

Issued in Washington, DC, on August 13, 2008.

Pamela Hamilton,

Director, Office of Rulemaking.

[FR Doc. E8-19039 Filed 8-15-08; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 530

[Docket No. FDA-2008-N-0326]

New Animal Drugs; Cephalosporin Drugs; Extralabel Animal Drug Use; Order of Prohibition; Extension of Comment Period; Delay of Effective Date of Final Rule

AGENCY: Food and Drug Administration, HHS.

ACTION: Extension of comment period; delay of effective date of final rule.

SUMMARY: The Food and Drug Administration (FDA) is extending to November 1, 2008, the comment period for the order of prohibition. FDA is also delaying the effective date of this final rule to November 30, 2008. In the final rule, FDA requested comments on the document. The agency is taking this action in response to requests for an extension to allow additional time to submit comments.

DATES: The effective date of the rule amending 21 CFR 530.41 published at 73 FR 38110, July 3, 2008 is delayed until November 30, 2008. Submit written and electronic comments by November 1, 2008.

ADDRESSES: You may submit comments, identified by [Docket No. FDA-2008-N-0326], by any of the following methods: *Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301-827-6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]: Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using

the Federal eRulemaking Portal, as described previously, in the **ADDRESSES Electronic Submissions**.

Instructions: All submissions received must include the agency name and Docket No(s), and Regulatory Information Number (RIN) (if a RIN number has been assigned) for this rulemaking. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the "Request for Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket number(s), found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Neal Bataller, Center for Veterinary Medicine (HFV-230), Food and Drug Administration, 7519 Standish Pl., Rockville, MD, 20855, 240-276-9200, e-mail: neal.bataller@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the *Federal Register* of July 3, 2008 (73 FR 38110), FDA published an order prohibiting the extralabel use of cephalosporin antimicrobial drugs in food-producing animals, with a 60-day comment period and a 90-day effective date for the final rule.

The agency has received requests for a 60-day extension of the comment period for the order of prohibition. The requests conveyed concern that the current 60-day comment period does not allow sufficient time to examine the available evidence, consider the impact of the ruling, and provide constructive comment.

FDA has considered the requests and is extending the comment period for the order for 60 days, until November 1, 2008. Accordingly, FDA is also delaying the effective date of the final rule 60 days, until November 30, 2008. The agency believes that a 60-day extension allows adequate time for interested persons to submit comments without significantly delaying implementation of the final rule.

II. Request for Comments

Interested persons may submit to the Division of Dockets Management (see

ADDRESSES) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

Dated: July 31, 2008.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. E8-18967 Filed 8-15-08; 8:45 am]

BILLING CODE 4160-01-S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R04-OAR-2008-0051-200805(a); FRL-8705-3]

Approval and Promulgation of Air Quality Implementation Plans; Tennessee; Approval of Revisions to the Nashville/Davidson County Portion

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final action to approve a revision to the State Implementation Plan (SIP) submitted by the State of Tennessee on October 19, 2007. The revision affects the Nashville/Davidson County portion of the Tennessee SIP. Specifically, the revision pertains to the Metropolitan Public Health Department, Pollution Control Division's Regulation Number 8, "Inspection and Maintenance of Light-Duty Motor Vehicles." The revision is part of Nashville/Davidson County's strategy to meet the requirements of EPA's 1997 8-hour ozone standard. Regulation Number 8 is amended by reducing the vehicle emission inspection fee to \$9.00 and updating the definitions section. This revision is considered by the Tennessee Department of Environment and Conservation (TDEC), to be at least as stringent as the State of Tennessee's

preexisting requirements. This action is being taken pursuant to section 110 of the Clean Air Act (CAA).

DATES: This direct final rule is effective October 17, 2008 without further notice, unless EPA receives adverse comment by September 17, 2008. If EPA receives such comments, it will publish a timely withdrawal of the direct final rule in the **Federal Register** and inform the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-R04-OAR-2008-0051, by one of the following methods:

1. *www.regulations.gov*: Follow the on-line instructions for submitting comments.
2. *E-mail*: hou.james@epa.gov.
3. *Fax*: (404) 562-9019.
4. *Mail*: "EPA-R04-OAR-2008-0051," Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street, SW., Atlanta, Georgia 30303-8960.

