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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2008–0024; Airspace Docket No. 08–AGL–4]

Amendment of Class E Airspace; Black River Falls, WI

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: This action confirms the effective date of the direct final rule that amended Class E airspace at Black River Falls, WI, published in the **Federal Register** August 6, 2008 (73 FR 45606) Docket No. FAA–2008–0024.

DATES: *Effective Date:* 0901 UTC October 8, 2008. The Director of the Federal Register approves this incorporation by reference action under Title 1, Code of Federal Regulations, part 51, subject to the annual revision of FAA Order 7400.9 and publication of conforming amendments.

FOR FURTHER INFORMATION CONTACT: Scott Enander, Central Service Center, System Support Group, Federal Aviation Administration, Southwest Region, 2601 Meacham Blvd., Fort Worth, TX 76193–0530; telephone (817) 222–5582.

SUPPLEMENTARY INFORMATION:

History

The FAA published a direct final rule with request for comments in the **Federal Register** August 6, 2008 (73 FR 45606), Docket No. FAA–2008–0024. This rule amended Class E airspace at Black River Falls Area Airport, Black River Falls, WI. The FAA uses the direct final rule procedure for non-controversial rules where the FAA believes that there will be no adverse public comment. This direct final rule advised the public that no adverse comments were anticipated, and that unless a written adverse comment, or a written notice of intent to submit an adverse comment, was received within the comment period, the regulation would become effective on September 25, 2008. No adverse comments were received; thus, this notice confirms that the direct final rule became effective on this date.

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

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Issued in Fort Worth, TX, on September 25, 2008.

Donald R. Smith,

Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. E8–23770 Filed 10–7–08; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2008–0003; Airspace Docket No. 08–ASW–1]

Establishment of Class E Airspace; Lexington, OK

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: This action confirms the effective date of the direct final rule that established Class E airspace at Muldrow Army Heliport, Lexington, OK, published in the **Federal Register** August 6, 2008 (73 FR 45607) Docket No. FAA–2008–0003.

DATES: *Effective Dates:* 0901 UTC October 8, 2008. The Director of the Federal Register approves this incorporation by reference action under Title 1, Code of Federal Regulations, part 51, subject to the annual revision of FAA Order 7400.9 and publication of conforming amendments.

FOR FURTHER INFORMATION: Scott Enander, Central Service Center, System Support Group, Federal Aviation Administration, Southwest Region, 2601 Meacham Blvd., Fort Worth, TX 76193–0530; telephone (817) 222–5582.

SUPPLEMENTARY INFORMATION:

History

The FAA published a direct final rule with request for comments in the **Federal Register** August 6, 2008 (73 FR 45607), Docket No. FAA–2008–0003. This rule established Class E airspace at Muldrow Army Heliport, Lexington, OK. The FAA uses the direct final rule procedure for non-controversial rules where the FAA believes that there will be no adverse public comment. This direct final rule advised the public that no adverse comments were anticipated, and that unless a written adverse comment, or a written notice of intent to submit an adverse comment, was received within the comment period, the regulation would become effective on September 25, 2008. No adverse comments were received; thus, this notice confirms that the direct final rule became effective on this date.

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

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Issued in Fort Worth, TX, on September 25, 2008.

Donald R. Smith,

Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. E8–23777 Filed 10–7–08; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

[Docket No. FDA–2008–N–0039]

Implantation or Injectable Dosage Form New Animal Drugs; Ceftiofur Crystalline Free Acid

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 of a supplemental new animal drug application (NADA) filed by Pharmacia & Upjohn Co., a Division of Pfizer, Inc. The supplemental NADA provides for veterinarian prescription use of ceftiofur crystalline free acid injectable suspension for the treatment

of bovine foot rot (interdigital necrobacillosis).

DATES: This rule is effective October 8, 2008.

FOR FURTHER INFORMATION CONTACT: Donald A. Prater, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8343, e-mail: *donald.prater@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Pharmacia & Upjohn Co., a Division of Pfizer, Inc., 235 East 42d St., New York, NY 10017, filed a supplement to NADA 141–209 for EXCEDE (ceftiofur crystalline free acid) Sterile Suspension. The supplemental NADA provides for veterinarian prescription use of ceftiofur crystalline free acid injectable suspension for the treatment of bovine foot rot (interdigital necrobacillosis) in beef, non-lactating dairy, and lactating dairy cattle. The application is approved as of August 15, 2008, and the regulations are amended in 21 CFR 522.313a to reflect the approval.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), summaries of the safety and effectiveness data and information submitted to support approval of these applications 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.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this supplemental approval qualifies for 3 years of marketing exclusivity beginning on the date of approval. The 3 years of marketing exclusivity apply only to the bovine foot rot indication for which this supplement is approved.

The agency has determined under 21 CFR 25.33(d)(5) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

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 in 21 CFR Part 522

Animal drugs.

■ 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 part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

■ 2. In § 522.313a, amend paragraph (e)(2)(ii) by adding a third sentence to read as follows:

§ 522.313a Ceftiofur crystalline free acid.

* * * * *

(e) * * *

(2) * * *

(ii) * * * For the treatment of bovine foot rot (interdigital necrobacillosis) associated with *Fusobacterium necrophorum* and *Porphyromonas levii* in beef, non-lactating dairy, and lactating dairy cattle.

* * * * *

Dated: September 29, 2008.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. E8–23830 Filed 10–7–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

[Docket No. FDA–2008–N–0039]

Implantation or Injectable Dosage Form New Animal Drugs; Tulathromycin

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 of a supplemental new animal drug application (NADA) filed by Pfizer, Inc. The supplemental NADA provides for veterinarian prescription use of tulathromycin injectable solution for the treatment of bovine foot rot (interdigital necrobacillosis) in beef and non-lactating dairy cattle.

DATES: This rule is effective October 8, 2008.

FOR FURTHER INFORMATION CONTACT: Donald A. Prater, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8343, e-mail: *donald.prater@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017, filed a supplement to NADA 141–244 for DRAXXIN (tulathromycin) Injectable Solution. The supplemental NADA provides for treatment of bovine foot rot (interdigital necrobacillosis) associated with *Fusobacterium necrophorum* and *Porphyromonas levii* in beef and non-lactating dairy cattle. The application is approved as of August 28, 2008, and the regulations are amended in 21 CFR 522.2630 to reflect the approval.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application 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.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this supplemental approval qualifies for 3 years of marketing exclusivity beginning on the date of approval. The 3 years of marketing exclusivity apply only to the bovine foot rot indication for which this supplement is approved.

The agency has determined under 21 CFR 25.33(d)(5) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

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 in 21 CFR Part 522

Animal drugs.

■ 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 part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

■ 2. In § 522.2630, revise paragraph (d)(1)(ii) to read as follows: