navigation aid in the route description correctly and the associated aeronautical charts were published accordingly. To overcome any confusion or flight safety issues associated with conflicting route description information being published, the FAA is amending the V–14 legal description to reflect the airway aligned over the St. Louis, MO, VOR/DME. Accordingly, since this is an administrative correction to update the V–14 description to be in concert with the FAA's aeronautical database and charting, notice and public procedures under Title 5 U.S.C. 553(b) are unnecessary.

The Rule

The FAA amends Title 14 Code of Federal Regulations (14 CFR) part 71 by amending the legal description of VOR Federal airway V–14 in the vicinity of St. Louis, MO. Specifically, the FAA amends V–14 to reflect the airway aligned over the St. Louis, MO, VOR/DME; thus, matching the information currently contained in the FAA's aeronautical database and the charted depiction of the airway.

VOR Federal airways are listed in paragraph 6010 of FAA Order 7400.9V dated August 9, 2011, and effective September 15, 2011, which is incorporated by reference in 14 CFR 71.1. The VOR Federal airway listed in this document will be revised subsequently in the Order.

The FAA has determined that 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 Department of Transportation (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.

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes 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 the 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 amends an existing VOR Federal airway within the NAS.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with 311a, FAA Order 1050.1E, ''Environmental Impacts: Policies and Procedures.'' 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 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 FAA Order 7400.9V, Airspace Designations and Reporting Points, signed August 9, 2011, and effective September 15, 2011, is amended as follows:

Paragraph 6010 VOR Federal airways.

(a) Domestic VOR Federal airways.

* * * * *

V–14

From Chisum, NM; Lubbock, TX; Childress, TX; Hobart, OK; Will Rogers, OK; INT Will Rogers 052° and Tulsa, OK 246° radials; Tulsa; Neosho, MO; Springfield, MO; Vichy, MO; INT Vichy 067° and St. Louis, MO, 225° radials; St. Louis; Vandalia, IL; Terre Haute, IN; Brickyard, IN; Muncie, IN; Flag City, OH; INT Flag City 079° and Dryer, OH, 240° radials; Dryer; Jefferson, OH; Erie, PA; Dunkirk, NY; Buffalo, NY; Geneseo, NY; Georgetown, NY; INT Georgetown 093° and Albany, NY, 270° radials; Albany; INT Albany 084° and Gardner, MA, 284° radials; Gardner; to Norwich, CT.

* * * * *

Issued in Washington, DC, April 24, 2012.

Paul Gallant,

Acting Manager, Airspace, Regulations and ATC Procedures Group.

[FR Doc. 2012–10362 Filed 5–2–12; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 522 and 558

[Docket No. FDA–2012–N–0002]

New Animal Drugs; Ceftiofur Crystalline Free Acid; Gamithromycin; Tylosin

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 February 2012. FDA is also informing the public of the availability of summaries of the basis of approval and of environmental review documents, where applicable.

DATES: This rule is effective May 3, 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's Center for Veterinary Medicine is adopting the use of a monthly **Federal Register** document to codify approval actions for NADAs and ANADAs. CVM will no longer publish a separate rule for each action. This approach will allow a more efficient use of available resources.

In this document, FDA is amending the animal drug regulations to reflect the original and supplemental approval actions during February 2012, as listed in table 1 of this document. FDA is also informing the public of the availability of summaries of the basis of approval (FOI Summaries) under the Freedom of Information Act (FOIA) and of environmental review documents required under the National Environmental Policy Act (NEPA), where applicable.

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

NADA/ ANADA	Sponsor	New animal drug product name	Action	21 CFR Section	FOIA Summary	NEPA Review
141–328 ...	Merial Ltd., 3239 Satellite Blvd., Bldg. 500, Duluth, GA 30096–4640.	ZACTRAN (gamithromycin) Injectable Solution.	Supplement adding treatment of bovine respiratory disease (BRD) associated with *M. bovis.*	522.1014	yes	CE[1]
141–209 ...	Pharmacia & Upjohn Co., a Division of Pfizer, Inc., 235 East 42d St., New York, NY 10017.	EXCEDE (ceftiofur crystalline free acid) Sterile Suspension.	Supplement adding treatment of acute bovine metritis in lactating dairy cows; and modified injection techniques.	522.313a	yes	CE
200–484 ...	Huvepharma AD, 33 James Boucher Blvd., Sophia 1407, Bulgaria.	TYLOVET 100 (tylosin phosphate) Type A medicated Article.	Original approval as generic copy of NADA 012–491.	558.625	yes	CE

[1] The Agency has determined under 21 CFR 25.33 that this action is categorically excluded (CE) from the requirement to submit an environmental assessment (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.

The basis of approval of actions requiring review of safety or effectiveness data is discussed in an FOI Summary that 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.

List of Subjects

21 CFR Part 522

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 522 and 558 are 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, revise paragraphs (e)(2)(i), (e)(2)(ii), and (e)(2)(iii) to read as follows:

§ 522.313a Ceftiofur crystalline free acid.

* * * * *

(e) * * *

(2) * * *

(i) *Amount.* For subcutaneous (SC) injection in the posterior aspect of the ear where it attaches to the head (base of the ear) in lactating dairy cattle. For SC injection in the middle third of the posterior aspect of the ear or in the base of the ear in beef and non-lactating dairy cattle.

(A) Single-dose regimen: 6.6 mg ceftiofur equivalents per kg of body weight as a single injection.

(B) Two-dose regimen: 6.6 mg ceftiofur equivalents per kg of body weight given as two injections in the base of the ear approximately 72 hours apart.

(ii) *Indications for use*—(A) Single-dose regimen: For the treatment of bovine respiratory disease (BRD, shipping fever, pneumonia) associated with *Mannheimia haemolytica, Pasteurella multocida,* and *Histophilus somni* in beef, non-lactating dairy, and lactating dairy cattle. For the control of respiratory disease in beef and non-lactating dairy cattle which are at high risk of developing BRD associated with *M. haemolytica, P. multocida,* and *H. somni.* 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.

(B) Two-dose regimen: For the treatment of acute metritis (0-to 10-days postpartum) associated with bacterial organisms susceptible to ceftiofur in lactating dairy cattle.

(iii) *Limitations.* Following label use as either a single-dose or 2-dose regimen, a 13-day pre-slaughter withdrawal period is required after the last treatment. A withdrawal period has not been established in preruminating calves. Do not use in calves to be processed for veal.

* * * * *

■ 3. In 522.1014, revise paragraph (d)(1)(ii) to read as follows:

§ 522.1014 Gamithromycin.

* * * * *

(d) * * *

(1) * * *

(ii) *Indications for use.* For the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica, Pasteurella multocida, Histophilus somni,* and *Mycoplasma bovis* in beef and non-lactating dairy cattle; and for the control of respiratory disease in beef and non-lactating dairy cattle at high risk of developing BRD associated with *M. haemolytica* and *P. multocida.*

* * * * *

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

■ 5. In § 558.625, add paragraph (b)(90) to read as follows:

§ 558.625 Tylosin.

* * * * *

(b) * * *

(90) No. 016592: 100 grams per pound for use as in paragraph (f) of this section.

* * * * *

Dated: April 26, 2012.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2012–10632 Filed 5–2–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 600, 610, and 680

[Docket No. FDA–2011–N–0080]

Amendments to Sterility Test Requirements for Biological Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the sterility test requirements for biological products. This rule provides manufacturers of biological products greater flexibility, as appropriate, and encourages use of the most appropriate and state-of-the-art test methods for assuring the safety of biological