

The Class E airspace areas designated as surface areas are published in paragraph 6002 and the Class E airspace areas designated as an extension to a Class D or Class E surface area are published in paragraph 6004 in FAA Order 7400.9H, Airspace Designations and Reporting Points, dated September 1, 2000, and effective September 16, 2000, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document would be published subsequently in the Order.

The Rule

This amendment to 14 CFR part 71 revises the Class E airspace at Bethel, AK, in two ways: (1) Reduces the amount of controlled airspace required southwest of the Bethel airport; and (2) modifies the Class E (surface area) airspace description to exclude the Hanger Lake seaplane base operations. The area will be depicted on aeronautical charts for pilot reference. The intended effects of this rule are: (1) To reduce the controlled airspace for IFR operations at Bethel, AK, thus allowing for VFR operations at Napakiak Airport during Special VFR operations at Bethel Airport and (2) fix an administrative oversight by adding the Hanger Lake exclusion area to the Class E airspace description.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(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 that 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.

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, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS; 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 71.1 of Federal Aviation Administration Order 7400.9H, *Airspace Designations and Reporting Points*, dated September 1, 2000, and effective September 16, 2000, is amended as follows:

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Paragraph 6002 Class E airspace designated as surface areas.

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AAL AK E2 Bethel, AK [REVISED]

Bethel Airport, AK
(Lat. 60°46'47" N., long. 161°50'17" W.)
Bethel VORTAC
(Lat. 60°47'05" N., long. 161°49'27" W.)

Within a 4.1-mile radius of the Bethel Airport, excluding that portion below 1,100 feet MSL between the 061° radial and the 081° radial from 2.9 miles northeast of the Bethel VORTAC. This Class E airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

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Paragraph 6004 Class E airspace designated as an Extension to a Class D or Class E surface area.

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AAL AK E4 Bethel, AK [REVISED]

Bethel Airport, AK
(Lat. 60°46'47" N., long. 161°50'17" W.)
Bethel VORTAC
(Lat. 60°47'05" N., long. 161°49'27" W.)

That airspace extending upward from the surface within 3 miles each side of the 022° radial from the Bethel VORTAC, extending from the 4.1-mile radius of the Bethel Airport to 8.2 miles northeast of the airport, excluding that portion below 1,100 feet MSL between the 061° radial and the 081° radial from 2.9 miles northeast of the Bethel VORTAC, within 3.4 miles each side of the Bethel VORTAC 006° radial, extending from the 4.1-mile radius of the Bethel Airport to 11 miles north of the Bethel VORTAC and within 3.5 miles each side of the Bethel VORTAC 213° radial extending from the 4.1-mile radius of the Bethel Airport to 5 miles southwest of the airport.

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Issued in Anchorage, AK, on April 23, 2001.

Trent S. Cummings,

Manager, Air Traffic Division, Alaskan Region.

[FR Doc. 01–10669 Filed 4–27–01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Oxytetracycline Hydrochloride Soluble Powder

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 Alpharma, Inc. The NADA which provides for a revised withdrawal time for use of oxytetracycline hydrochloride soluble powder in the drinking water of turkeys and swine.

DATES: This rule is effective April 30, 2001.

FOR FURTHER INFORMATION CONTACT:

Janis R. Messenheimer, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7578.

SUPPLEMENTARY INFORMATION: Alpharma, Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, filed a supplement to NADA 130–435 that provides for use of Oxytet (oxytetracycline HCl) Soluble for making medicated drinking water for the treatment of various bacterial diseases of livestock. The NADA provides for a zero-day slaughter withdrawal time after the use of the product in drinking water of turkeys and swine. The supplemental application is approved as of November 29, 2000, and the regulations are amended in 21 CFR 520.1660d to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 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 Dockets Management Branch (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.

The agency has determined under 21 CFR 25.24(a)(1) 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 Subject in 21 CFR Part 520

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 520 is 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.

§ 520.1660d [Amended]

2. Section 520.1660d *Oxytetracycline hydrochloride soluble powder* is amended in the sixth sentence in paragraphs (d)(1)(ii)(A)(3), (d)(1)(ii)(B)(3), and (d)(1)(ii)(C)(3) by removing "046573"; in the last sentence in paragraphs (d)(1)(ii)(A)(3), (d)(1)(ii)(B)(3), and (d)(1)(ii)(C)(3) by removing "No. 053389" and by adding in its place "Nos. 046573 and 053389"; and in the fourth sentence in paragraph (d)(1)(iii)(C) by removing "Nos. 046573 and 057561" and by adding in its place "No. 057561 and zero days those products sponsored by No. 046573."

Dated: April 16, 2001.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 01–10621 Filed 4–27–01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520, 522, and 556

Animal Drugs, Feeds, and Related Products; Sarafloxacin for Poultry; Withdrawal of Approval of NADAs

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations by removing the portions reflecting approval of two new animal drug applications (NADAs) for which the sponsor has requested withdrawal of approval. The NADAs provide for use of sarafloxacin to treat poultry. In a notice published elsewhere in this issue of the **Federal Register**, FDA is withdrawing approval of two NADAs sponsored by Abbott Laboratories.

DATES: This rule is effective April 30, 2001.

FOR FURTHER INFORMATION CONTACT:

Mohammad I. Sharar, Center for Veterinary Medicine (HFV–216), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0159.

SUPPLEMENTARY INFORMATION: In a notice published elsewhere in this issue of the **Federal Register**, FDA is withdrawing approval of two NADAs held by Abbott Laboratories, North Chicago, IL 60064. The NADAs provide for use of sarafloxacin to treat poultry. NADA 141–017 provides for the use of SaraFloX® (sarafloxacin hydrochloride) WSP and is under § 520.2095 (21 CFR 520.2095) and NADA 141–018 provides for the use of SaraFloX® (sarafloxacin hydrochloride) Injection and is under § 522.2095 (21 CFR 522.2095). Relevant information concerning tolerances for residues of sarafloxacin in edible tissues of poultry is under § 556.594 (21 CFR 556.594).

Abbott Laboratories requested withdrawal of approval in response to safety questions raised by FDA regarding the products.

No other NADAs for use of sarafloxacin have been approved. Therefore, in accordance with the notice of withdrawal of approvals, FDA is amending the regulations to remove §§ 520.2095, 522.2095, and 556.594 effective April 30, 2001.

The agency has determined under 21 CFR 25.33(g) 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

21 CFR Parts 520 and 522

Animal drugs.

21 CFR Part 556

Animal drugs, Foods.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Food and Drug Administration and redelegated to the Center for Veterinary Medicine, 21 CFR parts 520, 522, and 556 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.

§ 520.2095 [Removed]

2. Section 520.2095 *Sarafloxacin soluble powder* is removed.

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.

§ 522.2095 [Removed]

4. Section 522.2095 *Sarafloxacin solution for injection* is removed.

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

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

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

§ 556.594 [Removed]

6. Section 556.594 *Sarafloxacin* is removed.

Dated: April 17, 2001.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 01–10069 Filed 4–27–01; 8:45 am]

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