The FAA has determined this rulemaking action qualifies for the categorical exclusion identified in paragraph 312f and involves no extraordinary circumstances.

**Regulations That Significantly Affect Energy, Supply, Distribution, or Use**

The FAA has analyzed this NPRM under Executive Order 13211, Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use (May 18, 2001). We have determined that it is not a “significant energy action” under the executive order because it is not a “significant regulatory action” under Executive Order 12866, and it is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

**Availability of Rulemaking Documents**

You can get an electronic copy of rulemaking documents using the Internet by—

1. Searching the Federal eRulemaking Portal (http://www.regulations.gov);
2. Visiting the FAA’s Regulations and Policies Web page at http://www.faa.gov/regulations_policies/ or

You can also get a copy by sending a request to the Federal Aviation Administration, Office of Rulemaking, ARM–1, 800 Independence Avenue, SW., Washington, DC 20591, or by calling (202) 267–0680. Make sure to identify the amendment number or docket number of this rulemaking.

You may search the electronic form of all comments received into any of our docket files by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT’s complete Privacy Act statement in the Federal Register published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78) or you may visit http://DocketsInfo.dot.gov.

**Small Business Regulatory Enforcement Fairness Act**

The Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996 requires FAA to comply with small entity requests for information or advice about compliance with statutes and regulations within its jurisdiction. If you are a small entity and you have a question regarding this document, you may contact your local FAA official, or the person listed under the **FOR FURTHER INFORMATION CONTACT** heading at the beginning of the preamble. You can find out more about SBREFA on the Internet at http://www.faa.gov/ regulations_policies/rulemaking/ sbre_act/.

**List of Subjects in 14 CFR part 91**

- Aircraft, Noise control, Reporting and recordkeeping requirements.

**The Amendment**

In consideration of the foregoing, the Federal Aviation Administration amends Chapter 1 of Title 14, Code of Federal Regulations, as follows:

**PART 91—GENERAL OPERATING AND FLIGHT RULES**

1. The authority citation for part 91 continues to read as follows:

   **Authority:** 49 U.S.C. 106(g), 1155, 40103, 40113, 40120, 44101, 44111, 44701, 44709, 44713, 44712, 44716, 44717, 44722, 46306, 46315, 46316, 46504, 46506, 46507, 47122, 47508, 47528–47531, articles 12 and 29 of the Convention on International Civil Aviation (61 stat 1180).

2. Amend §91.703 by adding paragraph (a)(5) to read as follows:

   §91.703 Operations of civil aircraft of U.S. registry outside of the United States.

   **(a)**

   *(5)* For aircraft subject to ICAO Annex 16, carry on board the aircraft documents that summarize the noise operating characteristics and certifications of the aircraft that demonstrate compliance with this part and part 36 of this chapter.

   Issued in Washington, DC, on February 18, 2010.

   J. Randolph Babbitt,
   Administrator.

   [FR Doc. 2010–4316 Filed 3–1–10; 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–2010–N–0002]

**Implantation or Injectable Dosage Form New Animal Drugs; Tilmicosin**

**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 Elanco Animal Health, A Division of Eli Lilly & Co. The supplemental NADA provides a dose range for use of an injectable solution of tilmicosin phosphate for treatment of respiratory disease in cattle and additional pathogens for which this therapy is effective.

**DATES:** This rule is effective March 2, 2010.

**FOR FURTHER INFORMATION CONTACT:** Cindy L. Burnsteil, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8341, e-mail: cindy.burnsteil@fda.hhs.gov.

**SUPPLEMENTARY INFORMATION:** Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed a supplement to NADA 140–929 for MICOTIL 300 (tilmicosin injection, USP) Injection, available by veterinary prescription for use in the treatment and control of respiratory disease in cattle and the treatment of respiratory disease in sheep. The supplemental NADA establishes a dose range and adds pathogens for which this therapy is effective in the management of bovine respiratory disease. As a consequence of revising the dosage, the preslaughter withdrawal period has been recalculated. The supplemental NADA is approved as of December 30, 2009, and the regulations in 21 CFR 522.2471 are amended 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)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)[F][ii]), this supplemental approval qualifies for 3 years of marketing exclusivity beginning on the date of approval.

The agency has determined under 21 CFR 25.33 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
PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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


2. In §522.2471, revise paragraphs (e)(1)(i), (e)(1)(ii), and (e)(1)(iii) to read as follows:

§522.2471 Tilmicosin.

(e) * * * * *

(i) Amount. 10 to 20 milligrams per kilograms (mg/kg) of body weight as a single subcutaneous injection.

(ii) Indications for use. For the treatment of bovine respiratory disease (BRD) associated with Mannheimia haemolytica, Pasteurella multocida, and Histophilus somni. For the control of respiratory disease in cattle at high risk of developing BRD associated with M. haemolytica.

(iii) Limitations. Do not use in female dairy cattle 20 months of age or older. Use of this antibiotic in this class of cattle may cause milk residues. Do not slaughter within 42 days of last treatment.


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

[FR Doc. 2010–4205 Filed 3–1–10; 8:45 am]

BILLING CODE 4160–01–S

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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


2. In §558.128, revise paragraph (b)(2) to read as follows:

§558.128 Chlortetracycline.

(b) * * * *

(2) No. 012286: 50, 90, or 100 grams per pound of Type A medicated article.


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

[FR Doc. 2010–4205 Filed 3–1–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

[Docket No. FDA–2010–N–0002]

New Animal Drugs for Use in Animal Feeds; Chlortetracycline

AGENCY: Food and Drug Administration, HHS.