

through which a pilot can request a replacement airman certificate or obtain a document that provides temporary authority to exercise the privileges of an airman certificate by facsimile or through internet download at the FAA Web site: [http://www.faa.gov/licenses\\_certificates/airmen\\_certification/certificate\\_replacement/](http://www.faa.gov/licenses_certificates/airmen_certification/certificate_replacement/). The use of Airmen Online Services is not addressed or recognized in § 61.29. Therefore, in the direct final rule published September 16, 2013, the FAA amended the language in § 61.29 to reflect the use of Airmen Online Services or any method acceptable to the FAA for the purpose of obtaining a replacement certificate or 60-day authority to exercise the privileges of a lost or stolen certificate.

The FAA also revised § 61.3 to clarify that temporary documents issued under § 61.29(e) are acceptable for meeting the § 61.3 requirement that a pilot have his or her pilot certificate and medical certificate in the person's physical possession when serving as a required flightcrew member.

#### Discussion of Comments

The FAA received 7 comments to the direct final rule. All commenters supported the rule as published. Commenters supported the regulatory changes, noting that they would relieve burdens for the regulated community, and would potentially reduce costs for certified flight instructors.

#### Conclusion

After consideration of the comments submitted in response to the direct final rule, the FAA has determined that no further rulemaking action is necessary. Therefore, the direct final rule published September 16, 2013 at 78 FR 56822, Amendment No. 61–131, will become effective November 15, 2013.

#### How To Obtain Additional Information

##### A. Rulemaking Documents

An electronic copy of a rulemaking document may be obtained by using the Internet—

1. Search the Federal eRulemaking Portal at <http://www.regulations.gov>;
2. Visit the FAA's Regulations and Policies Web page at [http://www.faa.gov/regulations\\_policies/](http://www.faa.gov/regulations_policies/) or
3. Access the Government Printing Office's Web page at <http://www.gpo.gov/fdsys/>.

Copies may also be obtained by sending a request (identified by notice, amendment, or docket number of this rulemaking) to the Federal Aviation Administration, Office of Rulemaking,

ARM-1, 800 Independence Avenue SW., Washington, DC 20591, or by calling (202) 267-9680.

##### B. Comments Submitted to the Docket

Comments received may be viewed by going to <http://www.regulations.gov> and following the online instructions to search the docket number for this action. Anyone is able to search the electronic form of all comments received into any of the FAA's dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.).

##### C. Small Business Regulatory Enforcement Fairness Act

The Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996 requires FAA to comply with small entity requests for information or advice about compliance with statutes and regulations within its jurisdiction. A small entity with questions regarding this document, may contact its local FAA official, or the person listed under the **FOR FURTHER INFORMATION CONTACT** heading at the beginning of the preamble. To find out more about SBREFA on the Internet, visit [http://www.faa.gov/regulations\\_policies/rulemaking/sbre\\_act/](http://www.faa.gov/regulations_policies/rulemaking/sbre_act/).

Issued under authority provided by 49 U.S.C. 106(f), 44701(a), and 44703 in Washington, DC, on December 31, 2013.

**Lirio Liu,**

*Director, Office of Rulemaking.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

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

**[Docket No. FDA-2013-N-0002]**

#### New Animal Drugs; Afoxolaner; Carprofen; Ceftiofur Hydrochloride; Monensin

**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 September 2013. FDA is also informing the public of the

availability of summaries on 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 November 5, 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](mailto:george.haibel@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** FDA is amending the animal drug regulations to reflect approval actions for NADAs and ANADAs during September 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 Center for Veterinary Medicine FOIA Electronic Reading Room: <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CVM/CVMFOIA/ElectronicReadingRoom/default.htm>.

In addition, Piedmont Animal Health, 204 Muirs Chapel Rd., suite 200, Greensboro, NC 27410 has informed FDA that it has transferred ownership of, and all rights and interest in, ANADA 200-555 for LIBREVIA (carprofen) Soft Chewable Tablets to Bayer HealthCare LLC, Animal Health Division, P.O. Box 390, Shawnee Mission, KS 66201. Accordingly, the Agency is amending the regulations to reflect this change of sponsorship.

Following this change of sponsorship, Piedmont Animal Health is no longer a sponsor of an approved NADA. Accordingly, FDA is amending 21 CFR 510.600 to remove the entries for this firm.

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 SEPTEMBER 2013

NADA/ANADA	Sponsor	New animal drug product name	Action	21 CFR Section	FOIA Summary	NEPA Review
141-406 ...	Merial Ltd., 3239 Satellite Blvd., Bldg. 500, Duluth, GA 30096-4640.	NEXGARD (afoxolaner), Chewable Tablets.	Original approval for the treatment and prevention of flea infestations, and the treatment and control of American dog tick infestations in dogs.	520.43	yes .....	CE <sup>1,2</sup> .
095-735 ...	Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285.	RUMENSIN (monensin). Type A medicated article.	Supplement extending the lower dose limit of monensin medicated feed for pasture cattle from 25 grams per ton (g/ton) to 15 g/ton.	558.355	yes .....	CE <sup>1,3</sup> .
141-288 ...	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.	EXCENEL RTU EZ (ceftiofur hydrochloride), Injectable Suspension.	Supplemental approval of a reformulated product for use in cattle and swine, addition of an intramuscular route of injection in cattle, change in withdrawal period for cattle, and addition of a warning statement.	522.313b	yes .....	CE <sup>1,4</sup> .

<sup>1</sup> 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.

<sup>2</sup> CE granted under 21 CFR 25.33(d)(1).

<sup>3</sup> CE granted under 21 CFR 25.33(a)(1).

<sup>4</sup> CE granted under 21 CFR 25.33(a)(3).

## List of Subjects

### 21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

### 21 CFR Parts 520 and 522

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, 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, 360b, 371, 379e.

### § 510.600 [Amended]

■ 2. In § 510.600, in the table in paragraph (c)(1), remove the entry for “Piedmont Animal Health”; and in the table in paragraph (c)(2), remove the entry for “058147”.

## 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.

### §§ 520.44, 520.45, 520.45a, and 520.45b [Redesignated as §§ 520.28, 520.38, 520.38a, and 520.38b]

- 4. Redesignate §§ 520.44, 520.45, 520.45a, and 520.45b as §§ 520.28, 520.38, 520.38a, and 520.38b, respectively.
- 5. Add § 520.43 to read as follows:

#### § 520.43 Afoxolaner.

(a) *Specifications.* Each chewable tablet contains 11.3, 28.3, 68, or 136 milligrams (mg) afoxolaner.

(b) *Sponsor.* See No. 050604 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Amount.* Administer orally once a month at a minimum dosage of 1.14 mg/pound (lb) (2.5 mg/kilogram (kg)).

(2) *Indications for use.* For the treatment and prevention of flea infestations (*Ctenocephalides felis*), and the treatment and control of American dog tick (*Dermacentor variabilis*) infestations in dogs and puppies 8 weeks of age and older, weighing 4 pounds of body weight or greater, for 1 month.

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

### § 520.309 [Amended]

- 6. In paragraph (b)(2) of § 520.309, remove “Nos. 000115, 055529, 058147, and 062250” and in its place add “Nos. 000115, 000859, 055529, and 062250”.

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

- 7. The authority citation for 21 CFR part 522 continues to read as follows:

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

- 8. In 522.313b, revise paragraphs (b), (d), (e)(2)(i), and (e)(2)(iii) to read as follows:

### § 522.313b Ceftiofur hydrochloride.

\* \* \* \* \*

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

\* \* \* \* \*

(d) *Special considerations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits extra-label use of this drug in cattle and swine for disease prevention purposes; at unapproved doses, frequencies, durations, or routes of administration; and in unapproved major food-producing species/production classes.

(e) \* \* \*

(2) \* \* \*

(i) *Amount.* Administer by subcutaneous or intramuscular injection as follows:

(A) For bovine respiratory disease and acute bovine interdigital necrobacillosis: 1.1 to 2.2 mg/kg of body weight at 24-hour intervals for 3 to 5 consecutive days.

(B) For bovine respiratory disease: 2.2 mg/kg of body weight administered twice at a 48 hour interval.

(C) For acute metritis: 2.2 mg/kg of body weight at 24-hour intervals for 5 consecutive days.

\* \* \* \* \*

(iii) *Limitations.* Treated cattle must not be slaughtered for 4 days following the last treatment. A withdrawal period has not been established in preruminating calves. Do not use in calves to be processed for veal.

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

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

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

**§ 558.355 [Amended]**

■ 10. In § 558.355, in the introductory text in paragraph (f)(3)(iii), remove “Monensin, 25 to 400 grams” and in its place add “Monensin, 15 to 400 grams”.

Dated: October 31, 2013.

**Bernadette Dunham,**

*Director, Center for Veterinary Medicine.*

[FR Doc. 2013-26473 Filed 11-4-13; 8:45 am]

**BILLING CODE 4160-01-P**

**DEPARTMENT OF HOMELAND SECURITY****Coast Guard****33 CFR Part 117**

[USCG-2013-0901]

**Drawbridge Operation Regulations; Reynolds Channel, Lawrence, NY**

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of temporary deviation from regulations.

