

a street address, to the Branch Chief, Regulations and Paperwork Management Branch, U.S. Department of Agriculture, 300 7th Street SW., 7th Floor, Washington, DC 20024.

All written comments will be available for public inspection during regular work hours at the 300 7th Street, SW., 7th Floor address listed above.

**FOR FURTHER INFORMATION CONTACT:** Farah Ahmad, Rural Business-Cooperative Service, U.S. Department of Agriculture, Stop 3254, 1400 Independence Avenue SW., Washington, DC 20250-0783, Telephone: 202-245-1169. Email: [Farah.Ahmad@wdc.usda.gov](mailto:Farah.Ahmad@wdc.usda.gov).

**SUPPLEMENTARY INFORMATION:** On July 20, 2015, the Rural Housing Service, the Rural Business-Cooperative Service, the Rural Utilities Service, and the Farm Service Agency published an interim rule with comment in the **Federal Register** (80 FR 28807), “Strategic Economic and Community Development.” The interim rule identified that public comments were to be submitted by August 18, 2015. Unfortunately, the Web site [Regulations.gov](http://Regulations.gov) inadvertently closed the comment period on July 20, 2015, which was the closing date for comments on the information collection request. To compensate for closing the comment period early via the [Regulations.gov](http://Regulations.gov) Web site, this action provides commenters additional time to submit comments on the interim rule.

Dated: August 26, 2015.  
**Lisa Mensah,**  
*Under Secretary, Rural Development.*

Dated: August 27, 2015.  
**Michael Scuse,**  
*Under Secretary, Farm and Foreign Agricultural Services.*

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**BILLING CODE 3410-XY-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Parts 520, 524, and 558**

[Docket No. FDA-2015-N-0002]

**New Animal Drugs; Approval of New Animal Drug Applications**

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

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

**SUMMARY:** The Food and Drug Administration (FDA) 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 May and June 2015. 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 nonsubstantive change. This technical amendment is being made to improve the accuracy of the regulations.

**DATES:** This rule is effective September 4, 2015.

**FOR FURTHER INFORMATION CONTACT:** George K. Haibel, Center for Veterinary Medicine (HFV-6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-402-5689, [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 May and June 2015, 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>. Marketing exclusivity and patent information may be accessed in FDA’s publication, Approved Animal Drug Products Online (Green Book) at: <http://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/default.htm>.

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAs AND ANADAs APPROVED DURING MAY AND JUNE 2015

NADA/ANADA	Sponsor	New animal drug product name	Action	21 CFR sections	FOIA summary	NEPA review
141-417	Bayer HealthCare LLC, Animal Health Division, P.O. Box 390, Shawnee Mission, KS 66201.	CORAXIS (moxidectin) Topical Solution for Dogs.	Original approval for the prevention of heartworm disease, and for the treatment and control of intestinal hookworm, roundworm and whipworm infections in dogs.	524.1450	yes	CE. <sup>1,2</sup>
141-188	Merial Inc., 3239 Satellite Blvd., Bldg. 500, Duluth, GA 30096-4640.	MARQUIS (ponazuril) Oral Paste.	Supplemental approval of a revised dosage that includes a loading dose on the first day of treatment.	520.1855	yes	CE. <sup>1,2</sup>
141-262	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.	CERENIA (maropitant citrate) Tablets.	Supplemental approval extending duration of daily administration until resolution of acute vomiting.	520.1315	yes	CE. <sup>1,2</sup>

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS AND ANADAS APPROVED DURING MAY AND JUNE 2015—Continued

