

significant impact of a rule on small entities. Because this proposed rule would not impose any compliance costs on sponsors of animal drug products that are currently marketed or in development, the Agency proposes to certify that the proposed rule if finalized would not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is \$141 million, using the most current (2012) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

VI. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule, if finalized, would not contain policies that 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. Accordingly, the Agency tentatively concludes that the proposed rule does not contain policies that have federalism implications as defined in the Executive Order and, consequently, a federalism summary impact statement is not required.

VII. Paperwork Reduction Act of 1995

This proposed rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) is not required.

VIII. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments 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, and will be posted to the docket at <http://www.regulations.gov>.

List of Subjects in 21 CFR Part 514

Administrative practice and procedure, Animal drugs, Confidential business information, Reporting and recordkeeping requirements.

Therefore under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 514 be amended as follows:

PART 514—NEW ANIMAL DRUG APPLICATIONS

■ 1. The authority citation for 21 CFR part 514 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 356a, 360b, 371, 379e, 381.

■ 2. In § 514.11, revise paragraphs (b), (d), (e) introductory text, and (e)(2)(ii) introductory text to read as follows:

§ 514.11 Confidentiality of data and information in a new animal drug application file.

* * * * *

(b) The existence of an NADA file will not be disclosed by the Food and Drug Administration before the application has been approved, unless it has been previously disclosed or acknowledged.

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(d) If the existence of an NADA file has been publicly disclosed or acknowledged before the application has been approved, no data or information contained in the file is available for public disclosure, but the Commissioner may, in his discretion, disclose a summary of such selected portions of the safety and effectiveness data as are appropriate for public consideration of a specific pending issue, i.e., at an open session of a Food and Drug Administration advisory committee or pursuant to an exchange of important regulatory information with a foreign government.

(e) After an application has been approved, the following data and information in the NADA file are immediately available for public disclosure unless extraordinary circumstances are shown:

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(2) * * *

(ii) For an NADA approved after July 1, 1975, a summary of such data and information prepared in one of the following two alternative ways shall be publicly released when the application is approved.

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Dated: March 7, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–05432 Filed 3–14–14; 8:45 am]

BILLING CODE 4160–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52, 62, and 70

[EPA–R07–OAR–2013–0724; FRL 9907–78–Region 7]

Approval and Promulgation of Implementation Plans, State Plans for Designated Facilities and Pollutants, and Operating Permits Program; State of Missouri

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve revisions to the Missouri State Implementation Plan (SIP), the 40 CFR part 62 state plans for designated facilities and pollutants (111(d)), and the 40 CFR part 70 operating permits program, which were received on August 25, 2011, May 8, 2012, and February 11, 2013, respectively. The revisions submitted by the state move definitions currently in individual rules into one rule and eliminates the risk of the same term being defined differently for different rules. This action provides more clarity for the regulated public. These revisions do not have an adverse affect on air quality. EPA's proposed approval of these rule revisions is being done in accordance with the requirements of the Clean Air Act (CAA).

DATES: Comments on this proposed action must be received in writing by April 16, 2014.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R07–OAR–2013–0724, by mail to Paula Higbee, Environmental Protection Agency, Air Planning and Development Branch, 11201 Renner Boulevard, Lenexa, Kansas 66219. Comments may also be submitted electronically or through hand delivery/courier by following the detailed instructions in the **ADDRESSES** section of the direct final rule located in the rules section of this **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Paula Higbee, Environmental Protection Agency, Air Planning and Development Branch, 11201 Renner Boulevard, Lenexa, Kansas 66219 at 913–551–7028, or by email at higbee.paula@epa.gov.

SUPPLEMENTARY INFORMATION: In the final rules section of the **Federal Register**, EPA is approving the state's SIP revision as a direct final rule without prior proposal because the Agency views this as a noncontroversial revision amendment and anticipates no relevant adverse comments to this action. A detailed rationale for the approval is set forth in the direct final rule. If no relevant adverse comments are received in response to this action, no further activity is contemplated in relation to this action. If EPA receives relevant adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed action. EPA will not institute a second comment period on this action. Any parties interested in commenting on this action should do so at this time. 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. For additional information, see the direct final rule which is located in the rules section of this **Federal Register**.

