(NIH), NIH Clinical Center, Bldg. 10, Jack Masur Auditorium, 9000 Rockville Pike, Bethesda, MD.

Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the appropriate docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

For registration and meeting information: Kathy Eberhart, Center for Biologics Evaluation and Research (HFM–49), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–1317, FAX 301–827–3079, e-mail: eberhart@cber.fda.gov.

For information about this document: Nathaniel L. Geary, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of August 19, 1999 (64 FR 45340 and 45355), FDA published two proposed rules that were intended to help protect the safety and ensure the quality of the nation's blood supply and to promote consistency in the industry. The document entitled ''Requirements for Testing Human Blood Donors for Evidence of Infection Due to Communicable Disease Agents'' (64 FR 45340) [Docket No. 98N–0581] proposed to revise the general biological product standards by updating the hepatitis B virus (HBV) and human immunodeficiency virus (HIV) testing requirements, by adding testing requirements for hepatitis C virus (HCV), human T-lymphotropic virus (HTLV), and by adding requirements for licensed supplemental (i.e., additional, more specific) testing when a donation is found to be repeatedly reactive for any of the required screening tests for evidence of infection due to communicable disease agents.

The document entitled ''General Requirements for Blood, Blood Components, and Blood Derivatives; Notification of Deferred Donors'' (64 FR 45355) [Docket No. 98N–0607] proposed to require blood and plasma establishments to notify donors of their deferral due to test results for communicable disease agents or failure to satisfy suitability requirements with the intent of reducing the risk of transmission of communicable disease through the use of blood, blood components, and blood derivatives. Blood and plasma establishments would notify donors that they have been deferred and the reason for the deferral; provide information concerning appropriate medical follow up and counseling; describe the types of donations the donors should not make in the future; and discuss the possibility that the donor may be found suitable in the future, where appropriate. FDA provided until November 17, 1999, to submit comments on these proposed rules.

The ANPRM entitled ''Plasma Derivatives and other Blood-Derived Products; Requirements for Tracking and Notification'' (64 FR 45383, August 19, 1999) [Docket No. 98N–0815] announced FDA's intention to propose regulations to require certain blood-derived products, including certain plasma derivatives, be tracked from a U.S. licensed manufacturer, through the distribution network, to any patient having custody of the product. FDA also announced its intention to propose to require notification of consignees and patients having custody of a blood-derived product or an analogous recombinant product in the event the product is associated with a potential increased risk of transmitting a communicable disease, as determined by FDA or by a U.S. licensed manufacturer. FDA provided until November 17, 1999, to submit comments on the ANPRM.

II. Comments

Interested persons may submit written comments on these proposed rules and the ANPRM to the Dockets Management Branch (address above) by the date listed above. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the appropriate docket number found in brackets in the heading of this document. If time permits, comments may be taken from the floor. FDA is requesting that those persons making oral presentations at the public meeting also submit their statements in writing by December 22, 1999, as described above, to ensure their adequate consideration. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

III. Registration and Requests for Oral Presentations

Mail or fax registration information (including name, title, firm name, address, telephone, and fax number), and written material and requests to make oral presentations, to Kathy Eberhart (address above) by Monday, November 15, 1999. If you do not intend to make a presentation, registration is not required. However, all interested persons are encouraged to pre-register.

If you need special accommodations due to a disability, please contact Kathy Eberhart at least 7 days in advance.

IV. Transcripts

Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page. The transcript will also be available on CBER's website at http://www.fda.gov/cber/minutes/workshop-min.htm.

Dated: November 2, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 99–29224 Filed 11–8–99; 8:45 am]

BILLING CODE 4160–01–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[MI23–01–6258; FRL–6472–6]

Approval and Promulgation of State Implementation Plans; Michigan

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: The United States Environmental Protection Agency (USEPA) is proposing to disapprove revisions to the State of Michigan's New Source Review (NSR) State Implementation Plan (SIP). The Michigan Department of Environmental Quality (MDEQ) submitted these revisions on November 11, 1993; May 16, 1996; April 3, 1998; and August 20, 1998. MDEQ submitted some of these revisions to meet the requirements of the Clean Air Act (CAA) amendments of 1990. Because these revisions are required under the CAA, a final disapproval would constitute a disapproval under section 179(a)(2) of the CAA. Pursuant to section 179(a) of the CAA, the State of Michigan has up to 18 months after a final disapproval to correct the deficiencies that are the subject of the disapproval before USEPA must impose sanctions.

DATES: Comments on this proposed rule must be received before December 9, 1999.

ADDRESSES: Send written comments to: Robert Miller, Chief, Permits and Grants Section (MI/MN/WI), Air Programs Branch (AR–18J), United States Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604.

Copies of the proposed SIP revision and the USEPA's analysis are available for inspection at the following location: United States Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604. (Please telephone Eaton Weiler at (312) 886–6041 before visiting the Region 5 Office.)

FOR FURTHER INFORMATION CONTACT: Eaton Weiler or Laura Hartman, Environmental Engineers, Permits and Grants Section (AR–18J), Air Programs Branch, Air and Radiation Division, United States Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–6041 or (312) 353–5703.

SUPPLEMENTARY INFORMATION:

I. Background

A. Introduction

The CAA mandates that states develop NSR programs for the construction and modification of stationary sources of air pollutants. See CAA sections 110(a)(2)(C), 165, 172, and 173. NSR programs are necessary under the CAA to help attain and maintain the National Ambient Air Quality Standards as well as to prevent significant degradation of air quality. NSR programs help achieve this goal by requiring owners and operators of new and modified sources of air pollutants to apply appropriate emissions control technology to sources at the time of construction. Furthermore, these programs achieve this goal by allowing the public an opportunity to review and comment on the effects of emissions on air quality from new and modified sources of air pollution prior to construction.

The CAA mandates that states develop NSR programs and submit them to the USEPA for approval into the SIP. The requirements for an approvable NSR program are laid out in the CAA and 40 Code of Federal Regulations (CFR) sections 51.160 to 51.166.

B. Current NSR SIP Submittals

The USEPA has not approved any revisions to the State's NSR SIP since January 27, 1982 (47 FR 3764). Since 1982, Michigan has submitted six rules packages to the USEPA for approval into the SIP. Michigan submitted three packages in 1993, one in 1996, and two in 1998. Each of the rules packages is identified in the table below by the date the rules package went into effect in the State (State Effective Date), and the date the State submitted the rules package to the USEPA (Submittal Date). Bold indicates the latest revision to the particular rule that is before USEPA for review.

Rules package (RP)	State effective date	Submittal date	Rules submitted 336.1xxx
1	4/20/89	11/12/93	107, 121, 240, 241.
2	4/17/92	11/12/93	102, 106, 109, 112, 115, 118, 120, 123, 201, 283.
3	11/18/93	11/12/93	101, 103, 104, 105, 113, 114, 116, 119, 220, 278, 279, 280, 281, 282, 284, 285, 286, 287, 288, 289, 290.
4	7/26/95	5/16/96	101, 103, 113, 116, 118, 119, 123, 201, 205, 208(RES), 209, 219, 278, 279, 280, 281, 282, 283, 284, 285, 286, 287, 288, 289, 290.
5	12/12/96	4/3/98	116(g), 116(m), 118(g), 119(b), 119(q), 201a, 205.
6	6/13/97	8/20/98	118, 122, 278, 283, 284, 285, 286, 287, 290.

C. USEPA Requirements for Disapproval

Under section 110(k)(3) of the CAA, the USEPA may fully approve or disapprove a state submittal. Where portions of the state submittal are separable, the USEPA may approve portions of the submittal that meet the requirements of the CAA, and disapprove the portions of the submittal that do not meet the requirements of the CAA. See 57 FR 13566 (April 16, 1992). However, in this context, separable means that the USEPA may not partially disapprove a portion of a SIP submittal if the effect of the disapproval would make the approved portion of the SIP submittal more stringent than the state intended. In this proposed action, any partial disapproval of Michigan's NSR SIP submittal would make the State's entire NSR SIP program more stringent than the State intended. Therefore, the elements of the Michigan NSR program discussed below that do not meet the requirements of the CAA make the entire SIP submittal disapprovable.

