

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

ANM MT E5 Wolf Point, MT [Modified]

Wolf Point, L M Clayton Airport, MT
(Lat. 48°05'40" N., long. 105°34'30" W.)

That airspace extending upward from 700 feet above the surface within an 8-mile radius of L M Clayton Airport; that airspace extending upward from 1,200 feet above the surface bounded by a line beginning at lat. 48°02'00" N., long. 104°13'00" W.; to lat. 47°48'00" N., long. 104°33'00" W.; to lat. 47°48'00" N., long. 106°00'02" W.; to lat. 48°20'00" N., long. 106°00'02" W.; to lat. 48°20'00" N., long. 104°17'00" W.; thence to the point of beginning.

Issued in Seattle, Washington, on October 11, 2012.

John Warner,

Manager, Operations Support Group, Western Service Center.

[FR Doc. 2012-26043 Filed 10-22-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 522, 524, 529, and 558

[Docket No. FDA-2012-N-0002]

New Animal Drugs; Approvals; Changes of Sponsor; Change of Sponsor's Name; Change of Sponsor's Address; Alfaxalone; Ivermectin and Clorsulon; Narasin; Triptorelin

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 2012. FDA is also informing the public of the availability of summaries 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 four ophthalmic ointments, a change of sponsor's name, and a change of sponsor's address.

DATES: This rule is effective October 23, 2012.

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, email: george.haibel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA is amending the animal drug regulations to reflect approval actions during September 2012, as listed in table 1. With respect to these actions, FDA is also 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 through the Center for Veterinary Medicine's FOIA Electronic Reading Room. FOI Summaries may be found listed by application number at: <http://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/FOIADrugSummaries/default.htm>.

www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/FOIADrugSummaries/default.htm. Environmental Assessments (EAs) and Finding Of No Serious Impacts (FONSIs) may be found listed by the established name of the active pharmaceutical ingredient at: <http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/EnvironmentalAssessments/ucm300656.htm>.

Also, Fougera Pharmaceuticals, Inc., P.O. Box 2006, 60 Baylis Rd., Melville, NY 11747, has informed FDA that it has transferred ownership of, and all rights and interest in, NADA 065-015 for VETROPOLYCIN HC (bacitracin zinc, polymyxin B sulfate, neomycin sulfate, and hydrocortisone) Ophthalmic Ointment, NADA 065-016 for VETROPOLYCIN (bacitracin zinc, neomycin sulfate, and polymyxin B sulfate) Ophthalmic Ointment, NADA 065-460 for VETROCLORICIN (chloramphenicol) Ophthalmic Ointment, and ANADA 200-273 for VETRO-GEN (gentamicin sulfate) Ophthalmic Ointment to Dechra Ltd., Dechra House, Jamage Industrial Estate, Talke Pits, Stoke-on-Trent, Staffordshire, ST7 1XW, United Kingdom. Accordingly, the Agency is amending the regulations in 21 CFR part 524 to reflect these changes.

In addition, UDL Laboratories, Inc., 12720 Dairy Ashford Rd., Sugar Land, TX 77478, has informed FDA that it has changed its name to Mylan Institutional, Inc., and ECO LLC, 8209 Hollister Ave., Las Vegas, NV 89131 has informed FDA of a change of address to 344 Nassau St., Princeton, NJ 08540. Accordingly, the Agency is amending the regulations in 21 CFR 510.600(c) to reflect these changes.

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS AND ANADAS APPROVED DURING JULY 2012

NADA/ ANADA	Sponsor	New animal drug product name	Action	21 CFR Section	FOIA Summary	NEPA Review
141-339 ...	JBS United Animal Health II LLC, 322 S. Main St., Sheridan, IN 46069.	OVUGEL (triptorelin acetate)	Original approval for the synchroni- zation of time of insemination in weaned sows to facilitate a sin- gle fixed-time artificial insemina- tion.	529.2620	yes	CE ¹
141-340 ...	Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285.	SKYCIS 100 (narasin) Type A medicated article.	Original approval for use in medi- cated feed for increased rate of weight gain and improved feed efficiency in growing-finishing swine.	558.363	yes	EA/ FONSI ²
141-342 ...	Jurox Pty. Ltd., 85 Gardiner Rd., Rutherford, NSW 2320, Australia.	ALFAXAN (alfaxalone) Intravenous Injectable Anesthetic for Cats and Dogs.	Original approval for the induction and maintenance of anesthesia and for induction of anesthesia followed by maintenance with an inhalant anesthetic, in dogs and cats.	522.52	yes	CE ¹