NADA/ANADA	Sponsor	New animal drug product name	Action	21 CFR sections	FOIA summary	NEPA review
141–291 .....	Dechra, Ltd., Snaygill Industrial Estate, Keighley Rd., Skipton, North Yorkshire, BD23 2RW, United Kingdom.	VETORYL (trilostane) Capsules.	Supplemental approval of a 5-milligram capsule size.	520.2598	no .....	CE. <sup>1,2</sup>
141–278 .....	Intervet, Inc., 2 Giralda Farms, Madison, NJ 07940.	ZILMAX (zilpaterol hydrochloride) plus RUMENSIN (monensin). Type A medicated articles.	Supplemental approval to provide for component feeding of combination drug Type C medicated feeds to cattle fed in confinement for slaughter.	558.665	yes .....	CE. <sup>1,3</sup>
141–282 .....	Intervet, Inc., 2 Giralda Farms, Madison, NJ 07940.	ZILMAX (zilpaterol hydrochloride) plus RUMENSIN (monensin) plus MGA (melengestrol acetate). Type A medicated articles.	Supplemental approval to provide for component feeding of combination drug Type C medicated feeds to heifers fed in confinement for slaughter.	558.665	yes .....	CE. <sup>1,3</sup>
141–284 .....	Intervet, Inc., 2 Giralda Farms, Madison, NJ 07940.	ZILMAX (zilpaterol hydrochloride) plus MGA (melengestrol acetate). Type A medicated articles.	Supplemental approval to provide for component feeding of combination drug Type C medicated feeds to heifers fed in confinement for slaughter.	558.665	yes .....	CE. <sup>1,3</sup>
200–497 .....	Norbrook Laboratories, Ltd., Station Works, Newry BT35 6JP, Northern Ireland.	LOXICOM (meloxicam) 1.5 mg/mL Oral Suspension.	Original approval as a generic copy of NADA 141–213.	520.1367	yes .....	CE. <sup>1,3</sup>
200–580 .....	Huvepharma AD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sofia, Bulgaria.	TYLOVET (tylosin phosphate) plus SACOX (salinomycin sodium) Type C medicated feeds.	Original approval as a generic copy of NADA 141–198.	<sup>4</sup> 558.550	yes .....	CE. <sup>1,3</sup>

<sup>1</sup> The Agency has determined 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 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> The regulation does not require amendment.

Also, the animal drug regulations are being amended to reflect approved labeling for hand feeding bambarmycins medicated cattle feed. This technical amendment is being made to improve the accuracy of the regulations.

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.

**List of Subjects**

21 CFR Parts 520 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 520, 524, and 558 are amended as follows:

**PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS**

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

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

■ 2. In § 520.1315, revise paragraph (c)(1) to read as follows:

**§ 520.1315 Maropitant.**

\* \* \* \* \*

(c) \* \* \*

(1) *Indications for use and amount.* (i) For prevention of acute vomiting in dogs 2 to 7 months of age, administer a minimum dose of 2.0 mg per kilogram (/kg) body weight once daily for up to 5 consecutive days.

(ii) For prevention of acute vomiting in dogs 7 months of age and older, administer a minimum dose of 2.0 mg/kg body weight once daily until resolution of acute vomiting.

(iii) For prevention of vomiting due to motion sickness in dogs 4 months of age and older, administer a minimum of 8.0 mg/kg body weight once daily for up to 2 consecutive days.

\* \* \* \* \*

**§ 520.1367 [Amended]**

■ 3. In § 520.1367, in paragraph (b)(2), remove “No. 013744” and in its place add “Nos. 013744 and 055529”.

■ 4. In § 520.1855, revise paragraph (c)(1) to read as follows:

**§ 520.1855 Ponazuril.**

\* \* \* \* \*

(c) \* \* \*

(1) *Amount.* Administer orally 15 mg per kilogram (kg) (6.81 mg per pound (lb)) body weight as the first dose, followed by 5 mg/kg (2.27 mg/lb) body weight once daily for a period of 27 additional days.

\* \* \* \* \*

**§ 520.2598 [Amended]**

■ 5. In § 520.2598, in paragraph (a), remove “10, 30, or 60 milligrams” and in its place add “5, 10, 30, 60, or 120 milligrams”.