Dated: February 28, 2014.

Karl Brooks,

Regional Administrator, Region 7.

[FR Doc. 2014-05684 Filed 3-14-14; 8:45 am]

BILLING CODE 6560-50-P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 67

[Docket ID FEMA-2014-0002; Internal Agency Docket No. FEMA-B-1152]

Proposed Flood Elevation Determinations for Washington County, Pennsylvania (All Jurisdictions)

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Proposed rule; withdrawal.

SUMMARY: The Federal Emergency Management Agency (FEMA) is withdrawing its proposed rule concerning proposed flood elevation determinations for Washington County, Pennsylvania (All Jurisdictions).

DATES: The withdrawal is effective on March 17, 2014.

ADDRESSES: You may submit comments, identified by Docket No. FEMA-B-

1152, to Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646-4064, or (email) Luis.Rodriguez3@fema.dhs.gov.

FOR FURTHER INFORMATION CONTACT: Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646-4064, or (email) Luis.Rodriguez3@fema.dhs.gov.

SUPPLEMENTARY INFORMATION: On November 2, 2010, FEMA published a proposed rulemaking at 75 FR 67308-67310, proposing flood elevation determinations along one or more flooding sources in Washington County, Pennsylvania. Because FEMA has or will be issuing a Revised Preliminary Flood Insurance Rate Map, and if necessary a Flood Insurance Study report, featuring updated flood hazard information, the proposed rulemaking is being withdrawn. A Notice of Proposed Flood Hazard Determinations will be published in the **Federal Register** and in the affected community's local newspaper.

Authority: 42 U.S.C. 4104; 44 CFR 67.4.

Dated: January 31, 2014.

Roy E. Wright,

Deputy Associate Administrator for Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

[FR Doc. 2014-05736 Filed 3-14-14; 8:45 am]

BILLING CODE 9110-12-P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 67

[Docket ID FEMA-2014-0002; Internal Agency Docket No. FEMA-B-1179]

Proposed Flood Elevation Determinations for Bennington County, Vermont (All Jurisdictions)

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Proposed rule; withdrawal.

SUMMARY: The Federal Emergency Management Agency (FEMA) is withdrawing its proposed rule concerning proposed flood elevation determinations for Bennington County, Vermont (All Jurisdictions).

DATES: This withdrawal is effective on March 17, 2014.

ADDRESSES: You may submit comments, identified by Docket No. FEMA-B-1179, to Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646-4064, or (email) Luis.Rodriguez3@fema.dhs.gov.

FOR FURTHER INFORMATION CONTACT: Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646-4064, or (email) Luis.Rodriguez3@fema.dhs.gov.

SUPPLEMENTARY INFORMATION: On April 6, 2011, FEMA published a proposed rulemaking at 76 FR 19020-19021, proposing flood elevation determinations along one or more flooding sources in Bennington County, Vermont. Because FEMA has or will be issuing a Revised Preliminary Flood Insurance Rate Map, and if necessary a Flood Insurance Study report, featuring updated flood hazard information, the proposed rulemaking is being withdrawn. A Notice of Proposed Flood Hazard Determinations will be published in the **Federal Register** and in the affected community's local newspaper.

Authority: 42 U.S.C. 4104; 44 CFR 67.4.

Dated: January 31, 2014.

Roy E. Wright,

Deputy Associate Administrator for Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

[FR Doc. 2014-05738 Filed 3-14-14; 8:45 am]

BILLING CODE 9110-12-P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 67

[Docket ID FEMA-2014-0002; Internal Agency Docket No. FEMA-B-1311]

Proposed Flood Hazard Determinations for Brown County, Texas, and Incorporated Areas

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Proposed notice; withdrawal.

SUMMARY: The Federal Emergency Management Agency (FEMA) is