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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.

2. *E-mail:* jay.michael@epa.gov.

3. *Mail:* Michael Jay, Environmental Protection Agency, Air Planning and Development Branch, 901 North 5th Street, Kansas City, Kansas 66101.

4. *Hand Delivery or Courier:* Deliver your comments to Michael Jay, Environmental Protection Agency, Air Planning and Development Branch, 901 North 5th Street, Kansas City, Kansas 66101.

Instructions: Direct your comments to Docket ID No. EPA-R07-OAR-2008-0100. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit through <http://www.regulations.gov> or e-mail information that you consider to be CBI or otherwise protected. The <http://www.regulations.gov> Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through <http://www.regulations.gov>, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the <http://www.regulations.gov> index. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in <http://www.regulations.gov> or in hard copy at the Environmental Protection Agency, Air Planning and Development Branch, 901 North 5th Street, Kansas City,

Kansas 66101. The Regional Office's official hours of business are Monday through Friday, 8 a.m. to 4:30 p.m. excluding Federal holidays. The interested persons wanting to examine these documents should make an appointment with the office at least 24 hours in advance.

FOR FURTHER INFORMATION CONTACT:

Michael Jay at (913) 551-7460 or by e-mail at jay.michael@epa.gov.

SUPPLEMENTARY INFORMATION:

Throughout this document whenever "we," "us," or "our" is used, we mean EPA. This section provides additional information by addressing the following questions:

- What is a SIP?
- What is the Federal approval process for a SIP?
- What does Federal approval of a state regulation mean to me?
- What is the background of this action?
- What is being addressed in this document?
- Have the requirements for approval of a SIP revision been met?
- What action is EPA taking?

What is a SIP?

Section 110 of the Clean Air Act (CAA) requires states to develop air pollution regulations and control strategies to ensure that state air quality meets the national ambient air quality standards established by EPA. These ambient standards are established under section 109 of the CAA, and they currently address six criteria pollutants. These pollutants are: carbon monoxide, nitrogen dioxide, ozone, lead, particulate matter, and sulfur dioxide.

Each state must submit these regulations and control strategies to us for approval and incorporation into the Federally-enforceable SIP.

Each Federally-approved SIP protects air quality primarily by addressing air pollution at its point of origin. These SIPs can be extensive, containing state regulations or other enforceable documents and supporting information such as emission inventories, monitoring networks, and modeling demonstrations.

What is the Federal approval process for a SIP?

In order for state regulations to be incorporated into the Federally-enforceable SIP, states must formally adopt the regulations and control strategies consistent with state and Federal requirements. This process generally includes a public notice, public hearing, public comment period, and a formal adoption by a state-authorized rulemaking body.

Once a state rule, regulation, or control strategy is adopted, the state

submits it to us for inclusion into the SIP. We must provide public notice and seek additional public comment regarding the proposed Federal action on the state submission. If adverse comments are received, they must be addressed prior to any final Federal action by us.

All state regulations and supporting information approved by EPA under section 110 of the CAA are incorporated into the Federally-approved SIP. Records of such SIP actions are maintained in the Code of Federal Regulations (CFR) at title 40, part 52, entitled "Approval and Promulgation of Implementation Plans." The actual state regulations which are approved are not reproduced in their entirety in the CFR outright but are "incorporated by reference," which means that we have approved a given state regulation with a specific effective date.

What does Federal approval of a state regulation mean to me?

Enforcement of the state regulation before and after it is incorporated into the Federally-approved SIP is primarily a state responsibility. However, after the regulation is Federally approved, we are authorized to take enforcement action against violators. Citizens are also offered legal recourse to address violations as described in section 304 of the CAA.

What is the background of this action?

The ozone season NO_x rules discussed in today's action were adopted by Missouri for different purposes. The first rule, 10 CSR 10-6.350, Emissions Limitations and Emissions Trading of Oxides of Nitrogen (statewide NO_x Rule), as amended in the SIP on September 19, 2005 (70 FR 54840), is designed to achieve emissions reductions to improve the air quality in the St. Louis ozone nonattainment area. This rule requires emissions reductions in the eastern one-third of the state and lesser reductions in the remainder of the state for large EGUs. The second rule, 10 CSR 10-6.360, Control of NO_x Emissions From Electric Generating Units and Non-Electric Generating Boilers, as adopted in the SIP on August 15, 2006 (71 FR 46860), is an interstate cap and trade rule for EGUs and Non-EGUs in the eastern one-third of the state and is designed to meet, in part, the requirements of EPA's NO_x SIP Call (69 FR 21604).

The two existing rules discussed above were revised by the State to allow for the transition into the recently adopted ozone season trading rule for compliance with CAIR. Missouri's ozone season trading rule 10 CSR 10-

6.364, Clean Air Interstate Rule Seasonal NO_x Trading Program, affects the entire State and reduces emissions of NO_x that significantly contribute to, and interfere with maintenance of, the national ambient air quality standard for ozone in any downwind state (72 FR 71073). Compliance with Missouri's ozone season CAIR rule is more restrictive than either 10 CSR 10-6.350 or 10 CSR 10-6.360, and today's SIP revision is necessary, as described below, to avoid imposing duplicative requirements on the affected sources for the ozone period beginning in 2009.

What is being addressed in this document?

EPA is approving a revision to Missouri's SIP to include two revised NO_x ozone season trading rules, 10 CSR 10-6.350, Emissions Limitations and Emissions Trading of Oxides of Nitrogen (statewide NO_x Rule), and 10 CSR 10-6.360, Control of NO_x Emissions From Electric Generating Units and Non-Electric Generating Boilers. The revised trading rules include new applicability provisions that remove the General Provisions, Reporting and Record Keeping, and Test Methods and Monitoring requirements beginning in the control period 2009 and thereafter. The purpose of the new applicability provisions is to avoid creating duplicative requirements with Missouri's recently adopted ozone season rule 10 CSR 10-6.364, Clean Air Interstate Rule Seasonal NO_x Trading Program, with which compliance is scheduled to begin in May 2009.

Have the requirements for approval of a SIP revision been met?

The state submittal has met the public notice requirements for SIP submissions in accordance with 40 CFR 51.102. The submittal also satisfied the completeness criteria of 40 CFR part 51, appendix V. In addition, the revision meets the substantive SIP requirements of the CAA, including section 110 and implementing regulations.

What action is EPA taking?

EPA is taking final action to approve Missouri's request to revise the SIP as submitted on May 18, 2007. We are processing this action as a direct final action because the revisions make routine changes to the existing rules which are noncontroversial. Therefore, we do not anticipate any adverse comments. Please note that if EPA receives adverse comment on part of this rule and if that part can be severed from the remainder of the rule, EPA may adopt as final those parts of the rule that

are not the subject of an adverse comment.

Statutory and Executive Order Reviews

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a "significant regulatory action" and therefore is not subject to review by the Office of Management and Budget. For this reason, this action is also not subject to Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001). This action merely approves state law as meeting Federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this rule approves pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4).

This rule also does not have tribal implications because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action also does not have Federalism implications because it does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely approves a state rule implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the CAA. This rule also is not subject to Executive Order 13045, "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997), because it approves a state rule implementing a Federal standard.

In reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. In this context, in the absence of a prior existing requirement for the

State to use voluntary consensus standards (VCS), EPA has no authority to disapprove a SIP submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a SIP submission, to use VCS in place of a SIP submission that otherwise satisfies the provisions of the CAA. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by *June 2, 2008*. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: March 24, 2008.

John B. Askew,
Regional Administrator, Region 7.

■ 40 CFR part 52 is amended as follows:

PART 52—[AMENDED]

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 et seq.

Subpart AA—Missouri

■ 2. In § 52.1320 the table in paragraph (c) is amended under Chapter 6 by revising the entries for 10–6.350 and 10–6.360 to read as follows:

§ 52.1320 Identification of plan.

* * * * *

(c) * * *

EPA-APPROVED MISSOURI REGULATIONS

Missouri citation	Title	State effective date	EPA approval date	Explanation
Missouri Department of Natural Resources				
*	*	*	*	*
10–6.350	Emissions Limitations and Emissions Trading of Oxides of Nitrogen.	5/30/07	4/2/08 [insert FR page number where the document begins].	*
10–6.360	Control of NO _x Emissions From Electric Generating Units and Non-Electric Generating Boilers.	5/30/07	4/2/08 [insert FR page number where the document begins].	*
*	*	*	*	*

* * * * *
[FR Doc. E8–6651 Filed 4–1–08; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 52**

[EPA–R07–OAR–2008–0103; FRL–8549–8]

Approval and Promulgation of Implementation Plans; State of Missouri

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is approving a State Implementation Plan (SIP) revision to exempt initial fueling of motor vehicles at automobile assembly plants in the St. Louis metropolitan area from the Missouri Performance Evaluation Test Procedures (MO/PETP) approval test requirements. MO/PETP requirements were initially implemented to maintain the integrity of local air quality by regulating gasoline fueling emissions. The Missouri Department of Natural Resources (MDNR) provided an air quality analysis and it was determined that removal of these test requirements for initial fueling at automobile assembly plants will not adversely affect air quality in the St. Louis area. In addition, certain portions of the rule were renumbered and reformatted. This revision will ensure consistency

between the state and the federally-approved rules.

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–2008–0103, by one of the following methods:

1. *www.regulations.gov*. Follow the on-line instructions for submitting comments.
2. *E-mail*: *algae-eakin.amy@epa.gov*.
3. *Mail*: Amy Algoe-Eakin, Environmental Protection Agency, Air Planning and Development Branch, 901 North 5th Street, Kansas City, Kansas 66101.

4. *Hand Delivery or Courier*. Deliver your comments to Amy Algoe-Eakin, Environmental Protection Agency, Air Planning and Development Branch, 901 North 5th Street, Kansas City, Kansas 66101.

Instructions: Direct your comments to Docket ID No. EPA–R07–OAR–2008–0103. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *www.regulations.gov*, including any personal information provided, unless the comment includes information

claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit through *www.regulations.gov* or e-mail information that you consider to be CBI or otherwise protected. The *www.regulations.gov* Web site is an “anonymous access” system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *www.regulations.gov*, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on