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

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

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

■ 7. In § 524.1450, and revise paragraphs (a), (b), and (d), and remove paragraph (e).

The revisions read as follows:

**§ 524.1450 Moxidectin.**

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

- (1) 5 milligrams (mg) moxidectin (0.5 percent solution).
- (2) 25 mg moxidectin (2.5 percent solution).

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

(1) No. 000010 for use of product described in paragraph (a)(1) of this section as in paragraph (d)(1) of this section;

(2) No. 000859 for use of product described in paragraph (a)(2) of this section as in paragraph (d)(2) of this section.

\* \* \* \* \*

(d) *Conditions of use*—(1) *Cattle*—(i) *Amount.* Administer topically 0.5 mg per kilogram (kg) of body weight.

(ii) *Indications for use.* Beef and dairy cattle: For treatment and control of internal and external parasites: gastrointestinal roundworms (*Ostertagia ostertagi* (adult and L4, including inhibited larvae), *Haemonchus placei* (adult and L4), *Trichostrongylus axei* (adult and L4), *T. colubriformis* (adult and L4), *Cooperia oncophora* (adult and L4), *C. pectinata* (adult), *C. punctata* (adult and L4), *C. spatulata* (adult), *C. surnabada* (adult and L4), *Bunostomum phlebotomum* (adult),

*Oesophagostomum radiatum* (adult and L4), *Nematodirus helvetianus* (adult and L4); lungworms (*Dictyocaulus viviparus* (adult and L4)); cattle grubs (*Hypoderma bovis*, *H. lineatum*); mites (*Chorioptes bovis*, *Psoroptes ovis* (*P. communis* var. *bovis*)); lice (*Linognathus vituli*, *Haematopinus eurysternus*, *Solenopotes capillatus*, *Bovicola (Damalinia) bovis*); and horn flies (*Haematobia irritans*). To control infections and to protect from reinfection with *H. placei* for 14 days after treatment, *O. radiatum* and *O. ostertagi* for 28 days after treatment, and *D. viviparus* for 42 days after treatment.

(iii) *Limitations.* A withdrawal period has not been established for this product on preruminating calves. Do not use on calves to be processed for veal. See § 500.25 of this chapter.

(2) *Dogs*—(i) *Amount.* Administer topically a minimum of 1.1 mg per pound (lb) (2.5 mg/kg) of body weight, once monthly using the appropriate preloaded applicator tube.

(ii) *Indications for use.* For the prevention of heartworm disease caused by *Dirofilaria immitis*, as well as the treatment and control of intestinal hookworm (*Ancylostoma caninum* (adult, immature adult, and L4 larvae) and *Uncinaria stenocephala* (adult, immature adult, and L4 larvae)),

roundworm (*Toxocara canis* (adult and L4 larvae) and *Toxascaris leonina* (adult)), and whipworm (*Trichuris vulpis* (adult)) infections in dogs and puppies that are at least 7 weeks of age and that weigh at least 3 lbs.

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

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

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

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

**§ 558.95 [Amended]**

■ 9. In § 558.95, in the table in paragraph (d)(4)(ii), in the “Bambermycins in grams/ton” column, remove “2 to 40” and in its place add “2 to 80”; and in the “Limitations” column, remove the first sentence and in its place add “Feed continuously on a hand-fed basis at a rate of 10 to 40 milligrams per head per day in 1 to 10 pounds of supplemental Type C medicated feed.”.

■ 10. In § 558.665, revise paragraphs (d)(2) and (e) to read as follows:

**§ 558.665 Zilpaterol.**

\* \* \* \* \*

(d) \* \* \*

(2) Labeling of Type A medicated articles and Type B medicated feeds used to manufacture complete Type C medicated feeds shall bear the caution statement in paragraph (d)(3) of this section.

