# Rules and Regulations

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## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

### 14 CFR Part 73

**[Docket No. FAA–2023–1957; Airspace Docket No. 23–AAL–28]**

**RIN 2120–AA66**

## Amendment of Jet Route J–133 and Establishment of Area Navigation Route Q–801 in the Vicinity of Anchorage, AK

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Final rule; correction.

**SUMMARY:** This action corrects a final rule correction published in the **Federal Register** of September 19, 2024, that amends Jet Route J–133 and establishes Area Navigation Route (RNAV) Q–801 in the vicinity of Anchorage, AK. This action corrects a typographical error in the regulatory text for J–133.

**DATES:** Effective date: 0901 UTC October 31, 2024.

**ADDRESSES:** FAA Order JO 7400.11J, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *www.faa.gov/air_traffic/publications/.* You may also contact the Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 600 Independence Avenue SW, Washington, DC 20597; telephone: (202) 267–8783.

**FOR FURTHER INFORMATION CONTACT:** Steven Roff, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 600 Independence Avenue SW, Washington, DC 20597; telephone (202) 267–8783.

**SUPPLEMENTARY INFORMATION:**

### History

The FAA published a final rule for Docket No. FAA–2023–1957 in the **Federal Register** (89 FR 70474; August 30, 2024) that amended Jet Route J–133 and established RNAV Q–801 in the vicinity of Anchorage, AK. Subsequent to publication, the FAA published a final rule correction for Docket No. FAA–2023–1957 in the **Federal Register** (89 FR 76713; September 19, 2024) that corrected a typographical error in the rule section of the final rule preamble, but inadvertently retained a typographical error in the regulatory text for J–133. The final rule and final rule correction listed the J–133 route points in a North to South order in error. The route points should be listed in a South to North order. This action corrects that error.

### Correction to Final Rule

Accordingly, pursuant to the authority delegated to me, Amendment of Jet Route J–133 and Establishment of Area Navigation Route Q–801 in the Vicinity of Anchorage, AK, published in the **Federal Register** of September 19, 2024 (89 FR 76713), FR Doc. 2024–21260, is corrected as follows:

On page 76714, in the middle of column 1, the description for Jet Route J–133 is revised to read as follows:

**J–133 [Amended]**

From Anchorage, AK; to Galena, AK.

* * * * *

Issued in Washington, DC, on October 22, 2024.

**Frank Lias,**

*Manager, Rules and Regulations Group.*

[FR Doc. 2024–24934 Filed 10–25–24; 8:45 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

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

**[Docket No. FDA–2024–N–0002]**

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

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

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

**SUMMARY:** The Food and Drug Administration (FDA or we) is amending the animal drug regulations to reflect application-related actions for new animal drug applications (NADAs), abbreviated new animal drug applications (ANADAs), and conditionally approved new animal drug applications (CNADAs) during April, May, and June 2024. The animal drug regulations are also being amended to improve their accuracy and readability.

