boundaries; designated altitudes; times of designation; or activities conducted within the affected restricted areas.

DATES: *Effective date:* 0901 UTC, December 12, 2013.

FOR FURTHER INFORMATION CONTACT: Colby Abbott, Airspace Policy and ATC Procedures Group, Office of Airspace Services, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Background

As a result of the realignment of organizational responsibilities between federal agencies, U.S. Customs and Border Protection has been assigned the function of using agency for restricted areas R–2309 and R–2312 located in Arizona. The transfer of using agency operational control occurs October 1, 2013. This action is an administrative name change only and does not affect the current dimensions or use of the restricted areas.

The Rule

This action amends Title 14 Code of Federal Regulations (14 CFR) part 73 by amending the using agency name for Restricted Areas R–2309 Yuma, AZ, and R–2312 Fort Huachuca, AZ. The using agency for these restricted areas is changed from ''U.S. Air Force, Western Air Defense Sector/DOS, McChord AFB, WA'' to ''U.S. Customs and Border Protection, Air and Marine Operations Center (AMOC), Riverside, CA.''

This is an administrative change to update the title of the using agencies. It does not affect the boundaries, designated altitudes, or activities conducted within the restricted areas; therefore, notice and public procedures under 5 U.S.C. 553(b) are unnecessary.

The FAA has determined that this action only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this regulation: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority.

This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it amends the descriptions of restricted areas R–2309 and R–2312 to reflect current organizational responsibilities.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1E, Environmental Impacts: Policies and Procedures, paragraph 311d. This airspace action is an administrative change to the descriptions of the affected restricted areas to update the using agency name. It does not alter the dimensions, altitudes, or times of designation of the airspace; therefore, it is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exists that warrant preparation of an environmental assessment.

List of Subjects in 14 CFR Part 73

Airspace, Prohibited areas, Restricted areas.

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 73, as follows:

PART 73—SPECIAL USE AIRSPACE

■ 1. The authority citation for part 73 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 73.23 [Amended]

■ 2. Section 73.23 is amended as follows:

* * * * *

R–2309 Yuma, AZ [Amended]

By removing the current using agency and substituting the following:

Using agency. U.S. Customs and Border Protection, Air and Marine Operations Center (AMOC), Riverside, CA.

* * * * *

R–2312 Fort Huachuca, AZ [Amended]

By removing the current using agency and substituting the following:

Using agency. U.S. Customs and Border Protection, Air and Marine Operations Center (AMOC), Riverside, CA.

Issued in Washington, DC, on October 21, 2013.

Gary A. Norek,

Manager, Airspace Policy and ATC Procedures Group.

[FR Doc. 2013–25210 Filed 10–24–13; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

[Docket No. FDA–2013–N–0002]

New Animal Drugs; Change of Sponsor; Gonadorelin; Ivermectin; Ractopamine; Trimethoprim and Sulfadiazine Suspension; Tulathromycin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval actions for new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) during July 2013. FDA is also informing the public of the availability of summaries of the basis of approval and of environmental review documents, where applicable. The animal drug regulations are also being amended to reflect a change of sponsorship for an ANADA.

DATES: This rule is effective October 25, 2013.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV–6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855; 240–276–9019; *george.haibel@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA is amending the animal drug regulations to reflect approval actions for NADAs and ANADAs during July 2013, as listed in table 1. In addition, FDA is informing the public of the availability, where

applicable, of documentation of environmental review required under the National Environmental Policy Act (NEPA) and, for actions requiring review of safety or effectiveness data, summaries of the basis of approval (FOI Summaries) under the Freedom of Information Act (FOIA). These public documents may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday. Persons with access to the Internet may obtain these documents at the CVM FOIA Electronic Reading Room: *http://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CVM/CVMFOIAElectronicReadingRoom/default.htm.*

In addition, ECO LLC, 344 Nassau St., Princeton, NJ 08540 has informed FDA that it has transferred ownership of, and all rights and interest in, ANADA 200–348 for ECOMECTIN (ivermectin) Topical Solution to SmartVet USA, Inc., 22201 West Innovation Dr., Suite 170A, Olathe, KS 66061–1304. Accordingly, the Agency is amending the regulations to reflect this change of sponsorship.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS AND ANADAS APPROVED DURING JULY 2013

NADA/ ANADA	Sponsor	New Animal drug product name	Action	21 CFR Section	FOIA Summary	NEPA Review
139–237	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.	FACTREL (gonadorelin injection) Injection.	Supplemental approval for use with LUTALYSE (dinoprost tromethamine) Sterile Solution to synchronize estrous cycles to allow fixed-time artificial insemination (FTAI) in lactating dairy cows.	522.1077	Yes	CE [1]
141–349	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.	DRAXXIN 25 (tulathromycin) Injectable Solution.	Original approval for the treatment and control of swine respiratory disease (SRD).	522.2630	Yes	CE [1]
141–360	Aurora Pharmaceutical, LLC, 1196 Highway 3 South, Northfield, MN 55057–3009.	EQUISUL–SDT (sulfadiazine/ trimethoprim) Oral Suspension.	Original approval for the treatment of lower respiratory tract infections in horses caused by susceptible strains of *Streptococcus equi* subsp. *zooepidemicus*.	520.2612	Yes	CE [1]
200–542	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.	ENGAIN 9 and ENGAIN 45 (ractopamine hydrochloride) Type A medicated articles.	Original approval as a generic copy of NADA 140–863.	558.500	Yes	CE [1]
200–548	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.	ACTOGAIN 45 (ractopamine hydrochloride) Type A medicated articles.	Original approval as a generic copy of NADA 141–221.	558.500	Yes	CE [1]

[1] The Agency has determined under 21 CFR 25.33 that this action is categorically excluded (CE) from the requirement to submit an environmental assessment or an environmental impact statement because it is of a type that does not individually or cumulatively have a significant effect on the human environment.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, 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 and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510, 520, 522, 524, and 558 are amended as follows:

PART 510—NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR 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), alphabetically add entries for ''Aurora Pharmaceutical, LLC'' and ''SmartVet USA, Inc.''; and in the table in paragraph (c)(2), numerically add entries for ''051072'' and ''086001'' to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * * *	
Aurora Pharmaceutical, LLC, 1196 Highway 3 South, Northfield, MN 55057–3009	051072
* * * * *	
SmartVet USA, Inc., 22201 West Innovation Dr., Suite 170A, Olathe, KS 66061–1304	086001
* * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * *	
051072	Aurora Pharmaceutical, LLC, 1196 Highway 3 South, Northfield, MN 55057–3009
* * * * *	
086001	SmartVet USA, Inc., 22201 West Innovation Dr., Suite 170A, Olathe, KS 66061–1304
* * * * *	

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 3. The authority citation for 21 CFR part 520 continues to read as follows:

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

■ 4. Revise § 520.2612 to read as follows:

§ 520.2612 Trimethoprim and sulfadiazine suspension.

(a) *Specifications.* Each milliliter (mL) of suspension contains:

(1) 10 milligrams (mg) trimethoprim and 50 mg sulfadiazine; or

(2) 400 mg combined active ingredients (67 mg trimethoprim and 333 mg sulfadiazine).

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

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

(2) No. 051072 for use of product described in paragraph (a)(2) for use as in paragraph (c)(2) of this section.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Administer 1 mL (10 mg trimethoprim and 50 mg sulfadiazine) per 5 pounds (lb) of body weight once daily, or one-half the recommended daily dose every 12 hours, for up to 14 consecutive days.

(ii) *Indications for use.* The drug is used in dogs where systemic antibacterial action against sensitive organisms is required, either alone or as an adjunct to surgery or debridement with associated infection. The drug is indicated where control of bacterial infection is required during the treatment of acute urinary tract infections, acute bacterial complications of distemper, acute respiratory tract infections, acute alimentary tract infections, wound infections, and abscesses.

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

(2) *Horses*—(i) *Amount.* Administer 24 mg combined active ingredients per kilogram of body weight (2.7 mL/100 lb) twice daily for 10 days.

(ii) *Indications for use.* For the treatment of lower respiratory tract infections in horses caused by susceptible strains of *Streptococcus equi* subsp. *zooepidemicus.*

(iii) *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.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 5. The authority citation for 21 CFR part 522 continues to read as follows:

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

■ 6. Revise § 522.1077 to read as follows:

§ 522.1077 Gonadorelin hydrochloride.

(a) *Specifications.* Each milliliter of solution contains 50 micrograms (mcg) of gonadorelin (as hydrochloride).

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

(c) *Conditions of use in cattle*—(1) *Indications for use and amounts*—(i) For the treatment of ovarian follicular cysts in cattle, administer 100 mcg gonadorelin by intramuscular injection.

(ii) For use with dinoprost tromethamine to synchronize estrous cycles to allow fixed-time artificial insemination (FTAI) in lactating dairy cows, administer to each cow 100 to 200 mcg gonadorelin by intramuscular injection, followed 6 to 8 days later by 25 mg dinoprost tromethamine by intramuscular injection, followed 30 to 72 hours later by 100 to 200 mcg gonadorelin by intramuscular injection.

(2) *Limitations.* Dinoprost tromethamine as provided by sponsor No. 054771 in § 510.600(c) of this chapter. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

■ 7. In § 522.2630, revise paragraphs (a) and (b) to read as follows:

§ 522.2630 Tulathromycin.

(a) *Specifications.* Each milliliter of solution contains:

(1) 100 milligrams (mg) tulathromycin

(2) 25 mg tulathromycin

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter for use as in paragraph (d) of this section:

(1) Product described as in paragraph (a)(1) for use as in paragraph (d).

(2) Product described as in paragraph (a)(2) for use as in paragraph (d)(2).

* * * * *

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

■ 8. The authority citation for 21 CFR part 524 continues to read as follows:

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

§ 524.1193 [Amended]

■ 9. In paragraph (b)(2) of § 524.1193, remove ''066916'' and in its place add ''086001''.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 10. The authority citation for 21 CFR part 558 continues to read as follows:

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

§ 558.500 [Amended]

■ 11. In § 558.500, in paragraph (a), remove ''45'' and in its place add ''45.4''; in paragraph (b), remove ''No. 000986'' and in its place add ''Nos. 000986 and 054771''; in the table in paragraph (e)(1), in the ''Ractopamine in grams/ton'' column, remove ''4.5 to 9'' wherever it occurs and in its place add ''4.5 to 9.0''; and in the table in paragraphs (e)(1)(i), (e)(2)(i), (e)(2)(vi), and (e)(2)(xi), in the ''Sponsor'' column, add ''054771''.

Dated: October 22, 2013.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2013–25172 Filed 10–24–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1240

[Docket No. FDA–2013–N–0639]

Turtles Intrastate and Interstate Requirements

Correction

In rule document 2013–17751 appearing on pages 44878–44881 in the issue of July 25, 2013, make the following correction:

On page 44879, in the first column, under the **DATES** heading, in the first and second lines, ''January 16, 2014'' should read ''December 9, 2013''.

[FR Doc. C1–2013–17751 Filed 10–24–13; 8:45 am]

BILLING CODE 1505–01–D