\* \* \* \* \*

(e) *Conditions of use in cattle.* It is administered in feed as follows:

Zilpaterol hydrochloride in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(1) 6.8 .....	.....	Cattle fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and increased carcass leanness in cattle fed in confinement for slaughter during the last 20 to 40 days on feed.	Feed continuously as the sole ration during the last 20 to 40 days on feed to provide 60 to 90 mg zilpaterol hydrochloride per head per day. Withdrawal period: 3 days. See paragraph (d) of this section.	000061
(2) 6.8 .....	Monensin 10 to 40 ...	Cattle fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and increased carcass leanness in cattle fed in confinement for slaughter during the last 20 to 40 days on feed; for prevention and control of coccidiosis due to <i>Eimeria bovis</i> and <i>E. zuernii</i> .	Feed continuously as the sole ration during the last 20 to 40 days on feed to provide 60 to 90 mg zilpaterol hydrochloride per head per day and 0.14 to 0.42 mg monensin per pound of body weight per day depending on the severity of the coccidiosis challenge, up to 480 mg/head/day monensin. Withdrawal period: 3 days. See paragraph (d) of this section. See paragraph § 558.355(d) of this chapter Monensin as provided by No. 000986 in § 510.600(c) of this chapter.	000061 000986

Zilpaterol hydrochloride in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(3) 6.8 .....	Melengestrol acetate to provide 0.25 to 0.5 mg/head/day.	Heifers fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and increased carcass leanness in cattle fed in confinement for slaughter during the last 20 to 40 days on feed; and for suppression of estrus (heat).	Feed continuously as the sole ration during the last 20 to 40 days on feed to provide 60 to 90 mg zilpaterol hydrochloride per head per day. Withdrawal period: 3 days. See paragraph (d) of this section. Melengestrol acetate as provided by Nos. 000986 or 054771 in §510.600(c) of this chapter.	000061 000986
(4) 6.8 .....	Monensin 10 to 40 plus melengestrol acetate to provide 0.25 to 0.5 mg/head/day.	Heifers fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and increased carcass leanness in cattle fed in confinement for slaughter during the last 20 to 40 days on feed; for prevention and control of coccidiosis due to <i>Eimeria bovis</i> and <i>E. zuernii</i> ; and for suppression of estrus (heat).	Feed continuously as the sole ration during the last 20 to 40 days on feed to provide 60 to 90 mg zilpaterol hydrochloride per head per day and 0.14 to 0.42 mg monensin per pound of body weight per day depending on the severity of the coccidiosis challenge, up to 480 mg/head/day monensin. Withdrawal period: 3 days. See paragraph (d) of this section. See paragraphs §§558.342(d) and 558.355(d) of this chapter. Monensin as provided by No. 000986; melengestrol acetate as provided by Nos. 000986 or 054771 in §510.600(c) of this chapter.	000061 000986
(5) 6.8 .....	Monensin 10 to 40, plus tylosin 8 to 10.	For increased rate of weight gain, improved feed efficiency, and increased carcass leanness in cattle fed in confinement for slaughter during the last 20 to 40 days on feed; for prevention and control of coccidiosis due to <i>Eimeria bovis</i> and <i>E. zuernii</i> ; and for reduction of incidence of liver abscesses caused by <i>Fusobacterium necrophorum</i> and <i>Arcanobacterium</i> ( <i>Actinomyces</i> ) <i>pyogenes</i> .	Feed continuously as the sole ration during the last 20 to 40 days on feed to provide 60 to 90 mg zilpaterol hydrochloride per head per day and 0.14 to 0.42 mg monensin per pound of body weight per day depending on the severity of the coccidiosis challenge, up to 480 mg/head/day monensin. Withdrawal period: 3 days. See paragraph (d) of this section. See paragraphs §§558.355(d) and 558.625(c) of this chapter. Monensin as provided by No. 000986; tylosin as provided by Nos. 000986 or 016592 in §510.600(c) of this chapter.	000061 016592
(6) 6.8 .....	Monensin 10 to 40, plus tylosin 8 to 10, plus melengestrol acetate to provide 0.25 to 0.5 mg/head/day.	Heifers fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and increased carcass leanness in cattle fed in confinement for slaughter during the last 20 to 40 days on feed; for prevention and control of coccidiosis due to <i>Eimeria bovis</i> and <i>E. zuernii</i> ; for reduction of incidence of liver abscesses caused by <i>Fusobacterium necrophorum</i> and <i>Arcanobacterium</i> ( <i>Actinomyces</i> ) <i>pyogenes</i> ; and for suppression of estrus (heat).	Feed continuously as the sole ration during the last 20 to 40 days on feed to provide 60 to 90 mg zilpaterol hydrochloride per head per day and 0.14 to 0.42 mg monensin per pound of body weight per day depending on the severity of the coccidiosis challenge, up to 480 mg/head/day monensin. Withdrawal period: 3 days. See paragraph (d) of this section. See paragraphs §§558.342(d), 558.355(d), and 558.625(c) of this chapter. Monensin as provided by No. 000986; tylosin as provided by Nos. 000986 or 016592; and melengestrol acetate as provided by Nos. 000986 or 054771 in §510.600(c) of this chapter.	000061 000986 016592
(7) 6.8 to 24 ..	.....	Cattle fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and increased carcass leanness in cattle fed in confinement for slaughter during the last 20 to 40 days on feed.	Feed continuously during the last 20 to 40 days on feed to provide 60 mg zilpaterol hydrochloride per head per day. Withdrawal period: 3 days. See paragraph (d) of this section.	000061

