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Acting Manager, System Support Group, ATO Central Service Center.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Enrofloxacin

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 Bayer HealthCare, LLC. The supplemental NADA provides for the use of enrofloxacin injectable solution in female dairy cattle less than 20 months of age.

DATES: This rule is effective April 2, 2008.

FOR FURTHER INFORMATION CONTACT: Joan C. Gotthardt, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8342, e-mail: *joan.gotthardt@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Bayer HealthCare, LLC, Animal Health Division, P.O. Box 390, Shawnee Mission, KS 66201, filed a supplement to NADA 141–068 for BAYTRIL 100 (enrofloxacin) injectable solution used for the treatment of bovine respiratory disease associated with several bacterial pathogens. The supplemental NADA provides for the use of enrofloxacin injectable solution in female dairy cattle less than 20 months of age. The supplemental NADA is approved as of February 13, 2008, and the regulations in 21 CFR 522.812 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)(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 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 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 § 522.812, revise paragraphs (e)(2)(i) through (e)(2)(iii) to read as follows:

§ 522.812 Enrofloxacin.

* * * * *

(e) * * *

(2) * * *

(i) *Amount.* Single-dose therapy: 7.5 to 12.5 mg/kg of body weight by subcutaneous injection. Multiple-day therapy: 2.5 to 5.0 mg/kg of body weight by subcutaneous injection. Treatment should be repeated at 24-hour intervals for 3 days. Additional treatments may be given on days 4 and 5 to animals that have shown clinical improvement but not total recovery.

(ii) *Indications for use.* For the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Histophilus somni* (previously *Haemophilus somnus*) in beef and non-lactating dairy cattle.

(iii) *Limitations.* Animals intended for human consumption must not be slaughtered within 28 days from the last treatment. Do not use in female dairy cattle 20 months of age or older. Use of enrofloxacin in this class of cattle may cause milk residues. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

Dated: March 21, 2008.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. E8–6706 Filed 4–1–08; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R07–OAR–2008–0100; FRL–8549–6]

Approval and Promulgation of Implementation Plans; State of Missouri

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final action to approve Missouri's request to revise the State Implementation Plan (SIP) to include the State's recently revised ozone season NO_X cap and trade rules for electric generating units (EGUs) and non-electric generating units (Non–EGUs) submitted on May 18, 2007. Two existing rules were revised by the State to allow for the transition into the State's recently adopted ozone season trading rule to meet the requirements of the Clean Air Interstate Rule (CAIR). The ozone season rules, an interstate cap and trade rule for EGUs and Non–EGUs in the eastern one-third of the State and a statewide intrastate trading rule for EGUs, were revised to include language that will rescind their requirements in the year 2009, the year CAIR compliance begins. The CAIR ozone season trading rule is more restrictive than the aforementioned rules, and this action is needed to avoid imposing duplicative requirements for the affected sources in the year 2009 and thereafter.

DATES: This direct final rule will be effective June 2, 2008, without further notice, unless EPA receives adverse comment by May 2, 2008. If adverse comment is received, EPA will publish a timely withdrawal of the direct final rule in the **Federal Register** informing the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R07–OAR–2008–0100, by one of the following methods:

1. *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.