**DATES:** This rule is effective October 28, 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, ANADAs, and CNADAs during April, May, and June 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, ANADAS, AND CNADAS APPROVED DURING APRIL, MAY, AND JUNE 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 |
|---|---|---|---|---|---|
| April 5, 2024 | 141–043 | Zoetis Inc, 333 Portage St., Kalamazoo, MI 49007 (054771). | SYNOVEX CHOICE (trenbolone acetate and estradiol benzoate) and SYNOVEX PRIMER (trenbolone acetate and estradiol benzoate). | Supplemental approval for increased rate of weight gain in growing beef steers and heifers in a dry lot. | 522.2478 |
| April 9, 2024 | 141–550 | Elanco US Inc., 2500 Innovation Way, Greenfield, IN 46140 (058198). | PRADALEX (pradofloxacin injection) | Original approval for treatment of bovine respiratory disease and swine respiratory disease. | 522.1860<br>556.530 |
| April 10, 2024 | 200–777 | Felix Pharmaceuticals PVT Ltd., 25–28 North Wall Quay, Dublin 1, Ireland (086101). | Carprofen Injectable Solution | Original approval as a generic copy of NADA 141–199. | 522.304 |
| April 25, 2024 | 200–728 | Cronus Pharma Specialties 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). | PIMOMEDIN (pimobendan) Tablets | Original approval as a generic copy of NADA 141–033. | 520.1780 |
| April 26, 2024 | 141–582 | Warburton Technology Ltd., 36 Fitzwilliam Square, Dublin, Dublin, D02HX82, Ireland (066679). | MULTIMIN 90 (zinc, copper, manganese, and selenium injection). | Original approval as a supplemental source of zinc, copper, manganese, and selenium in cattle. | 522.2694 |
| May 8, 2024 | 200–780 | Aurora Pharmaceutical, Inc., 1196 Highway 3 South, Northfield, MN 55057–3009 (051072). | COCCIAID (amprolium) for Calves | Original approval as a generic copy of NADA 013–149. | 520.100 |
| May 9, 2024 | 200–782 | Cronus Pharma Specialties 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). | ENROPRO Silver Otic (enrofloxacin/silver sulfadiazine) Otic Emulsion. | Original approval as a generic copy of NADA 141–176. | 524.802 |
| May 10, 2024 | 141–577 | Vetoquinol USA, Inc., 4250 N Sylvania Ave., Fort Worth, TX 76137 (017030). | UPCARD–CA1 (torsemide oral solution). | Conditional approval as concurrent therapy with pimobendan, spironolactone, and an angiotensin converting enzyme (ACE) inhibitor for the management of pulmonary edema in dogs with congestive heart failure caused by myxomatous mitral valve disease (MMVD). | 516.2475 |
| May 16, 2024 | 200–781 | Cronus Pharma Specialties 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). | FLUNINE (flunixin meglumine injection). | Original approval as a generic copy of NADA 101–479. | 522.970 |
| May 23, 2024 | 131–675 | Intervet, Inc., 126 E Lincoln Ave., Rahway, NJ 07065 (000061). | SAFE–GUARD 20% (fenbendazole) Type A medicated article. | Supplemental approval for the treatment and control of cecal worms (*Aulonocephalus* spp.) in wild quail. | 558.258 |
| June 4, 2024 | 138–255 | Sparhawk Laboratories, Inc., 12340 Santa Fe Trail Dr., Lenexa, KS 66215 (058005). | Iron Dextran 20% Injection (iron hydrogenated dextran injection) Injectable Solution. | Supplemental approval for the prevention or treatment of iron deficiency anemia in nursing piglets. | 522.1182 |
| June 11, 2024 | 200–787 | ZyVet Animal Health, Inc., 73 Route 31N, Pennington, NJ 08534 (086117). | Phenylpropanolamine Hydrochloride Chewable Tablets. | Original approval for the control of urinary incontinence due to urethral sphincter hypotonus in dogs as a generic copy of NADA 141–324. | 520.1760 |
| June 17, 2024 | 200–785 | Felix Pharmaceuticals PVT Ltd., 25–28 North Wall Quay, Dublin 1, IRELAND. | Maropitant Citrate Tablets (maropitant citrate). | Original approval as a generic copy of NADA 141–262. | 520.1315 |
| June 20, 2024 | 200–784 | ZyVet Animal Health, Inc., 73 Route 31N, Pennington, NJ 08534 (086117). | Trimeprazine with prednisolone tablets. | Original approval as a generic copy of NADA 012–437. | 520.2604 |

## II. Change of Sponsor

Elanco US Inc., 2500 Innovation Way, Greenfield, IN 46140 has informed FDA that it has transferred ownership of, and all rights and interest in, ANADA 200–582 for LONCOR 300 (florfenicol) Injectable Solution to Zoetis Inc, 333 Portage St., Kalamazoo, MI 49007. As provided in the regulatory text of this document, the animal drug regulations are amended to reflect this action.

## III. Change of Sponsor Address

Ivaoes Animal Health (drug labeler code 086064 in 21 CFR 510.600(c)) has informed FDA that it has changed its address to 2101 W Atlantic Blvd., Suite 108, Pompano Beach, FL 33069. The entries in § 510.600(c) are amended to reflect this action.

## IV. 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 revise the entries for Ivaoes Animal Health Inc. in the lists of sponsors of approved applications and to add entries for Warburton Technology Ltd.

- 21 CFR 516.1760 is being amended to provide for additional strengths of phenobarbital tablets.
- 21 CFR 520.2130 is amended to revise body weights of dogs and cats for treatment with spinosad chewable tablets.
- 21 CFR 520.2598 is being amended to reflect an additional strength trilostane capsule.
- 21 CFR 522.772 is amended to revise specific parasite indications and to reflect the prescription marketing status of doramectin and levamisole injectable solution for use in cattle.
- 21 CFR 522.970 is amended to reflect approved food-producing animal species for separate sponsor products.
- 21 CFR 522.1696b is amended to revise the preslaughter withdrawal period for cattle administered a penicillin G procaine aqueous suspension.
- 21 CFR 529.1004 is amended to reflect approved conditions of use for formalin in finfish.
- 21 CFR 529.1150 is amended to reflect approved conditions of use for hydrogen peroxide in freshwater-reared salmonids.
- 21 CFR 556.275 is amended by adding a tolerance for residues of fenbendazole in edible tissues of quail established as a consequence of the supplemental approval of fenbendazole medicated quail feed.
- 21 CFR 556.530 is added to provide tolerances for residues of pradofloxacin in edible tissues of cattle and swine.
- 21 CFR 558.261 is being amended to reflect incorporation levels of florfenicol in medicated feed for freshwater-reared salmonids.
- 21 CFR 558.450 is being amended to provide inclusion rates for oxytetracycline in medicated feed for finfish.

## V. 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, 524, and 529*

Animal drugs.

*21 CFR Part 556*

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

*21 CFR Part 558*

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 510, 516, 520, 522, 524, 529, 556, and 558 are amended as follows:

## PART 510—NEW ANIMAL DRUGS

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

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

■ 2. In § 510.600(c):

■ a. In the table in paragraph (c)(1), revise the entry for ''Ivaoes Animal Health'' and add in alphabetical order an entry for ''Warburton Technology Ltd.''; and

■ b. In the table in paragraph (c)(2), add an entry in numerical order for ''066679'' and revise the entry for ''086064''.

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 |
|---|---|
| * * * * * * * | |
| Ivaoes Animal Health, 2101 W Atlantic Blvd., Suite 108, Pompano Beach, FL 33069 | 086064 |
| * * * * * * * | |
| Warburton Technology Ltd., 36 Fitzwilliam Square, Dublin 2, Dublin, D02HX82, Ireland | 066679 |
| * * * * * * * | |

(2) * * *

| Drug labeler code | Firm name and address |
|---|---|
| * * * * * * * | |
| 066679 | Warburton Technology Ltd., 36 Fitzwilliam Square, Dublin 2, Dublin, D02HX82, Ireland. |
| * * * * * * * | |
| 086064 | Ivaoes Animal Health, 2101 W Atlantic Blvd., Suite 108, Pompano Beach, FL 33069. |
| * * * * * * * | |

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

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

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

■ 4. In § 516.1760, revise paragraph (a) to read as follows:

**§ 516.1760 Phenobarbital.**

(a) *Specifications.* Each tablet contains 15, 16.2, 30, 32.4, 60, 64.8, 97.2 or 100 milligrams (mg) phenobarbital.

* * * * *

■ 5. Add § 516.2475 to subpart E to read as follows:

**§ 516.2475 Torsemide.**

(a) *Specifications.* Each milliliter of solution contains 0.2 milligrams (mg) torsemide.

(b) *Sponsor.* See No. 017030 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer orally once daily at a dose of 0.05 to 0.2 mg/lb (0.11 to 0.44 mg/kg) of bodyweight.

(2) *Indications for use.* For use as concurrent therapy with pimobendan, spironolactone, and an angiotensin converting enzyme (ACE) inhibitor for the management of pulmonary edema in dogs with congestive heart failure caused by myxomatous mitral valve disease (MMVD).

(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 § 520.100, revise paragraph (b)(2), and remove paragraph (b)(3) to read as follows:

**§ 520.100 Amprolium.**

* * * * *

(b) * * *

(2) Nos. 051072 and 066104 for use of product described in paragraph (a)(1) of this section as in paragraph (d) of this section.

* * * * *

■ 8. In § 520.1315, revise paragraph (b) to read as follows:

**§ 520.1315 Maropitant.**

* * * * *

(b) *Sponsors.* See Nos. 054771, 086101, and 086117 in § 510.600(c) of this chapter.

* * * * *

■ 9. In § 520.1760, revise paragraph (b) to read as follows:

**§ 520.1760 Phenylpropanolamine.**

* * * * *

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

(1) Nos. 055246 and 086117 for use of product described in paragraph (a)(1) of this section as in paragraphs (c)(1)(i) and (c)(2) and (3) of this section.

(2) No. 055246 for use of product described in paragraph (a)(2) of this section as in paragraph (c)(1)(ii) and (c)(2) and)(3) of this section.

* * * * *

■ 10. In § 520.1780, revise paragraph (b) to read as follows:

**§ 520.1780 Pimobendan tablets.**

* * * * *

(b) *Sponsors.* See Nos. 000010 and 069043 in § 510.600(c) of this chapter.

* * * * *

**§ 520.2130 [Amended]**

■ 11. In § 520.2130:

■ a. In paragraph (d)(1)(ii), remove the text ''3.3 pounds'' and in its place add the text ''5.0 pounds''; and

■ b. In paragraph (d)(2)(ii), remove the text ''2 pounds'' and in its place add the text ''4.1 pounds''.

■ 12. In § 520.2598, revise paragraph (a) to read as follows:

**§ 520.2598 Trilostane.**

(a) *Specifications.* Each capsule contains 5, 10, 20, 30, 60, or 120 milligrams (mg) trilostane.

* * * * *

■ 13. In § 520.2604, revise paragraph (b) to read as follows:

**§ 520.2604 Trimeprazine and prednisolone tablets.**

* * * * *

(b) *Sponsors.* See Nos. 054771 and 086117 in § 510.600(c) of this chapter.

* * * * *

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

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

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

■ 15. In § 522.304, revise paragraph (b) to read as follows:

**§ 522.304 Carprofen.**

* * * * *

(b) *Sponsors.* See Nos. 016729, 017033, 054771, 055529, 069043, and 086101 in § 510.600(c) of this chapter.

* * * * *

■ 16. In § 522.772:

■ a. Revise paragraph (d)(1)(ii); and

■ b. In paragraph (d)(1)(iii), add a sentence to the end of the paragraph.

The revision and addition read as follows:

**§ 522.772 Doramectin and levamisole.**

* * * * *

(d) * * *

(1) * * *

(ii) *Indications for use.* For treatment and control of gastrointestinal roundworms (adults and fourth stage larvae): *Ostertagia ostertagi* (including inhibited larvae), *O. lyrata, Haemonchus placei, Trichostrongylus axei, T. colubriformis, T. longispicularis* (adults only), *Oncophora, Cooperia pectinata* (adults only), *C. punctata, C. surnabada, Bunostomum phlebotomum* (adults only), *Strongyloides papillosus* (adults only), *Oesophagostomum radiatum, Trichuris* spp. (adults only) and *Nematodirus helvetianus* (adults only); lungworms (adults and fourth stage larvae): *Dictyocaulus viviparus;* eyeworms (adults): *Thelazia* spp.; grubs (parasitic stages): *Hypoderma bovis* and *H. lineatum;* sucking lice: *Haematopinus eurysternus, Linognathus vituli,* and *Solenopotes capillatus;* mange mites: *Psoroptes bovis* and *Sarcoptes scabiei* in beef cattle 2 months of age and older and replacement dairy heifers less than 20 months of age. Not for use in beef bulls intended for breeding over 1 year of age, dairy calves, and veal calves.

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

* * * * *

**§ 522.955 [Amended]**

■ 17. In § 522.955:

■ a. In paragraph (b)(3), remove the text ''Nos. 058005, 058198, and 069043'' and in its place add the text ''Nos. 054771, 058005, and 069043''; and

■ b. In paragraph (d)(1)(ii)(C), in the second sentence, remove the text ''Nos. 000061, 058005, 058198, and 069043'' and in its place add the text ''Nos. 000061, 054771, 058005, and 069043''.

■ 18. In § 522.970, revise paragraphs (b)(1) and (3) to read as follows:

**§ 522.970 Flunixin.**

* * * * *

(b) * * *

(1) See Nos. 000061, 055529, and 061133 for use as in paragraph (e) of this section.

* * * * *

(3) See Nos. 016592, 058198, and 069043 for use as in paragraphs (e)(1) and (2) of this section.

* * * * *

■ 19. In § 522.1182, revise introductory text of paragraph (b)(7) to read as follows:

**§ 522.1182 Iron injection.**

* * * * *

(b) * * *

(7) Nos. 016592, 042552, and 058005 for use product described in paragraph (a)(2) of this section as follows:

* * * * *

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

**§ 522.1696b Penicillin G procaine aqueous suspension.**

* * * * *

(d) * * *

(2) * * *

(iii) * * *

(B) For Nos. 016592 and 055529: treatment should not exceed 4 consecutive days. A withdrawal period has not been established for this product in pre-ruminating calves. Discontinue treatment for the following number of days before slaughter: cattle—14; sheep—9; and swine—7.

* * * * *

■ 21. Add § 522.1860 to read as follows:

**§ 522.1860 Pradofloxacin.**

(a) *Specifications.* Each milliliter (mL) of solution contains 200 milligrams (mg) pradofloxacin.

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

(c) *Related tolerances.* See § 556.530 of this chapter.

(d) *Conditions of use*—(1) *Cattle*—(i) *Amount.* Administer a single dose of 10 mg/kg (2.3 mL/100 lb) body weight by subcutaneous injection.

(ii) *Indications for use.* Cattle intended for slaughter (beef calves 2 months of age and older, growing beef steers, growing beef heifers, and beef bulls intended for slaughter), and in cattle intended for breeding less than 1 year of age (replacement beef and dairy heifers less than 1 year of age and beef and dairy bulls less than 1 year of age): for the treatment of bovine respiratory disease associated with *Mannheimia haemolytica, Pasteurella multocida, Histophilus somni,* and *Mycoplasma bovis.*

(iii) *Limitations.* Cattle intended for human consumption must not be slaughtered within 4 days of treatment. Not for use in female dairy cattle 1 year of age and older, including dry dairy cows; use in these cattle may cause drug residues in milk and/or in calves born to these cows. Not for use in beef calves less than 2 months of age, dairy calves, and veal calves. A withdrawal period has not been established for this product in pre-ruminating calves. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the extralabel use of this drug in food-producing animals.

(2) *Swine*—(i) *Amount.* Administer a single dose of 7.5 mg/kg (1.7 mL/100 lb) body weight by intramuscular injection.

(ii) *Indications for use.* Weaned swine intended for slaughter (nursery, growing, and finishing swine, boars intended for slaughter, barrows, gilts intended for slaughter, and sows intended for slaughter): for the treatment of swine respiratory disease associated with *Bordetella bronchiseptica, Glaesserella (Haemophilus) parasuis, Pasteurella multocida, Streptococcus suis,* and *Mycoplasma hyopneumoniae.*

(iii) *Limitations.* Swine intended for human consumption must not be slaughtered within 2 days of treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the extralabel use of this drug in food-producing animals.

■ 22. In § 522.2478:

■ a. Redesignate paragraphs (a)(1)(i) and (ii) as paragraphs (a)(1)(ii) and (iii);

■ b. Add new paragraph (a)(1)(i);

■ c. Revise paragraphs (d)(1)(i)(A), (B), and (D); and

■ d. Add paragraph (d)(3).

