Rules and Regulations

Federal Register
Vol. 67, No. 234
Thursday, December 5, 2002

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 02–ACE–5]

Amendment to Class E Airspace; Fremont, NE

AGENCY: Federal Aviation Administration, DOT.

ACTION: Direct final rule; correction; and confirmation of effective date.

SUMMARY: This document contains a correction to a direct final rule and confirms the effective date of the direct final rule which revises Class E airspace at Fremont, NE.

EFFECTIVE DATE: 0901 UTC, October 3, 2002.

FOR FURTHER INFORMATION CONTACT: Brenda Mumper, Air Traffic Division, Airspace Branch, ACE–520A, DOT Regional Headquarters Building, Federal Aviation Administration, 901 Locust, Kansas City, MO 64106; telephone: (816) 329–2524.

SUPPLEMENTARY INFORMATION: The FAA published this direct final rule with a request for comments in the **Federal Register** on May 30, 2002 (67 FR 37667–37669). The FAA uses the direct final rulemaking procedure for a non-controversial rule 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 such an adverse comment, were received within the comment period, the regulation would become effective on October 3, 2002. No adverse comments were received, and thus this document confirms that this direct final rule became effective on that date.

Correction

In rule document 02–13549 beginning on page 37667 in the issue of Thursday, May 30, 2002, make the following correction:

§ 71.1 [Corrected]

On page 37669, in the first line of the first column, in § 71.1, ''lat 41° 27′ 02″N.'' should read ''lat. 41°27′01″N.''

Issued in Kansas City, MO on November 21, 2002.

Herman J. Lyons, Jr.,

Manager, Air Traffic Division, Central Region.

[FR Doc. 02–30849 Filed 12–4–02; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 520

New Animal Drugs; Neomycin Sulfate Soluble Powder; Change of Sponsor's Address

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 abbreviated new animal drug application (ANADA) filed by Bimeda, Inc., and a change of this sponsor's address. The supplemental ANADA provides for use of neomycin sulfate soluble powder in the drinking water of growing turkeys for the control of mortality associated with *Escherichia coli* organisms susceptible to neomycin.

DATES: This rule is effective December 5, 2002.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–8549, e-mail: lluther@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Bimeda, Inc., 288 County Rd. 28, LeSueur, MN 56058–9322, filed a supplement to ANADA 200–050 that provides for use of Neomycin 325 Soluble Powder for making medicated drinking water for administration to cattle (excluding veal calves), swine, sheep, and goats for the treatment and control of colibacillosis (bacterial enteritis) caused by *E. coli* susceptible to neomycin. The supplemental ANADA provides for use of neomycin in the drinking water of growing turkeys for the control of mortality associated with *E. coli* organisms susceptible to neomycin. The supplemental application is approved as of July 10, 2002, and the regulations are amended in 21 CFR 520.1484 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, Bimeda, Inc., has informed FDA of a change of sponsor address to 291 Forest Prairie Rd., LeSueur, MN 56058. Accordingly, the agency is amending the regulations in 21 CFR 510.600 to reflect the change of sponsor address.

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 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 25.33(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 Subjects

21 CFR Part 510

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

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 parts 510 and 520 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. Section 510.600 is amended in the table in paragraph (c)(1) by revising the entry for ''Bimeda, Inc.'' and in the table in paragraph (c)(2) by revising the entry for ''061133'' 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
* * * * * * *	
Bimeda, Inc., 291 Forest Prairie Rd., LeSueur, MN 56058	061133
* * * * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * * * *	
061133	Bimeda, Inc., 291 Forest Prairie Rd., LeSueur, MN 56058
* * * * * * *	

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.

4. Section 520.1484 is amended by revising paragraphs (a) and (b) to read as follows:

§ 520.1484 Neomycin sulfate soluble powder.

(a) *Specifications.* Each ounce of powder contains 20.3 grams of neomycin sulfate (equivalent to 14.2 grams of neomycin base).

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(1) Nos. 000069, 046573, and 051259 for use as in paragraph (d)(1) of this section.

(2) Nos. 000009 and 061133 for use as in paragraphs (d)(1) and (d)(2) of this section.

* * * * *

Dated: November 19, 2002.

Steven D. Vaughn,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 02–30785 Filed 12–4–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Oxytetracycline Injection

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 abbreviated new animal drug application (ANADA) filed by Pennfield Oil Co. which provides for the administration of an oxytetracycline injectable solution to lactating dairy cattle.

DATES: This rule is effective December 5, 2002.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–101), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0209, e-mail: *lluther@cvm.fda.gov.*

SUPPLEMENTARY INFORMATION: Pennfield Oil Co., 14040 Industrial Rd., Omaha, NE 68137, filed a supplement to approved ANADA 200–154 that provides for the use of PENNOX 200 (oxytetracycline) Injection as a treatment for various bacterial diseases in cattle and swine. The supplemental ANADA provides for the administration of this oxytetracycline injectable solution to lactating dairy cattle. The supplemental application is approved as of June 13, 2002, and the regulations are amended in 21 CFR 522.1660 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 25.33(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 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.

§ 522.1660 [Amended]

2. Section 522.1660 *Oxytetracycline injection* is amended in paragraph (d)(1)(iii) in the eighth sentence by removing ''053389''; and in the ninth sentence by removing ''000069 and 011722'' and by adding in its place ''000069, 011722, and 053389''.

Dated: November 8, 2002.

Steven D. Vaughn,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 02–30781 Filed 12–4–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Oxytetracycline Injection

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 an original abbreviated new animal drug application (ANADA) filed by Norbrook Laboratories, Ltd. The ANADA provides for the administration