adults and fourth-stage larvae) *Ostertagia ostertagi* (including inhibited stage), *Haemonchus placei, Trichostrongylus axei, T. colubriformis, Cooperia oncophora, C. punctata, C. surnabada, Oesophagostomum radiatum* (adults); *Strongyloides papillosus, Trichuris* spp.; lungworms (adults and fourth-stage larvae) *Dictyocaulus viviparus;* cattle grubs (parasitic stages) *Hypoderma bovis, H. lineatum;* mites *Sarcoptes scabiei* var. *bovis;* lice *Linognathus vituli, Haematopinus eurysternus, Damalinia bovis, Solenoptes capillatus;* and horn flies *Haematobia irritans.* It controls infections and prevents reinfection with *O. radiatum* and *D. viviparus* for 28 days after treatment, *C. punctata* and *T. axei* for 21 days after treatment, *O. ostertagi, H. placei, C. oncophora,* and *C. surnabada* for 14 days after treatment, and *D. bovis* for 56 days after treatment.

(3) *Limitations.* Do not treat cattle within 48 days of slaughter. Do not use on female dairy cattle of breeding age or on calves to be processed for veal. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

■ 24. In § 524.2098, revise paragraph (b) to read as follows:

§ 524.2098 Selamectin.

* * * * *

(b) *Sponsors.* See Nos. 051072, 051311, 054771, 055529, 061133, and 086117 of this chapter.

* * * * *

■ 25. Add § 524.2338 to read as follows:

§ 524.2338 Terbinafine and betamethasone acetate.

(a) *Specifications.* Each milliliter of gel contains 10 milligrams (mg) terbinafine and 1 mg betamethasone acetate.

(b) *Sponsor.* See No. 043264 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer one dose (1 tube) per affected ear(s) and repeat administration in 7 days.

(2) *Indications for use.* For the treatment of otitis externa in dogs, associated with susceptible strains of yeast (*Malassezia pachydermatis*).

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

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

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

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

■ 27. In § 529.1186, revise paragraph (b) to read as follows:

§ 529.1186 Isoflurane.

* * * * *

(b) *Sponsors.* See Nos. 017033, 054771, and 065085 in § 510.600(c) of this chapter.

* * * * *

■ 28. In § 529.2110, revise paragraph (b) to read as follows:

§ 529.2110 Sevoflurane.

* * * * *

(b) *Sponsors.* See Nos. 017033, 054771, and 065085 in § 510.600(c) of this chapter.

* * * * *

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 § 558.485, revise (e)(2) to read as follows:

§ 558.485 Pyrantel.

* * * * *

(e) * * *

(2) *Horses*—

Pyrantel tartrate g/ton	Indications for use	Limitation	Sponsor
(i) 120 to 1,200 to provide 1.2 mg/lb body weight.	For prevention of *Strongylus vulgaris* larval infections; control of adult large strongyles (*S. vulgaris,* and *S. edentatus*), adult and 4th stage larvae small strongyles (*Cyathostomum* spp., *Cylicocyclus* spp., *Cylicostephanus* spp., *Cylicodontophorus* spp., *Poteriostomum* spp., and *Triodontophorus* spp.), adult and 4th stage larvae pinworms (*Oxyuris equi*), and adult and 4th stage larvae ascarids (*Parascaris equorum*).	Feed continuously as the horse's daily grain ration during the time that the animal is at risk of exposure to internal parasites. Do not use in horses intended for human consumption. Consult your veterinarian before using in severely debilitated animals and for assistance in the diagnosis, treatment, and control of parasitism.	017135 054771

(ii) *Top dress medicated feed*—(A) *Proprietary Formulas.* The following feed can be manufactured only per an approved proprietary formula and specifications:

Pyrantel tartrate amount	Indications for use	Limitations	Sponsor
(*1*) 9.6 g/lb to provide 1.2 mg/lb body weight.	Prevention of *Strongylus vulgaris* larval infections; control of adult large strongyles (*S. vulgaris,* and *S. edentatus*), adult and 4th stage larvae small strongyles (*Cyathostomum* spp., *Cylicocyclus* spp., *Cylicostephanus* spp., *Cylicodontophorus* spp., *Poteriostomum* spp., and *Triodontophorus* spp.), adult and 4th stage larvae pinworms (*Oxyuris equi*), and adult and 4th stage larvae ascarids (*Parascaris equorum*).	Feed continuously as a top dress during the time that the animal is at risk of exposure to internal parasites. Do not use in horses intended for human consumption. Consult your veterinarian before using in severely debilitated animals and for assistance in the diagnosis, treatment, and control of parasitism.	017135 054771
(*2*) [Reserved].	.....	.....	.....

(B) [Reserved]

* * * * *

■ 31. In § 558.500, revise (b)(1), (b)(2), and (e)(1)(i) to read as follows:

§ 558.500 Ractopamine.

* * * * *

(b) * * *

(1) Nos. 016592 and 058198: Type A medicated articles containing 9 or 45.4 grams per pound (g/lb) ractopamine hydrochloride.

(2) Nos. 051311 and 054771: Type A medicated articles containing 45.4 g/lb ractopamine hydrochloride.

* * * * *

(e) * * *

(1) * * *

Ractopamine in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsors
(i) 4.5 to 9.0	.....	For increased rate of weight gain, improved feed efficiency, and increased carcass leanness in finishing swine, weighing not less than 150 lb, fed a complete ration containing at least 16% crude protein for the last 45 to 90 lb of gain prior to slaughter.	Feed continuously as sole ration.	016592 054771 058198

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Dated: May 9, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–10586 Filed 5–14–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 516

[Docket No. FDA–2006–N–0239]

Index of Legally Marketed Unapproved New Animal Drugs for Minor Species

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is amending the animal drug regulations for labeling of new animal drugs included on FDA's Index of Legally Marketed Unapproved New Animal Drugs for Minor Species (indexed products) to reflect the 2018 statutory changes to the Federal Food, Drug, and Cosmetic Act (FD&C Act). This amendment is intended to ensure accuracy and clarity in the Agency's regulations. This amendment is nonsubstantive.

DATES: This rule is effective May 15, 2024.

FOR FURTHER INFORMATION CONTACT: Lucy Lee, Center for Veterinary Medicine (HFV–50), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0563, *lucy.lee@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Minor Use and Minor Species Animal Health Act of 2004 (MUMS Act of 2004) (Pub. L. 108–282) amended the FD&C Act to establish regulatory procedures that provide incentives intended to make more drugs legally available to veterinarians and animal owners for the treatment of minor animal species and uncommon diseases in major animal species.

In 2007, FDA issued final regulations (72 FR 69108, December 6, 2007) to implement section 572 of the MUMS Act entitled ''Index of Legally Marketed Unapproved New Animal Drugs for Minor Species.'' These regulations establish administrative procedures and criteria for index listing a new animal drug that provide a basis for legally marketing an unapproved new animal drug for use in a minor species.

The MUMS Act and the 2007 regulations derived from it required indexed products to state their