5. *Hand Delivery or Courier*: Mr. James Hou, Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street, SW., Atlanta, Georgia 30303-8960. Such deliveries are only accepted during the Regional Office's normal hours of operation. The Regional Office's official hours of business are Monday through Friday, 8:30 to 4:30, excluding federal holidays.

Instructions: Direct your comments to Docket ID No. "EPA-R04-OAR-2008-0051." 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. For additional information about EPA's public docket visit the EPA Docket Center home page at <http://www.epa.gov/epahome/dockets.htm>.

Docket: All documents in the electronic 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 the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy at the Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street, SW., Atlanta, Georgia 30303-8960. EPA requests that if at all possible, you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 8:30 to 4:30, excluding federal holidays.

FOR FURTHER INFORMATION CONTACT: Mr. James Hou, Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street, SW., Atlanta, Georgia 30303-8960. The telephone number is (404) 562-8965. Mr. Hou can also be reached via electronic mail at hou.james@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Analysis of Submittal

On October 19, 2007, the State of Tennessee submitted a revision to the Nashville/Davidson County portion of the Tennessee SIP, which included a revision to the Metropolitan Public Health Department, Pollution Control Division's Regulation Number 8, "Inspection and Maintenance of Light-Duty Motor Vehicles." This revision was promulgated by the Davidson County Metropolitan Health Department, which is the local agency

overseeing implementation of air pollution control regulations for Davidson County, including Early Action Compact (EAC) related obligations. The SIP revision currently at issue amends Regulation Number 8 by reducing the emissions inspection fee for light-duty motor vehicles from \$10.00 to \$9.00 per inspection. The revision also updates the "Definitions" section by clarifying the definition of 'Carbon Monoxide,' adding the term 'Catalytic Converter,' and clarifying the definition of 'Heavy-Duty Motor Vehicle.' Specifically, the definitions will be changed to the following:

Carbon Monoxide—means a compound consisting of the chemical formula (CO).

Catalytic Converter—means a pollution control device containing a catalyst for converting automobile exhaust into mostly harmless products.

Heavy-Duty Motor Vehicle—means any motor vehicle having a combined manufacturer vehicle and maximum loading rate (GVWR) to be carried thereon in excess of 10,500 pounds (4773 kilograms or more).

The above revision is consistent with the EAC Protocol¹ and is considered by the State of Tennessee to be at least as stringent as preexisting requirements under the SIP.

II. Final Action

EPA has reviewed the submittal and determined that is consistent with the requirements of the CAA and EPA's Policy. Therefore, EPA is approving the aforementioned change to the SIP. EPA is publishing this rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. However, in the proposed rules section of this **Federal Register** publication, EPA is publishing a separate document that will serve as the proposal to approve the SIP revision should adverse comments be filed. This rule will be effective October 17, 2008 without further notice unless the Agency receives adverse comments by September 17, 2008.

If EPA receives such comments, then EPA will publish a document withdrawing the final rule and informing the public that the rule will not take effect. All public comments received will then be addressed in a subsequent final rule based on the proposed rule. EPA will not institute a second comment period. Parties interested in commenting should do so at this time. If no such comments are

¹ The EAC Protocol can be found at <http://www.epa.gov/air/eac/>.

received, the public is advised that this rule will be effective on October 17, 2008 and no further action will be taken on the proposed rule.

III. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a "significant regulatory action" subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- 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);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or

- safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of voluntary consensus standards would be inconsistent with the CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

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 action 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 October 17, 2008. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action 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, Catalytic converter, Heavy-duty motor vehicles, Incorporation by reference, Motor vehicle inspection fee, Ozone.

Dated: July 30, 2008.

Russell L. Wright, Jr.,
Acting Regional Administrator, Region 4.

■ 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 (RR)—(Tennessee)

■ 2. Section 52.2220(c) Table 5 is amended by revising the entry for "Regulation No. 8" to read as follows:

§ 52.2220 Identification of plan.
* * * * *
(c) * * *

TABLE 5—EPA APPROVED NASHVILLE-DAVIDSON, REGULATIONS

State citation	Title/subject	State effective date	EPA approval date	Explanation
* * * * *	* * * * *	* * * * *	* * * * *	* * * * *
Regulation No. 8	Regulation of Emissions from Light-Duty Motor Vehicles Through Mandatory Vehicle Inspection and Maintenance Program.	10/10/2007	8/18/08 [Insert citation of publication].	
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[FR Doc. E8-18968 Filed 8-15-08; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY**Federal Emergency Management Agency****44 CFR Part 64****[Docket No. FEMA-8035]****Suspension of Community Eligibility****AGENCY:** Federal Emergency Management Agency, DHS.**ACTION:** Final rule.

