funded. The Council may thereafter revise this list.

[FR Doc. 2014–25610 Filed 10–24–14; 4:15 pm]

BILLING CODE 3510–22–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 522, 524, and 556

[Docket No. FDA–2014–N–0002]

New Animal Drugs; Alfaxalone; Dinoprost; Ivermectin and Clorsulon; Nitrofurazone; Trenbolone and Estradiol Benzoate; Trimethoprim and Sulfadiazine; Tylosin; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule, technical amendment.

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 August 2014. 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 of two NADAs and one ANADA, and to reflect a revised food safety warning.

DATES: This rule is effective October 28, 2014.

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 August 2014, 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.*

In addition, Macleod Pharmaceuticals, Inc., 2600 Canton Ct., Fort Collins, CO 80525 has transferred ownership of, and all rights and interest in ANADA 200–033 for UNIPRIM (trimethoprim and sulfadiazine) Powder to Neogen Corp. (Neogen), 944 Nandino Blvd., Lexington, KY 40511. In 2004, Hess & Clark, Inc., transferred ownership of, and all rights and interest in NADA 011–154 for NFZ Puffer (nitrofurazone soluble powder) and NADA 140–851 for NFZ Wound Dressing (nitrofurazone ointment) to Neogen. At this time, the regulations are being amended to reflect these transfers.

Following these changes of sponsorship, Macleod Pharmaceuticals, Inc., and Hess & Clark, Inc., will no longer be the sponsor of an approved application. Accordingly, 21 CFR 510.600(c) is being amended to remove the entries for these firms.

Also, the animal drug regulations are being amended in 21 CFR 522.690 to revise a human food safety warning for dinoprost tromethamine injectable solution. This 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.

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS AND ANADAS APPROVED DURING AUGUST 2014

NADA/ ANADA	Sponsor	New animal drug product name	Action	21 CFR Sections	FOIA Summary	NEPA Review
140–833	Merial Ltd., 3239 Satellite Blvd., Bldg. 500, Duluth, GA 30096–4640.	IVOMEC Plus (ivermectin and clorsulon) Injection for Cattle.	Supplemental approval reducing the preslaughter withdrawal period from 49 days to 21 days.	522.1193 ..... 556.344	yes	CE.[1 2]
141–043	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.	SYNOVEX CHOICE (trenbolone and estradiol implant).	Supplemental approval for increased rate of weight gain and improved feed efficiency in heifers fed in confinement for slaughter.	522.2478	yes	EA/FONSI.[3]
141–342	Jurox Pty. Ltd., 85 Gardiner Rd., Rutherford, NSW 2320, Australia.	ALFAXAN (alfaxalone) Injectable Anesthetic for Dogs and Cats.	Supplemental approval adding a label statement that alfaxalone is a Class IV controlled substance.	522.52	no	CE.[1 4]

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS AND ANADAS APPROVED DURING AUGUST 2014—Continued

NADA/ ANADA	Sponsor	New animal drug product name	Action	21 CFR Sections	FOIA Summary	NEPA Review
141–348	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.	SYNOVEX ONE FEEDLOT (trenbolone and estradiol extended release implant). SYNOVEX ONE GRASS (trenbolone and estradiol extended release implant).	Original approval for increased rate of weight gain and improved feed efficiency for up to 200 days in steers and heifers fed in confinement for slaughter. Original approval for increased rate of weight gain for up to 200 days in pasture steers and heifers (slaughter, stocker, and feeder).	522.2478	yes	EA/FONSI.[1 3]
200–455[5]	Cross Vetpharm Group Ltd. Broomhill Rd., Tallaght,. Dublin 24, Ireland	TYLOMED–WS (tylosin tartrate) Soluble Powder.	Supplemental approval of a change to veterinary prescription (Rx) marketing status to conform with reference (pioneer) product.	520.2640	no	CE.[1 6]

[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.
[2] CE granted under 21 CFR 25.33(a).
[3] The Agency has carefully considered an environmental assessment (EA) of the potential environmental impact of this action and has made a finding of no significant impact (FONSI).
[4] CE granted under 21 CFR 25.33(d)(1).
[5] This application was listed as being affected by guidance for industry (GFI) #213, ''New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209'', December 2013.
[6] CE granted under 21 CFR 25.33(a)(1).

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 556

Animal drugs, Foods.

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 556 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), remove the entries for ''Macleod Pharmaceuticals, Inc.'' and ''Hess & Clark, Inc.'' and alphabetically add an entry for ''Neogen Corp.''; and in the table in paragraph (c)(2), remove the entries for ''058711'' and ''050749'' and numerically add an entry for ''059051'' 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
* * * * * * *	
Neogen Corp., 944 Nandino Blvd., Lexington, KY 40511	059051
* * * * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * * * *	
059051	Neogen Corp., 944 Nandino Blvd., Lexington, KY 40511

Drug labeler code	Firm name and address
*	* * * * * *

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.

§ 520.2613 [Amended]

■ 4. In paragraph (b) of § 520.2613, remove ''058711'' and in its place add ''059051''.

■ 5. In § 520.2640, revise paragraphs (b), (d), and (e)(2)(ii) to read as follows:

§ 520.2640 Tylosin.

* * * * *

(b) *Sponsors*—(1) No. 000986 for use as in paragraph (e) of this section.

(2) Nos. 016592 and 061623 for use as in paragraphs (e)(1)(i)(A), (e)(1)(ii), (e)(2), (e)(3), and (e)(4) of this section.

* * * * *

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

(e) * * *

(2) * * *

(ii) *Indications for use.* For the reduction in severity of effects of infectious sinusitis associated with *Mycoplasma gallisepticum.*

* * * * *

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

■ 7. In § 522.52, in paragraph (c)(3), add a second sentence to read as follows:

§ 522.52 Alfaxalone.

* * * * *

(c) * * *

(3) * * * Alfaxalone is a Class IV controlled substance.

■ 8. In § 522.690, revise paragraph (d)(1)(iii) to read as follows:

§ 522.690 Dinoprost.

* * * * *

(d) * * *

(1) * * *

(iii) *Limitations.* Do not use in horses intended for human consumption.

* * * * *

■ 9. In § 522.1193, revise paragraph (e)(3) to read as follows:

§ 522.1193 Ivermectin and clorsulon.

* * * * *

(e) * * *

(3) *Limitations.* For No. 050604: Do not treat cattle within 21 days of slaughter. For Nos. 055529 and 058005: Do not treat cattle within 49 days of slaughter. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. A withdrawal period has not been established for preruminating calves. Do not use in calves to be processed for veal.

■ 10. In § 522.2478, revise paragraphs (a), (d)(1)(i) introductory text, (d)(1)(ii) introductory text, and (d)(2); and add paragraphs (d)(1)(iii) and (d)(3) to read as follows:

§ 522.2478 Trenbolone acetate and estradiol benzoate.

(a) *Specifications*—(1) Each implant consists of:

(i) 8 pellets, each pellet containing 25 milligrams (mg) trenbolone acetate and 3.5 mg estradiol benzoate.

(ii) 4 pellets, each pellet containing 25 mg trenbolone acetate and 3.5 mg estradiol benzoate.

(2) Each extended release implant consists of:

(i) 8 pellets with a porous polymer film coating, each pellet containing 25 mg trenbolone acetate and 3.5 mg estradiol benzoate.

(ii) 6 pellets with a porous polymer film coating, each pellet containing 25 mg trenbolone acetate and 3.5 mg estradiol benzoate.

* * * * *

(d) * * *

(1) * * *

(i) For an implant as described in paragraph (a)(1)(i) of this section:

* * * * *

(ii) For an implant as described in paragraph (a)(1)(ii) of this section:

* * * * *

(iii) For an implant as described in paragraph (a)(2)(i) of this section:

(A) *Amount.* 200 mg trenbolone acetate and 28 mg estradiol benzoate in an extended release implant.

(B) *Indications for use.* For increased rate of weight gain and improved feed efficiency for up to 200 days.

(C) *Limitations.* Implant subcutaneously in ear only. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(2) *Heifers fed in confinement for slaughter*—(i) For an implant as described in paragraph (a)(1)(i) of this section:

(A) *Amount.* 200 mg trenbolone acetate and 28 mg estradiol benzoate.

(B) *Indications for use.* For increased rate of weight gain.

(C) *Limitations.* Implant subcutaneously in ear only. Not for use in dairy or beef replacement heifers. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(ii) For an implant as described in paragraph (a)(1)(ii) of this section:

(A) *Amount.* 100 mg trenbolone acetate and 14 mg estradiol benzoate.

(B) *Indications for use.* For increased rate of weight gain and improved feed efficiency.

(C) *Limitations.* Implant subcutaneously in ear only. Not for use in dairy or beef replacement heifers. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(iii) For an implant as described in paragraph (a)(2)(i) of this section:

(A) *Amount.* 200 mg trenbolone acetate and 28 mg estradiol benzoate in an extended release implant.

(B) *Indications for use.* For increased rate of weight gain and improved feed efficiency for up to 200 days.

(C) *Limitations.* Implant subcutaneously in ear only. Not for use in dairy or beef replacement heifers. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(3) *Pasture steers and heifers (slaughter, stocker, and feeder)*—(i) For an implant as described in paragraph (a)(2)(ii) of this section:

(A) *Amount.* 150 mg trenbolone acetate and 21 mg estradiol benzoate in an extended release implant.

(B) *Indications for use.* For increased rate of weight gain for up to 200 days.

(C) *Limitations.* Implant subcutaneously in ear only. Not for use in dairy or beef replacement heifers.

Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(ii) [Reserved]

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 524.1580a [Amended]

■ 12. In paragraph (b)(1) of § 524.1580a, remove ''Nos. 050749, 054628, 054925, 058005, and 061623'' and add in its place ''Nos. 054628, 054925, 058005, 059051, and 061623''.

§ 524.1580b [Amended]

■ 13. In paragraph (b) of § 524.1580b, remove ''No. 054628'' and in its place add ''Nos. 054628 and 059051''.

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

■ 14. The authority citation for 21 CFR part 556 continues to read as follows:

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

■ 15. In § 556.344, revise paragraphs (a), (b)(1)(i), and (b)(2)(ii); and add paragraph (c) to read as follows:

§ 556.344 Ivermectin.

(a) *Acceptable Daily Intake (ADI).* The ADI for total residues of ivermectin is 5 micrograms per kilogram of body weight per day.

(b) * * *

(1) * * *

(i) *Cattle.* 1.6 parts per million.

(2) * * *

(ii) *Cattle.* 650 parts per billion.

(c) *Related conditions of use.* See §§ 520.1192, 520.1195, 520.1197, 522.1192, 522.1193, 524.1193, and 558.300 of this chapter.

Dated: *October 23, 2014.*

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2014–25588 Filed 10–27–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2014–0747]

RIN 1625–AA00

Safety Zone; Allegheny River; Mile 45.7; Kittanning, PA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on the Allegheny River at mile 45.7. This safety zone is needed to protect vessels transiting the area and event spectators from the hazards associated with a barge-based fireworks display. Entry into this zone is prohibited unless specifically authorized by the Captain of the Port (COTP) Pittsburgh or a designated representative.

DATES: This rule is effective from 8:30 p.m. until 10:00 p.m. on November 21, 2014.

ADDRESSES: Documents mentioned in this preamble are part of docket USCG–2014–0747. To view documents mentioned in this preamble as being available in the docket, go to *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 rulemaking. 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 rule, call or email Jennifer Haggins, Marine Safety Unit Pittsburgh, U.S. Coast Guard, at telephone 412–644–5808, email *Jennifer.L.Haggins@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Cheryl F. Collins, Program Manager, Docket Operations, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

Table of Acronyms

DHS Department of Homeland Security
FR Federal Register
NPRM Notice of Proposed Rulemaking

A. Regulatory History and Information

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not using the NPRM process. Upon receiving notice of this display and after full review of the event information and location, the Coast Guard determined that a safety zone is necessary. Delaying this rule by completing the full NPRM process would unnecessarily delay the safety zone and be contrary to public interest because the safety zone is needed to protect transiting vessels, spectators, and the personnel involved in the display from the hazards associated with fireworks displays taking place over the waterway. Completing the full NPRM process could also unnecessarily delay the locally advertised and planned event and possibly interfere with contractual obligations.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this temporary rule effective less than 30 days after publication in the **Federal Register** for the same reasons discussed in the preceding paragraph, waiting for a 30 day notice period to run would be impracticable and contrary to the public interest.

B. Basis and Purpose

On November 21, 2014, as a part of Light Up Night, Downtown Kittanning Inc. will sponsor a barge-based fireworks display. The display will take place in the vicinity of mile 45.7 on the Allegheny River. This event presents safety hazards for spectators and vessels navigating in the area, and therefore a safety zone is needed to protect persons and property from the hazards associated with a fireworks display over the waterway.

The legal basis and authorities for this rule are found in 33 U.S.C. 1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Public Law 107–295, 116 Stat. 2064; and Department of Homeland Security Delegation No. 0170.1, which collectively authorize the Coast Guard to establish and define regulatory safety zones.

C. Discussion of the Final Rule

The Coast Guard is establishing a safety zone for all waters of the Allegheny River, mile 45.7, extending the entire width of the river. Entry into this zone is prohibited to all vessels and