Zilpaterol hydrochloride in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(8) 6.8 to 24 ..	Monensin 10 to 40 ...	Cattle fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and increased carcass leanness in cattle fed in confinement for slaughter during the last 20 to 40 days on feed; and for prevention and control of coccidiosis due to <i>Eimeria bovis</i> and <i>E. zuernii</i> .	Feed continuously during the last 20 to 40 days on feed to provide 60 mg zilpaterol hydrochloride per head per day and 0.14 to 0.42 mg monensin per pound of body weight per day depending on the severity of the coccidiosis challenge, up to 480 mg/head/day monensin. Withdrawal period: 3 days. See paragraph (d) of this section. See paragraph §558.355(d) of this chapter. Monensin as provided by No. 000986 in §510.600(c) of this chapter.	000061
(9) 6.8 to 24 ..	Melengestrol acetate to provide 0.25 to 0.5 mg/head/day.	Heifers fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and increased carcass leanness in cattle fed in confinement for slaughter during the last 20 to 40 days on feed; and for suppression of estrus (heat).	Feed continuously during the last 20 to 40 days on feed to provide 60 mg zilpaterol hydrochloride per head per day. Withdrawal period: 3 days. See paragraph (d) of this section. See paragraph §558.342(d) of this part. Melengestrol acetate as provided by No. 054771 in §510.600(c) of this chapter.	000061
(10) 6.8 to 24	Monensin 10 to 40, plus melengestrol acetate to provide 0.25 to 0.5 mg/head/day.	Heifers fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and increased carcass leanness in cattle fed in confinement for slaughter during the last 20 to 40 days on feed; for prevention and control of coccidiosis due to <i>Eimeria bovis</i> and <i>E. zuernii</i> ; and for suppression of estrus (heat).	Feed continuously during the last 20 to 40 days on feed to provide 60 mg zilpaterol hydrochloride per head per day and 0.14 to 0.42 mg monensin per pound of body weight per day depending on the severity of the coccidiosis challenge, up to 480 mg/head/day monensin. Withdrawal period: 3 days. See paragraph (d) of this section. See paragraphs §§558.342(d) and 558.355(d) of this chapter. Monensin as provided by No. 000986; melengestrol acetate as provided by No. 054771 in §510.600(c) of this chapter.	000061
(11) 6.8 to 24	Monensin 10 to 40, plus tylosin 8 to 10.	Cattle fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and increased carcass leanness in cattle fed in confinement for slaughter during the last 20 to 40 days on feed; for prevention and control of coccidiosis due to <i>Eimeria bovis</i> and <i>E. zuernii</i> ; and for reduction of incidence of liver abscesses caused by <i>Fusobacterium necrophorum</i> and <i>Arcanobacterium (Actinomyces) pyogenes</i> .	Feed continuously during the last 20 to 40 days on feed to provide 60 mg zilpaterol hydrochloride per head per day and 0.14 to 0.42 mg monensin per pound of body weight per day depending on the severity of the coccidiosis challenge, up to 480 mg/head/day monensin. Withdrawal period: 3 days. See paragraph (d) of this section. See paragraphs §§558.355(d) and 558.625(c) of this chapter. Monensin and tylosin as provided by No. 000986 in §510.600(c) of this chapter.	000061
(12) 6.8 to 24	Monensin 10 to 40, plus tylosin 8 to 10, plus melengestrol acetate to provide 0.25 to 0.5 mg/head/day.	Heifers fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and increased carcass leanness in cattle fed in confinement for slaughter during the last 20 to 40 days on feed; for prevention and control of coccidiosis due to <i>Eimeria bovis</i> and <i>E. zuernii</i> ; for reduction of incidence of liver abscesses caused by <i>Fusobacterium necrophorum</i> and <i>Arcanobacterium (Actinomyces) pyogenes</i> ; and for suppression of estrus (heat).	Feed continuously during the last 20 to 40 days on feed to provide 60 mg zilpaterol hydrochloride per head per day and 0.14 to 0.42 mg monensin per pound of body weight per day depending on the severity of the coccidiosis challenge, up to 480 mg/head/day monensin. Withdrawal period: 3 days. See paragraph (d) of this section. See paragraphs §§558.342(d), 558.355(d), and 558.625(c) of this chapter. Monensin and tylosin as provided by No. 000986; melengestrol acetate as provided by No. 054771 in §510.600(c) of this chapter.	000061

Dated: August 31, 2015.

**Bernadette Dunham,**

Director, Center for Veterinary Medicine.

[FR Doc. 2015-21905 Filed 9-3-15; 8:45 am]

BILLING CODE 4164-01-P

**DEPARTMENT OF HOMELAND SECURITY****Coast Guard****33 CFR Part 100**

[Docket No. USCG–2010–1024]

**Olympia Harbor Days Tug Boat Races, Budd Inlet, WA****AGENCY:** Coast Guard, DHS.**ACTION:** Notice of enforcement of regulation.

**SUMMARY:** The Coast Guard will enforce the Special Local Regulation, Olympia Harbor Days Tug Boat Races, Budd Inlet, WA from 11:00 a.m. through 8:00 p.m. on September 6, 2015. This action is necessary to restrict vessel movement within the specified race area immediately prior to, during, and immediately after racing activity in order to ensure the safety of participants, spectators and the maritime public. Entry into, transit through, mooring or anchoring within the specified race area is prohibited unless authorized by the Captain of the Port, Puget Sound or Designated Representatives.

**DATES:** The regulations in 33 CFR 100.1309 will be enforced from 11:00 a.m. through 8:00 p.m. on September 6, 2015.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this document, call or email Petty Officer Ryan Griffin, Sector Puget Sound Waterways Management Division, Coast Guard; telephone 206–510–7888, email [SectorPugetSoundWWM@uscg.mil](mailto:SectorPugetSoundWWM@uscg.mil).

**SUPPLEMENTARY INFORMATION:** The Coast Guard is providing notice of enforcement of the Special Local Regulation for Olympia Harbor Days Tug Boat Races, Budd Inlet, WA in 33 CFR 100.1309 on September 6, 2015, from 11:00 a.m. to 8:00 p.m.

The following area is specified as a race area: All waters of Budd Inlet, WA the width of the navigation channel south of a line connecting the following points: 47°05.530' N. 122°55.844' W. and 47°05.528' N. 122°55.680' W. until reaching the northernmost end of the navigation channel at a line connecting the following points: 47°05.108' N. 122°55.799' W. and 47°05.131' N. 122°55.659' W. then southeasterly until reaching the southernmost entrance of the navigation channel at a line connecting the following points: 47°03.946' N. 122°54.577' W., 47°04.004' N. 122°54.471' W.

Under the provisions of 33 CFR 100.1309, the regulated area shall be closed immediately prior to, during and immediately after the event to all persons and vessels not participating in the event and authorized by the event sponsor.

This document is issued under authority of 33 CFR 100.1309 and 5 U.S.C. 552(a). In addition to this document in the **Federal Register**, the Coast Guard will provide the maritime community with advance notification of this enforcement period via the Local Notice to Mariners. If the Captain of the Port determines that the regulated area need not be enforced for the full duration stated in this document, he may use a Broadcast Notice to Mariners to grant general permission to enter the regulated area.

Dated: August 25, 2015.

**M.W. Raymond,***Captain, U.S. Coast Guard, Captain of the Port, Puget Sound.*

[FR Doc. 2015–22024 Filed 9–3–15; 8:45 am]

**BILLING CODE 9110–04–P****DEPARTMENT OF HOMELAND SECURITY****Coast Guard****33 CFR Part 117**

[Docket No. USCG–2015–0708]

**Drawbridge Operation Regulation; Petaluma River, Petaluma, CA****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 Haystack Landing Drawbridge across the Petaluma River, mile 12.4, at Petaluma, CA. The deviation is necessary to allow the bridge owner to replace the bridge. This deviation allows the bridge to remain in the closed-to-navigation position during the deviation period.

**DATES:** This deviation is effective without actual notice from September 4, 2015 to 6 p.m. on October 19, 2015. For the purposes of enforcement, actual notice will be used from 6 a.m. on August 31, 2015, until September 4, 2015.

**ADDRESSES:** The docket for this deviation, [USCG–2015–0708], 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 David H. Sulouff, Chief, Bridge Section, Eleventh Coast Guard District; telephone 510–437–3516, email [David.H.Sulouff@uscg.mil](mailto:David.H.Sulouff@uscg.mil). If you have questions on viewing the docket, call Cheryl Collins, Program Manager, Docket Operations, telephone 202–366–9826.

**SUPPLEMENTARY INFORMATION:** Sonoma Marin Area Rail Transit has requested a temporary change to the operation of the Haystack Landing Drawbridge across the Petaluma River, mile 12.4, at Petaluma, CA. The drawbridge navigation span provides approximately 3 feet vertical clearance above Mean High Water in the closed-to-navigation position. In accordance with 33 CFR 117.187(a), the draw is maintained in the fully open position, except for the crossing of trains or for maintenance. Navigation on the waterway is commercial and recreational.

The drawspan will be periodically secured in the closed-to-navigation position, during daylight hours from 6 a.m. on August 31, 2015 to 6 p.m. on October 19, 2015, due to bridge replacement construction. During daylight hours, the bridge will be secured in the closed to navigation position for construction, and will require four hours advance notice for bridge openings for commercial vessels moving on the tide.

Scheduled 30-minute bridge openings will be provided at midday for the passage of accumulated, small vessels. The bridge will be secured in the open-to-navigation position nights and weekends, when no work is in progress. This temporary deviation has been coordinated with the waterway users.

Vessels able to pass through the bridge in the closed position may do so at anytime. The bridge will be able to open for emergencies upon two hours advance notice. There is no alternative route available for vessel traffic. The Coast Guard will inform waterway users of this temporary deviation via our Local and Broadcast Notices to Mariners