The revisions and additions read as follows:

**§ 522.2478 Trenbolone acetate and estradiol benzoate.**

(a) * * *

(1) * * *

(i) 50 milligrams (mg) trenbolone acetate and 7 mg estradiol benzoate (one implant consisting of two pellets, each pellet containing 25 mg trenbolone acetate and 3.5 mg estradiol benzoate) per implant dose.

* * * * *

(d) * * *

(1) * * *

(i) * * *

(A) An implant containing 100 mg trenbolone acetate and 14 mg estradiol benzoate as described in paragraph (a)(1)(ii) of this section for increased rate of weight gain in growing beef steers fed in confinement for slaughter and for increased rate of weight gain and improved feed efficiency in growing beef heifers fed in confinement for slaughter. For increased rate of weight gain for up to 200 days 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) or (iii) or (a)(2)(ii) of this section is administered 60 to 120 days later.

(B) An implant containing 200 mg trenbolone acetate and 28 mg estradiol benzoate as described in paragraph (a)(1)(iii) of this section for increased rate of weight gain and improved feed efficiency in growing beef steers fed in confinement for slaughter and for increased rate of weight gain in growing beef heifers fed in confinement for slaughter. For increased rate of weight gain for up to 200 days 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)(iii) of this section is administered 60 to 120 days later.

* * * * *

(D) An extended-release implant containing 200 mg trenbolone acetate and 28 mg estradiol benzoate as described in paragraph (a)(2)(ii) of this section for increased rate of weight gain and improved feed efficiency for up to 200 days. For increased rate of weight gain for up to 200 days 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)(2)(ii) of this section is administered 60 to 120 days later.

* * * * *

(3) *Growing beef steers and heifers in a dry lot*—(i) *Amount and indications for use.* (A) An implant containing 50 mg trenbolone acetate and 7 mg estradiol benzoate as described in paragraph (a)(1)(i) of this section for increased rate of weight gain in growing beef steers and heifers in a dry lot.

(B) An implant containing 100 mg trenbolone acetate and 14 mg estradiol benzoate as described in paragraph (a)(1)(ii) of this section for increased rate of weight gain in growing beef steers and heifers in a dry lot.

(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 in a dry lot. 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 because effectiveness and safety have not been established. 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.

■ 23. Add § 522.2694 to read as follows:

**§ 522.2694 Zinc, copper, manganese, and selenium.**

(a) *Specifications.* Each milliliter (mL) of solution contains 60 milligrams (mg) zinc as zinc oxide, 15 mg copper as copper carbonate, 10 mg manganese as manganese carbonate, and 5 mg selenium as sodium selenite.

(b) *Sponsor.* See No. 066679 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Administer a single dose by subcutaneous injection to cattle up to 1 year of age, 1 mL/100 lb bodyweight; to cattle from 1 to 2 years of age, 1 mL/150 lb bodyweight, and to cattle over 2 years of age, 1 mL/200 lb bodyweight.

(2) *Indications for use.* As a supplemental source of zinc, copper, manganese, and selenium in cattle.

(3) *Limitations.* Cattle must not be slaughtered for human food consumption within 14 days of the last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

## 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.

■ 25. In § 524.802, revise paragraph (b) to read as follows:

**§ 524.802 Enrofloxacin and silver sulfadiazine otic emulsion.**

* * * * *

(b) *Sponsors.* See Nos. 058198 and 069043 in § 510.600(c) of this chapter.

* * * * *

## 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 § 529.1004, in the table in paragraph (d)(2)(ii), revise footnote 1 to read as follows:

**§ 529.1004 Formalin.**

* * * * *

(d) * * *

(2) * * *

(ii) * * *

| Aquatic species | Administer in tanks and raceways for up to 1 hour (microliter/liter or part per million (μL/L or ppm)) | Administer in earthen ponds single treatment (μL/L or ppm) |
|---|---|---|
| * | * * * * * * | |

[1] Use the lower concentration when ponds are heavily loaded with phytoplankton or fish to avoid oxygen depletion due to the biological oxygen demand by decay of dead phytoplankton. Alternatively, a higher concentration may be used if dissolved oxygen is strictly monitored.

* * * * *

■ 28. In § 529.1150, revise paragraph (c)(1)(iv) to read as follows:

**§ 529.1150 Hydrogen peroxide.**

* * * * *

(c) * * *

(1) * * *

(iv) Freshwater-reared salmonids for the treatment and control of *Gyrodactylus* spp: 100 mg/L for 30 minutes, or 50 mg/L for 60 minutes, in a continuous flow water supply or as a static bath once per day on alternate days for three treatments.

* * * * *

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

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

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

■ 30. In § 556.275, add paragraph (b)(6) to read as follows:

**§ 556.275 Fenbendazole.**

* * * * *

(b) * * *

(6) *Quail.* (i) Liver (target tissue): 6 ppm fenbendazole sulfone (marker residue).

(ii) [Reserved]

* * * * *

■ 31. Add § 556.530 to subpart B to read as follows:

**§ 556.530 Pradofloxacin.**

(a) *Acceptable daily intake (ADI).* The ADI for total residue of pradofloxacin is 2 μg/kg of body weight per day.

(b) *Tolerances.* The tolerances for pradofloxacin (marker residue) are:

(1) *Cattle.* Kidney (target tissue): 30 ppb.

(2) *Swine.* Kidney (target tissue): 1 ppm.

(c) *Related conditions of use.* See § 522.1860 of this chapter.

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

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

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

■ 32. In § 558.258, add heading to paragraph (e)(1) and add paragraph (e)(5)(iv) to read as follows:

**§ 558.258 Fenbendazole.**

* * * * *

(e) * * *

(1) *Turkeys.*

* * * * *

(5) * * *

| Species/class | Fenbendazole grams per ton | Indications for use | Limitations | Sponsor |
|---|---|---|---|---|
| * | * | * | * | * |
| (iv) Wild quail ..... | 90.7 | For the treatment and control of Gastrointestinal worms: cecal worms (*Aulonocephalus* spp.). | Feed for 21 consecutive days. Prior withdrawal of feed is not necessary. | 000061 |

* * * * *

■ 33. In § 558.261, revise paragraph (e)(2)(ii) to read as follows:

**§ 558.261 Florfenicol.**

* * * * *

(e) * * *

(2) * * *

| Florfenicol in grams/ton of feed | Indications for use | Limitations |
|---|---|---|
| * | * | * |
| (ii) 182 to 2,724 ..... | Freshwater-reared salmonids: for the control of mortality due to coldwater disease associated with *Flavobacterium psychrophilum* and furunculosis associated with *Aeromonas salmonicida*. | Feed as a sole ration for 10 consecutive days to deliver 10 to 15 mg florfenicol per kg of fish. Feed containing florfenicol shall not be fed for more than 10 days. Following administration, fish should be reevaluated by a licensed veterinarian before initiating a further course of therapy. The effects of florfenicol on reproductive performance have not been determined. Feeds containing florfenicol must be withdrawn 15 days prior to slaughter. |
| * | * | * |

* * * * *

■ 34. In § 558.450, revise paragraphs (e)(5)(iv), (v), and (vi) to read as follows:

**§ 558.450 Oxytetracycline.**

* * * * *

(5) * * *

| Oxytetracycline amount | Indications for use | Limitations | Sponsor |
|---|---|---|---|
| * | * | * | |
| (iv) 333 to 7,500 g/ton to provide 2.5 to 3.75 g/100 lb of fish/day. | 1. Freshwater-reared salmonids: for control of ulcer disease caused by *Haemophilus piscium,* furunculosis caused by *Aeromonas salmonicida,* bacterial hemorrhagic septicemia caused by *A. hydrophila,* and pseudomonas disease. | Administer in mixed ration for 10 days. Do not liberate fish or slaughter fish for food for 21 days following the last administration of medicated feed. | 066104 |
| | 2. Catfish: for control of bacterial hemorrhagic septicemia caused by *A. hydrophila* and pseudomonas disease. | Administer in mixed ration for 10 days. Do not liberate fish or slaughter fish for food for 21 days following the last administration of medicated feed. Do not administer when water temperature is below 16.7 °C (62 °F). | 066104 |
| (v) 500 to 7,500 g/ton to provide 3.75 g/100 lb of fish/day. | 1. Freshwater-reared salmonids: for control of mortality due to coldwater disease associated with *Flavobacterium psychrophilum* or for control of mortality due to columnaris disease associated with *Flavobacterium columnare*. | Administer in mixed ration for 10 days. Do not liberate fish or slaughter fish for food for 21 days following the last administration of medicated feed. | 066104 |
| | 2. Freshwater-reared salmonids weighing up to 55 grams: for marking of the skeletal tissue. | Feed for 10 days. Immediate release is permitted following last feeding of medicated feed. | 066104 |
| | 3. Catfish: for control of mortality due to columnaris disease associated with *Flavobacterium columnare*. | Administer in mixed ration for 10 days. Do not liberate fish or slaughter fish for food for 21 days following the last administration of medicated feed. Do not administer when water temperature is below 16.7 °C (62 °F). | 066104 |
| (vi) 1.25 to 25 g/kg to provide 11.35 g/100 lb of fish/day. | Pacific salmon not over 30 grams body weight: for marking of the skeletal tissue. | Administer medicated feed as the sole ration for 4 consecutive days. Do not liberate for at least 7 days following last feeding of medicated feed. | 066104 |
| * | * | * | |

* * * * *

Dated: October 21, 2024.

**Eric Flamm,**

*Acting Associate Commissioner for Policy.*

[FR Doc. 2024–24820 Filed 10–25–24; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF STATE

### 22 CFR Part 92

**[Public Notice: 12553]**

**RIN 1400–AF89**

### Notarial and Related Services

**AGENCY:** Bureau of Consular Affairs, Department of State.

**ACTION:** Final rule.

**SUMMARY:** The Bureau of Consular Affairs amends its notarial rules to reflect that the Director, Deputy Directors, and regional Division Chiefs of the Office of American Citizens Services and Crisis Management, Overseas Citizens Services will designate U.S. citizen employees of the Department of State abroad, who are not diplomatic or consular officers, to perform notarial services. This change will streamline the designation process allowing expedited designation to provide this and expedite notarial service where needed at U.S. embassies and consulates abroad.

**DATES:** This rule is effective on November 27, 2024.

**FOR FURTHER INFORMATION CONTACT:** Thales Dus, U.S. Department of State, CA/OCS/MSU, SA–17, 10th Floor, Washington, DC 20522–1707, *OCSRegs@state.gov,* 202–485–6020.

**SUPPLEMENTARY INFORMATION:** This final rule modifies the Department's regulations on Notarial and Related Services in 22 CFR part 92. Amendments to § 92.1 authorize the Director, Deputy Directors and regional Division Chiefs of the Office of American Citizens Services and Crisis Management, Bureau of Consular Affairs, to designate U.S. citizen employees of the U.S. Department of State abroad, who are not diplomatic or consular officers, to perform notarial services at U.S. diplomatic and consular offices abroad. This change will replace the authorization for the Deputy Assistant Secretary for Overseas Citizens Services as the sole Department official able to designate U.S. citizen employees of the Department abroad as notarizing officers.

The Department is making this change to improve efficiencies in the process of designating Department employees as notarizing officers at U.S. embassies and consulates abroad. Demand for notarial services at 230 diplomatic and consular posts abroad varies from year to year but the trend line for requests for notarial services is ever increasing. The authority to designate U.S. citizen Department employees as notarizing officers has been a key resource for addressing increasing demand at posts abroad. The changes to this regulation authorizing an increase in the number of persons able to make such designations will place the Department on a more