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAs AND ANADAs APPROVED DURING JULY 2012—Continued

NADA/ ANADA	Sponsor	New animal drug product name	Action	21 CFR Section	FOIA Summary	NEPA Review
200-466 ...	Sparhawk Laboratories, Inc., 12340 Santa Fe Trail Dr., Ft. Lenexa, KS 66215.	SPARMECTIN Plus Clorsulon (ivermectin and clorsulon) Injec- tion for Cattle.	Original approval as a generic copy of NADA 140-833.	522.1193	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 EA or an environmental impact statement (EIS) because it is of a type that does not individually or cumulatively have a significant effect on the human environment.

² Based on its review of an EA submitted by the sponsor, the Agency has concluded that this action will not have a significant impact on the human environment and that an EIS is not required. A FONSI has been prepared.

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 Part 510

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

21 CFR Parts 522, 524, and 529

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, 522, 524, 529, 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. Amend § 510.600 as follows:

■ a. In the table in paragraph (c)(1), revise the entry for “ECO LLC”; alphabetically add entries for “Jurox

Pty. Ltd.”; “JBS United Animal Health II LLC”; and “Mylan Institutional, Inc.”; and remove the entry for “UDL Laboratories, Inc.”; and

■ b. In the table in paragraph (c)(2), numerically add entries for “049480” and “051233” and revise the entries for “051079” and “066916”.

The additions and revisions 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
*	*	*	*	*	*	*
ECO LLC, 344 Nassau St., Princeton, NJ 08540						066916
*	*	*	*	*	*	*
JBS United Animal Health II LLC, 322 S. Main St., Sheridan, IN 46069						051233
*	*	*	*	*	*	*
Jurox Pty. Ltd., 85 Gardiner Rd., Rutherford, NSW 2320, Australia						049480
*	*	*	*	*	*	*
Mylan Institutional, Inc., 12720 Dairy Ashford Rd., Sugar Land, TX 77478						051079
*	*	*	*	*	*	*

(2) * * *

Drug labeler code	Firm name and address					
*	*	*	*	*	*	*
049480	Jurox Pty. Ltd., 85 Gardiner Rd., Rutherford, NSW 2320, Australia.					
*	*	*	*	*	*	*
051079	Mylan Institutional, Inc., 12720 Dairy Ashford Rd., Sugar Land, TX 77478.					
*	*	*	*	*	*	*
051233	JBS United Animal Health II LLC, 322 S. Main St., Sheridan, IN 46069.					
*	*	*	*	*	*	*
066916	ECO LLC, 344 Nassau St., Princeton, NJ 08540.					
*	*	*	*	*	*	*

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

■ 4. Add § 522.52 to read as follows:

§ 522.52 Alfaxalone.

(a) *Specifications.* Each milliliter contains 10 milligrams (mg) alfaxalone.

(b) *Sponsor.* See No. 049480 in § 510.600(c) of this chapter.

(c) *Conditions of use in cats and dogs—(1) Amount—(i) Cats—(A) Induction of general anesthesia.* Administer by intravenous injection over approximately 60 seconds or until clinical signs show the onset of anesthesia, 2.2 to 9.7 mg/kilogram (kg) for cats that did not receive a preanesthetic or 1.0 to 10.8 mg/kg for cats that received a preanesthetic.

(B) *Maintenance of general anesthesia following induction.* Administer an intravenous bolus containing 1.1 to 1.3 mg/kg to provide an additional 7 to 8 minutes of anesthesia in preanesthetized cats; a dose containing 1.4 to 1.5 mg/kg provides an additional 3 to 5 minutes anesthesia in unpreanesthetized cats.

(ii) *Dogs—(A) Induction of general anesthesia.* Administer by intravenous injection over approximately 60 seconds or until clinical signs show the onset of anesthesia, 1.5 to 4.5 mg/kg for dogs that did not receive a preanesthetic or 0.2 to 3.5 mg/kg for dogs that received a preanesthetic.

(B) *Maintenance of general anesthesia following induction.* Administer an intravenous bolus containing 1.2 to 1.4 mg/kg to provide an additional 6 to 8 minutes of anesthesia in preanesthetized dogs; a dose of 1.5 to 2.2 mg/kg provides an additional 6 to 8 minutes of anesthesia in unpreanesthetized dogs.

(2) *Indications for use.* For the induction and maintenance of anesthesia and for induction of anesthesia followed by maintenance with an inhalant anesthetic, in dogs and cats.

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

■ 5. In § 522.1193, revise paragraph (b) to read as follows:

§ 522.1193 Ivermectin and clorsulon.

* * * * *

(b) *Sponsors.* See Nos. 050604, 055529, and 058005 in § 510.600(c) of this chapter.

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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.

§ 524.154 [Amended]

■ 7. In § 524.154, in paragraph (a)(2), remove “025463” and in its place add “043264”; and in paragraph (b)(3), remove the first sentence.

§ 524.155 [Amended]

■ 8. In § 524.155, in paragraph (a)(2), remove “025463” and in its place add “043264”; and in paragraph (b)(3), remove the first and second sentences.

§ 524.390 [Amended]

■ 9. In § 524.390, in paragraph (b), remove “025463” and in its place add “043264”.

§ 524.1044c [Amended]

■ 10. In § 524.1044c, in paragraph (b), remove “025463” and in its place add “043264”.

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

■ 11. The authority citation for 21 CFR part 529 continues to read as follows:

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

■ 12. Add § 529.2620 to read as follows:

§ 529.2620 Triptorelin.

(a) *Specifications.* Each milliliter of gel contains 100 micrograms (mcg) triptorelin as triptorelin acetate.

(b) *Sponsor.* See No. 051233 in § 510.600(c) of this chapter.

(c) *Conditions of use in swine—(1) Amount.* Administer 200 mcg intravaginally approximately 96 hours after weaning.

(2) *Indications for use.* For the synchronization of time of insemination in weaned sows to facilitate a single fixed-time artificial insemination.

(3) *Limitations.* Not approved for use in gilts. Safety and effectiveness have not been evaluated in these animals. Should not be used in sows with obvious reproductive tract abnormalities.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

■ 14. In § 558.363, add paragraphs (a)(8) and (c); revise paragraph (d)(1)(xi)(B); redesignate paragraph (d)(2) as

paragraph (d)(3); and add new paragraph (d)(2) to read as follows:

§ 558.363 Narasin.

(a) * * *

(8) To 000986: 45.4 grams per pound for use as in paragraph (d)(2) of this section.

* * * * *

(c) *Special considerations.* An expiration date of 2 months (8 weeks) is required for narasin Type C medicated swine feeds.

(d) * * *

(1) * * *

(xi) * * *

(B) *Limitations.* For broiler chickens only. Feed continuously as sole ration. Do not allow adult turkeys, horses, or other equines access to formulations containing narasin. Ingestion of narasin by these species has been fatal. Narasin and tylosin as provided by 000986 in § 510.600(c) of this chapter.

(2) *Growing-finishing swine—(i) Amount per ton.* Narasin, 13.6 to 27.2 grams.

(A) *Indications for use.* For increased rate of weight gain when fed for at least 4 weeks.

(B) *Limitations.* Feed continuously for at least 4 weeks to swine during the growing-finishing period as the sole ration. No increased benefit in rate of weight gain has been shown when narasin concentrations in the diet are greater than 13.6 g/ton. Effectiveness has not been demonstrated when fed for durations less than 4 weeks. Do not allow adult turkeys, horses, or other equines access to narasin formulations. Ingestion of narasin by these species has been fatal. Not approved for use in breeding animals because safety and effectiveness have not been evaluated in these animals. Swine being fed with narasin should not have access to feeds containing pleuromutilins (e.g., tiamulin) as adverse reactions may occur. If signs of toxicity occur, discontinue use.

(ii) *Amount per ton.* Narasin, 18.1 to 27.2 grams.

(A) *Indications for use.* For increased rate of weight gain and improved feed efficiency when fed for at least 4 weeks.