SUMMARY: This rule identifies communities, where the sale of flood insurance has been authorized under the National Flood Insurance Program (NFIP), that are scheduled for suspension on the effective dates listed within this rule because of noncompliance with the floodplain management requirements of the program. If the Federal Emergency Management Agency (FEMA) receives documentation that the community has adopted the required floodplain management measures prior to the effective suspension date given in this rule, the suspension will not occur and a notice of this will be provided by publication in the **Federal Register** on a subsequent date.

DATES: Effective Dates: The effective date of each community's scheduled suspension is the third date ("Susp.") listed in the third column of the following tables.

FOR FURTHER INFORMATION CONTACT: If you want to determine whether a particular community was suspended on the suspension date or for further information, contact David Stearrett, Mitigation Directorate, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472 (202) 646-2953.

SUPPLEMENTARY INFORMATION: The NFIP enables property owners to purchase flood insurance which is generally not otherwise available. In return, communities agree to adopt and administer local floodplain management aimed at protecting lives and new construction from future flooding. Section 1315 of the National Flood

Insurance Act of 1968, as amended, 42 U.S.C. 4022, prohibits flood insurance coverage as authorized under the NFIP, 42 U.S.C. 4001 *et seq.*; unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed in this document no longer meet that statutory requirement for compliance with program regulations, 44 CFR part 59. Accordingly, the communities will be suspended on the effective date in the third column. As of that date, flood insurance will no longer be available in the community. However, some of these communities may adopt and submit the required documentation of legally enforceable floodplain management measures after this rule is published but prior to the actual suspension date. These communities will not be suspended and will continue their eligibility for the sale of insurance. A notice withdrawing the suspension of the communities will be published in the **Federal Register**.

FEMA previously identified the Special Flood Hazard Areas (SFHAs) in these communities by publishing a Flood Insurance Rate Map (FIRM). The date of the FIRM is indicated in the fourth column of the table. No direct Federal financial assistance (except assistance pursuant to the Robert T. Stafford Disaster Relief and Emergency Assistance Act not in connection with a flood) may legally be provided for construction or acquisition of buildings in identified SFHAs for communities not participating in the NFIP and identified for more than a year, on FEMA's initial flood insurance map of the community as having flood-prone areas (section 202(a) of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4106(a), as amended). This prohibition against certain types of Federal assistance becomes effective for the communities listed on the date shown in the last column. The Administrator finds that notice and public comment under 5 U.S.C. 553(b) are impracticable and unnecessary because communities listed in this final rule have been adequately notified.

Each community receives 6-month, 90-day, and 30-day notification letters addressed to the Chief Executive Officer stating that the community will be suspended unless the required floodplain management measures are met prior to the effective suspension

date. Since these notifications were made, this final rule may take effect within less than 30 days.

National Environmental Policy Act. This rule is categorically excluded from the requirements of 44 CFR part 10, Environmental Considerations. No environmental impact assessment has been prepared.

Regulatory Flexibility Act. The Administrator has determined that this rule is exempt from the requirements of the Regulatory Flexibility Act because the National Flood Insurance Act of 1968, as amended, 42 U.S.C. 4022, prohibits flood insurance coverage unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed no longer comply with the statutory requirements, and after the effective date, flood insurance will no longer be available in the communities unless remedial action takes place.

Regulatory Classification. This final rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Executive Order 13132, Federalism. This rule involves no policies that have federalism implications under Executive Order 13132.

Executive Order 12988, Civil Justice Reform. This rule meets the applicable standards of Executive Order 12988.

Paperwork Reduction Act. This rule does not involve any collection of information for purposes of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*

List of Subjects in 44 CFR Part 64

Flood insurance, Floodplains.

■ Accordingly, 44 CFR part 64 is amended as follows:

PART 64—[AMENDED]

■ 1. The authority citation for part 64 continues to read as follows:

Authority: 42 U.S.C. 4001 *et seq.*; Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp.; p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp.; p. 376.

§ 64.6 [Amended]

■ 2. The tables published under the authority of § 64.6 are amended as follows: