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(I) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(3) The following service information was approved for IBR on November 27, 2012.

(i) Boeing Alert Service Bulletin 737-22A1211, dated April 13, 2010.

(ii) Boeing Alert Service Bulletin 737-22A1224, dated May 18, 2012.

(4) The following service information was approved for IBR on May 12, 2005 (70 FR 17603, April 7, 2005).

(i) Boeing Alert Service Bulletin 737-22A1164, dated May 20, 2004.

(ii) Reserved.

(5) For The Boeing Company service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H-65, Seattle, WA 98124-2207; telephone 206-544-5000, extension 1; fax 206-766-5680; Internet <https://www.myboeingfleet.com>.

(6) You may view this service information at FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington. For information on the availability of this material at the FAA, call 425-227-1221.

(7) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued in Renton, Washington, on October 5, 2012.

Ali Bahrami,

*Manager, Transport Airplane Directorate,
Airframe Certification Service.*

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA-2012-0569; Airspace
Docket No. 12-ANM-17]

Modification of Class E Airspace; Wolf Point, MT

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action modifies Class E airspace at Wolf Point, MT. Controlled airspace is necessary to accommodate aircraft using Nondirectional Radio

Beacon (NDB) standard instrument approach procedures at L M Clayton Airport, Wolf Point, MT. This improves the safety and management of Instrument Flight Rules (IFR) operations at the airport.

DATES: Effective date, 0901 UTC, January 10, 2013. The Director of the Federal Register approves this incorporation by reference action under 1 CFR Part 51, subject to the annual revision of FAA Order 7400.9 and publication of conforming amendments.

FOR FURTHER INFORMATION CONTACT: Eldon Taylor, Federal Aviation Administration, Operations Support Group, Western Service Center, 1601 Lind Avenue SW., Renton, WA 98057; telephone (425) 203-4537.

SUPPLEMENTARY INFORMATION:

History

On July 24, 2012, the FAA published in the **Federal Register** a notice of proposed rulemaking (NPRM) to modify controlled airspace at L M Clayton Airport, Wolf Point, MT (77 FR 43183). Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Class E airspace designations are published in paragraph 6005, of FAA Order 7400.9W dated August 8, 2012, and effective September 15, 2012, which is incorporated by reference in 14 CFR Part 71.1. The Class E airspace designations listed in this document will be published subsequently in that Order.

The Rule

This action amends Title 14 Code of Federal Regulations (14 CFR) part 71 by modifying Class E airspace extending upward from 700 feet above the surface, at L M Clayton Airport, to accommodate IFR aircraft executing NDB standard instrument approach procedures at the airport. This action is necessary for the safety and management of IFR operations.

The FAA has determined this regulation 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 will only affect air

traffic procedures and air navigation, it is certified this rule, when promulgated, will 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 U.S. Code. Subtitle 1, Section 106 discusses 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 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 modifies controlled airspace at L M Clayton Airport, Wolf Point, MT.

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 311a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR Part 71 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.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR Part 71.1 of the Federal Aviation Administration Order 7400.9W, Airspace Designations and Reporting Points, dated August 8, 2012, and effective September 15, 2012 is amended as follows:

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 (FONSI) 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 synchronization of time of insemination in weaned sows to facilitate a single fixed-time artificial insemination.	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 medicated 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