(B) *Limitations.* Feed continuously for at least 4 weeks to swine during the growing-finishing period as the sole ration. No increased benefit in rate of weight gain has been shown when narasin concentrations in the diet are greater than 13.6 g/ton. Effectiveness has not been demonstrated when fed for durations less than 4 weeks. Do not allow adult turkeys, horses, or other equines access to narasin formulations. Ingestion of narasin by these species has been fatal. Not approved for use in

breeding animals because safety and effectiveness have not been evaluated in these animals. Swine being fed with narasin should not have access to feeds containing pleuromutilins (e.g., tiamulin) as adverse reactions may occur. If signs of toxicity occur, discontinue use.

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Dated: October 17, 2012.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2012–25989 Filed 10–22–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2012–0939]

RIN 1625–AA00

Safety Zone; Steam Ship Col. James M. Schoonmaker Relocation Project, Maumee River, Toledo, OH

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary Safety Zone on the waters of Maumee River, Toledo, Ohio, in support of the relocation of S/S Col. James M. Schoonmaker (hereinafter referred to as ‘the Schoonmaker’). This temporary safety zone will encompass all waters of the Maumee River within a 100 yard radius of the Schoonmaker as it makes its transit from International Park to Skyway Marina. This temporary Safety Zone is necessary to protect persons operating around the area.

DATES: This regulation is effective from 10:00 a.m. on October 27, 2012 until 4:00 p.m. on November 3, 2012.

ADDRESSES: Comments and material received from the public, as well as documents mentioned in this preamble as being available in the docket, are part of docket USCG–2012–0939 and are available online by going to <http://www.regulations.gov>, inserting USCG–2011–0195 in the “Keyword” box, and then clicking “Search.” This material is 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 LT Mallorie Schell, Prevention Department, MSU Toledo, Coast Guard; telephone (419) 418–6030, email Mallorie.G.Schell@uscg.mil. If you have questions on viewing or submitting material to the docket, call Renee V. Wright, 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 publishing a notice of proposed rulemaking (NPRM) with respect to this rule because doing so would be impracticable and contrary to the public interest. Although the Coast Guard has known about the relocation of the Schoonmaker for several weeks, only recently did the Coast Guard become aware of an expected high volume of spectator vessel traffic. Consequently, the need for this safety zone was not identified until there was insufficient time to allow a full comment period to run. Thus, waiting for a comment period to run prior to enforcing this safety zone would inhibit the Coast Guard’s ability to protect the public and vessels from the hazards associated with the heightened spectator activity associated with the relocation of the Schoonmaker.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. For the same reasons discussed above about not publishing an NPRM, the Coast Guard finds that waiting for a 30 day notice period to run would be impracticable and contrary to the public interest.

B. Basis and Purpose

The legal basis for the rule is the Coast Guard’s authority to establish regulated navigation areas and limited access areas: 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, 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

The Great Lakes Historical Society (GLHS) is relocating the Schoonmaker from International Park to Skyway Marina. This relocation is scheduled for October 27, 2012. If the relocation of the vessel on October 27 is cancelled for any reason, this safety zone will be effective and enforced from 10:00 a.m. until 4:00 p.m. on October 28, 2012. Likewise, if relocation on October 28th is cancelled, this safety zone will be effective and enforced from 10:00 a.m. until 4:00 p.m. on November 3, 2012. In light of the expected volume of spectator activity, the Captain of the Port Detroit has determined that this operation could pose certain public hazards, such as the increased risk of collisions.

C. Discussion of Rule

With aforementioned hazards in mind, the Captain of the Port Detroit has determined that a safety zone is necessary to ensure the safety of participants and vessels during the operation. The temporary safety zone established herein will be effective and enforced from 10:00 a.m. until 4:00 p.m. on October 27, 2012. If the relocation of the vessel on October 27 is cancelled for any reason, this safety zone will be effective and enforced from 10:00 a.m. until 4:00 p.m. on October 28, 2012. Likewise, if relocation on October 28 is cancelled, this safety zone will be effective and enforced from 10:00 a.m. until 4:00 p.m. on November 3, 2012.

Entry into, transiting, or anchoring within the safety zone is prohibited unless authorized by the Captain of the Port, Sector Detroit or his designated on scene representative. The Captain of the Port, Sector Detroit or his designated on scene representative may be contacted via VHF Channel 16. All persons and vessels allowed to enter the safety zone shall comply with the instructions of the Coast Guard Captain of the Port, designated on scene patrol personnel, or operation personnel.

D. Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on these statutes or executive orders.

1. Regulatory Planning and Review

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, as supplemented