**SUMMARY:** The Commander, First Coast Guard District, has issued a temporary deviation from the regulations governing the operation of the Atlantic Beach Bridge, mile 0.4, across Reynolds Channel, at Lawrence, New York. This temporary deviation authorizes the Atlantic Beach Bridge to operate under an alternate schedule for 29 days, to complete bridge rehabilitation.

**DATES:** This deviation is effective from December 2, 2013 through December 31, 2013.

**ADDRESSES:** Documents mentioned in this preamble as being available in the docket are part of docket USCG-2013-0901 and are available online at [www.regulations.gov](http://www.regulations.gov), inserting USCG-2013-0901 in the “Keyword” and then clicking “Search”. They are also available for inspection or copying at the Docket Management Facility (M-30), U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this rule, call or email Ms. Judy Leung-Yee, Project Officer, First Coast Guard District, telephone (212) 668-7165, email

*judy.k.leung-yee@uscg.mil*. If you have questions on viewing the docket, call Barbara Hairston, Program Manager, Docket Operations, telephone 202-366-9826.

**SUPPLEMENTARY INFORMATION:** The Atlantic Beach Bridge, across Reynolds Channel, mile 0.4, at Lawrence, New York, has a vertical clearance in the closed position of 25 feet at mean high water and 30 feet at mean low water. The existing drawbridge operation regulations are listed at 33 CFR 117.799(e).

A temporary deviation for the drawbridge operations (78 FR 56610) is currently in effect. During ongoing rehabilitation of the bridge the contractor discovered more severe damage than originally anticipated, resulting from Super Storm Sandy in 2012. The owner of the bridge, Nassau County Bridge Authority, is requesting additional bridge closures in order to complete the bridge rehabilitation.

The waterway has commercial and seasonal recreational vessels of various sizes.

Under this temporary deviation the draw of the Atlantic Beach Bridge at mile 0.4, across Reynolds Channel shall operate as follows:

From December 2, 2013 through December 31, 2013, the bridge shall operate a single span on signal at 6 a.m., 12 p.m., 4 p.m., and 8 p.m. and at any time between 8 p.m. and 6 a.m. The draw shall open both spans at all times for commercial vessel traffic after at least a 48 hour advance notice is given by calling the number posted at the bridge. The draw may remain in the closed position between 12 a.m. and 5 a.m. on December 3, and December 4, 2013.

The Coast Guard contacted all known commercial waterway users regarding this deviation and no objections were received.

In accordance with 33 CFR 117.35(e), the bridge must return to its regular operating schedule immediately at the end of the designated time period. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: October 21, 2013.

**Gary Kassof,**

*Bridge Program Manager, First Coast Guard District.*

[FR Doc. 2013-26517 Filed 11-4-13; 8:45 am]

**BILLING CODE 9110-04-P**

**DEPARTMENT OF HOMELAND SECURITY****Coast Guard****33 CFR Part 117**

[Docket No. USCG-2013-0910]

**Drawbridge Operation Regulation; Elizabeth River, Eastern Branch, Norfolk, VA**

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of deviation from drawbridge regulation.

**SUMMARY:** The Coast Guard has issued a temporary deviation from the operating schedule that governs the draw of the Norfolk Southern #5 Railroad Bridge, across the Elizabeth River Eastern Branch, mile 1.1, at Norfolk, VA. This deviation is necessary to facilitate replacing the broken tread plates and milling the top of the plates and webs to create a flat surface on the Norfolk Southern #5 Railroad drawbridge. The final phase of repairs is shimming the tread plates into place. This temporary deviation allows the drawbridge to remain in the closed to navigation position.

**DATES:** This deviation is effective from November 5, 2013 through December 8, 2013, and has been enforced with actual notice since November 4, 2013.

**ADDRESSES:** The docket for this deviation, [USCG-2013-0910] is available at <http://www.regulations.gov>. Type the docket number in the “SEARCH” box and click “SEARCH.” Click on Open Docket Folder on the line associated with this deviation. You may also visit the Docket Management Facility in Room W12-140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this temporary deviation, call or email Mrs. Kashanda Booker, Bridge Administration Branch Fifth District, Coast Guard; telephone (757) 398-6227, email *Kashanda.l.booker@uscg.mil*. If you have questions on reviewing the docket, call Barbara Hairston, Program Manager, Docket Operations, 202-366-9826.

**SUPPLEMENTARY INFORMATION:** The Norfolk Southern Corporation, who owns and operates this drawbridge, has requested a temporary deviation from the current operating regulation set out in 33 CFR 117.5 to facilitate thermite welding on the rails.