II. Evaluation of State Submittals

Following below is a discussion of the portions of the State's NSR SIP submittals that USEPA is proposing as not meeting the requirements of the CAA. For each section, the requirements of the CAA and its implementing regulations are outlined followed by an analysis of why the State's submittal does not meet the requirements of the CAA.

A. Public Participation

The provisions of 40 CFR 51.161 require the State to implement specific public participation procedures. These procedures require the State to notify, inform, and invite comment from the public on all new and modified sources of air pollution subject to the NSR program. However, as discussed in a proposal to amend the federal operating permit program, 60 FR 45530, 45549 (August 31, 1995), USEPA believes that a state may exempt from public review certain categories of changes based upon de minimis or administrative necessity grounds, in accordance with the criteria set out in *Alabama Power Co.* v. *Costle*, 636 F.2d 323 (D.C. Cir. 1979).

Michigan rule 336.1205(3) requires public participation only for NSR sources that are major or major modifications, or limit their potential to emit to greater than 90 percent of the major or major modification thresholds. Under this provision, a source could have actual emissions of over 200 tons per year and not be subject to any public participation procedures. While this limitation may be acceptable if adequately justified, Michigan has not explained how the 90 percent threshold meets the de minimis criteria. Because Michigan has not provided an adequate explanation of why construction or modification of sources resulting in emissions of less than 90 percent of the new source review thresholds should not require public participation under the NSR program, the USEPA is proposing disapproval of Michigan Rule 336.1205(3).

Furthermore, Michigan rule 336.1205(3) incorrectly cites section 5h(3) instead of 5511(3) of the Michigan Act 451, part 55. Although the State

corrected this citation error in a State rulemaking effective July 2, 1998, it has not yet submitted the correction to USEPA for approval into the SIP.

B. Voiding of NSR Permits (Supersession)

As recently communicated in a letter from John S. Seitz to STAPPA/ALAPCO dated May 20, 1999, it is the USEPA's position that NSR permits may not be voided, superseded, or otherwise replaced by permits issued pursuant to Title V of the CAA Amendments of 1990. All terms and conditions of NSR permits must be independently enforceable under Title I of the CAA Amendments of 1990. While Title V permits must incorporate and record permit terms and conditions from NSR permits, Title V may not eliminate their independent enforceability and existence.

Michigan rule 336.1201(6) automatically voids the NSR permit when the ''appropriate'' terms and conditions are incorporated into a Title V permit. Therefore, USEPA is proposing to disapprove this rule.

C. Construction Before Permit Issuance

Pursuant to CAA sections 110(a)(2)(C), 165, 172, 173, and their implementing regulations, the State is required to develop a NSR program, under which a source shall not begin actual construction of a major source or major modification to a major source unless the source has obtained a NSR permit. Furthermore, pursuant to 40 CFR 51.165(a)(1) the State must adopt the federal definition of ''begin actual construction,'' or a definition that is demonstrably more stringent. The federal definition includes any construction of a permanent nature, such as foundations, pipework, building supports, and permanent storage structures. 40 CFR 51.165(a)(1)(xv). Michigan has not adopted and submitted for USEPA approval a definition of ''begin actual construction'' which is identical to or more stringent than the federal definition. Additionally, Michigan rule 336.1201(2) allows sources to begin phases of construction, including foundations and associated structures, before issuance of a NSR permit so long as it is not prohibited by the CAA. As stated above, the CAA prohibits construction of a major source or major modification to a major source before NSR permit issuance. Moreover, the CAA and its implementing regulations require the State to adopt provisions prohibiting construction before permit issuance. Michigan rule 336.1201(2) contradicts itself, and is contrary to the requirements of the CAA and its implementing regulations. Therefore, USEPA is proposing to disapprove Michigan rule 336.1201(2).

Michigan rule 336.1202 allows the MDEQ to waive the requirement for any source to obtain an NSR permit before beginning construction. As stated above, the CAA and its implementing regulations prohibit construction of major sources or major modifications to major sources without a preconstruction permit. Further, section 110(a)(2) of the CAA requires states to regulate the construction and modification of any stationary source as necessary to assure that the national ambient air quality standards are achieved. Similarly, 40 CFR 51.160(b) provides that a state must prevent the construction or modification of a source if it will result in a violation of applicable portions of the control strategy or interfere with the attainment or maintenance of a national ambient air quality standard. Therefore, Michigan may provide for a waiver from the preconstruction requirements of the CAA for minor sources if the waiver provisions include procedures to ensure that the source receiving the waiver is a ''true minor,'' that is, a source whose potential to emit is below the threshold for a major source or the potential to emit of the modification is below the major modification threshold without consideration of any limitations on emissions, and the state can verify that the construction or modification of the source will neither interfere with attainment or maintenance of the national ambient air quality standard nor result in a violation of applicable portions of the control strategy.

USEPA, in the past, mistakenly had approved a prior version of Michigan rules 336.1201(2) and 336.1202 into the SIP. Because the currently approved SIP rules do not comply with the requirements of the CAA, the USEPA is planning to issue a SIP call pursuant to section 110(k)(5) of the CAA. Section 110(k)(5) of the CAA allows the USEPA to require a revision to the SIP upon a finding that the currently approved SIP does not meet the requirements of the CAA. A final finding under section 110(k)(5) would allow the State up to 18 months to correct the deficiency.

D. Directors Discretion Exemption From NSR Permitting

Under Michigan rule 336.1279, a source is exempt from NSR permitting at the MDEQ's discretion where the source is not major or does not have actual emissions above the significance levels. CAA section 110(a)(2)(C) and 40 CFR 51.160(a) require the State to develop legally enforceable procedures to review new and modified sources. Furthermore, 40 CFR 51.160(e) requires the State to identify the types and sizes of sources subject to review under the State's NSR program. Exempting sources at the director's discretion does not identify the sources subject to review, and, therefore, is disapprovable. Because Michigan rule 336.1279 exempts sources from all review procedures without prior identification and approval of the exemption criteria into the SIP, USEPA is proposing to disapprove the rule.

E. Miscellaneous Exemptions From NSR Permitting

Michigan rules 336.1280 to 336.1290 significantly relax the types and sizes of sources that must obtain a NSR permit. While these exemptions may be acceptable, the State must demonstrate why these sources need not be subject to review in accordance with the *Alabama Power* de minimis or administrative necessity criteria. Such a demonstration may include: (1) An analysis of the types and quantities of emissions from exempted sources, and (2) an analysis which shows that exempting such facilities from permitting review will not interfere with maintenance of the NAAQS or applicable control strategy, and otherwise fulfills the purposes of the minor NSR regulations.

As part of the above demonstration, the State must require each exempted emissions unit with a potential for sizeable emissions to keep appropriate compliance records to verify that the emissions unit meets the specific exemption criteria, and to verify that the construction or modification of the emissions unit did not trigger major new source regulations or other exclusions from the exemptions as listed in Michigan rule 336.1278.

At a minimum, sources with sizeable potential emissions which are assuming exemptions must keep: (1) Records of the date of equipment installation and a description of the emissions unit, (2) records to show the emissions unit does not violate any of the rule 336.1278 exclusions from the exemptions, and (3) records to show that the emissions unit meets the specific exemption criteria outlined in the rule.

Michigan rule 336.1285 exempts sources from obtaining NSR permits where the quantity and nature of the emissions increases are not ''appreciable,'' or ''meaningful.'' Because these terms are undefined, this regulation does not comply adequately with 40 CFR 51.160(e), which requires the state to identify the types and sizes of sources subject to review. Therefore,

Michigan rule 336.1285 is not approvable at this time.

Additionally, because Michigan uses its NSR program to implement section 112(g) of the CAA, the exemptions in rules 336.1279 through 336.1290 would exempt a major Hazardous Air Pollutant source from complying with 112(g) of the CAA. For this reason, the State must add language that specifically excludes major HAP sources from the exemptions. Although the State has added such language in a State rulemaking effective July 2, 1998, it has not submitted these revisions to the USEPA for approval into the SIP.

Finally, Michigan should make clear in its rules that the exemptions in rules 336.1279 through 336.1290, even after approved into the Michigan SIP, do not exempt any source from complying with any other applicable federal requirements or existing NSR permit limitations. For all these reasons, USEPA is proposing to disapprove Michigan rules 336.1279 through 336.1290.

F. Relaxation of Permit Conditions

Pursuant to 40 CFR 51.165(a)(5)(ii), the State must develop regulations that would require sources to obtain a major NSR permit if the relaxation of an emission limitation that the source took to avoid NSR would make the original construction a major source or major modification. Because the Michigan NSR SIP contains no such provisions, it is deficient.

G. Emissions Reductions Required by the CAA Are Not Creditable

Pursuant to section 173(c)(2) of the CAA, the State must develop regulations to ensure that emissions reductions otherwise required by the CAA are not creditable as offsets. Because the Michigan NSR SIP contains no such restrictions, it is deficient.

H. Definition of ''Nonattainment Area''

The term ''nonattainment area,'' as defined in section 171(2) of the CAA, means ''an area which is designated 'nonattainment' with respect to that pollutant within the meaning of section 107(d)'' of the CAA.

The Michigan rule 336.114(g) defines ''nonattainment area'' as an area designated by the department as not having attained full compliance with all national ambient air quality standards. The State must make clear in its definition of ''nonattainment area'' that any major source or major modification to a stationary source located in an area promulgated as nonattainment by USEPA pursuant to section 107(d) of the CAA, must comply with the nonattainment NSR requirements. Therefore, USEPA is proposing to disapprove the State definition of ''nonattainment area.''

I. Federal Enforceability

Pursuant to section 173(a) of the CAA, the State must develop regulations under which all offsets required as a precondition to permit issuance must be federally enforceable.

The Michigan rule 336.1220(2) only requires that offsets shall be legally enforceable. Therefore, USEPA is proposing to disapprove Michigan rule 336.1220(2).

J. Exemption From Offset Requirements for Municipal Solid Waste Facilities

40 CFR 51.165 does not provide for exemptions from the offset requirements. As explained to the NRDC in a letter from the EPA Region II dated March 18, 1989, the regulations of 40 CFR 51.165 supercede the guidance of appendix S. Therefore, the EPA will not approve any offset exemptions from resource recovery facilities.

Michigan rule 336.1220(4)(b) impermissibly exempts municipal solid waste burning facilities from offset requirements laid out in the CFR. Therefore, USEPA is proposing to disapprove Michigan rule 336.1220(4)(b).

K. Modeling Requirements

40 CFR 51.160(f)(1) requires that all modeling shall be based on the applicable models, data bases, and other requirements specified in 40 CFR part 51, appendix W (Guideline on Air Quality Models).

Michigan rule 336.1240 outlines the required air quality models. Michigan rule 336.2240 requires the use of an air quality model cited in EPA's 1986, ''Guideline on Air Quality Models.'' The ''Guideline on Air Quality Models'' was updated in 1987, 1993, and 1995 and codified in part 51 appendix W.

Furthermore, Michigan rule 336.1240(2) impermissibly allows the use of an alternate model at the ''director's discretion'' without opportunity for public notice or comment, as required by 40 CFR 51.160(f)(2). Michigan rule 336.1240(2)(ii) allows the director to decide to allow use of an alternate model if the applicant demonstrates the alternate model is ''comparable'' to USEPA's outdated 1984 document, ''Interim Procedures for Evaluating Air Quality Models.'' Instead of the word ''comparable,'' the State rule should require that the alternate model produce concentration estimates equivalent to the estimates obtained using the preferred model in the current appendix W, and should reference the USEPA's updated 1992 document entitled ''Interim Procedures for Evaluating Air Quality Models.''

In addition to proposing to disapprove Michigan rule 336.1240 because it allows use of an alternate model to escape the public participation procedures of 40 CFR 51.160(f)2), USEPA also is proposing to disapprove Michigan rule 336.1240 because it references out-of-date modeling guidelines rather than the current codified modeling guidelines in 40 CFR part 51, appendix W.

L. Air Quality Modeling Demonstration Requirements

Michigan Rule 336.1241 outlines the requirements for air quality modeling demonstrations. These provisions must be updated to reflect the current modeling requirements laid out in 40 CFR part 51, appendix W.

In particular, the provisions require five years of meteorological data unless the applicant can demonstrate that a shorter meteorological record is more representative. The rule specifically should state that, if the applicant uses on site data, a minimum of one year of meteorological data is required.

M. Offset Restrictions

40 CFR 51.165(a)(3)(ii)(A) requires that where the SIP allows emissions greater than the potential to emit of the source, emissions offset credit will be allowed only for control below this potential. Michigan NSR rules contain no such restriction and, therefore, are unapprovable.

N. Failure To Rescind Michigan Rule 336.1221

Michigan rule 336.2221 impermissibly exempts sources that have significant net emissions increases of sulfur dioxide, particulate matter, and carbon monoxide from offset requirements.

MDEQ rescinded Michigan rule 336.1221 effective November 14, 1990. However, the State never submitted the rule to USEPA for recission. Because Michigan did not submit the recission to the USEPA for removal of the rule from the SIP, the Michigan NSR rules are not approvable at this time.

III. Proposed Action

To determine the approvability of a rule, USEPA must evaluate the rule for consistency with the requirements of the CAA and USEPA regulations as codified in the Code of Federal Regulations, and the EPA's interpretation of these requirements as

expressed in USEPA policy guidance documents. The USEPA has found the Michigan SIP revisions inconsistent with CAA sections 110(a)(2)(C), 165, 172, and 173. The USEPA has further found Michigan's proposed SIP revisions inconsistent with the provisions of 40 CFR part 51, and sections 160 through 165. For these reasons, USEPA is proposing to disapprove Michigan's proposed revisions to its NSR SIP.

Michigan submitted some of the proposed revisions to meet the requirements of the CAA amendments of 1990. Because Michigan failed to satisfy requirements of the CAA through these revisions, a final disapproval would constitute a disapproval under section 179(a)(2) of the CAA. As provided under section 179(a) of the CAA, the State of Michigan would have up to 18 months after a final disapproval to correct the deficiencies that are the subject of the disapproval before the CAA requires USEPA to impose sanctions.

Furthermore, pursuant to section 110(k)(5) of the CAA, the USEPA finds that the currently approved NSR SIP does not meet the requirements of the CAA. The specific provisions that USEPA finds do not meet the CAA are those that allow sources to construct before obtaining an NSR permit. The USEPA intends to issue a notice of SIP deficiency on this issue at the time of its final rulemaking on Michigan's NSR SIP submittal. This notice would allow the State up to 18 months to correct the deficiency before USEPA must impose sanctions.

IV. Administrative Requirements

A. Executive Order 12866

The Office of Management and Budget (OMB) has exempted this regulatory action from Executive Order (E.O.) 12866, entitled ''Regulatory Planning and Review.''

B. Executive Orders on Federalism

Under E.O. 12875, EPA may not issue a regulation that is not required by statute and that creates a mandate upon a state, local, or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to the Office of Management and Budget a description of the extent of EPA's prior consultation with representatives of affected state, local, and tribal governments, the nature of their concerns, copies of written communications from the governments, and a statement supporting the need to issue the regulation.

In addition, E.O. 12875 requires EPA to develop an effective process permitting elected officials and other representatives of state, local, and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.'' Today's rule does not create a mandate on state, local or tribal governments. Proposed disapproval of the rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of E.O. 12875 do not apply to this proposed rulemaking.

On August 4, 1999, President Clinton issued a new executive order on federalism, Executive Order 13132 (64 FR 43255 (August 10, 1999)), which will take effect on November 2, 1999. In the interim, the current Executive Order 12612 (52 FR 41685 (October 30, 1987)), on federalism still applies. This rule will not have a substantial direct effect on 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 12612. Proposed disapproval of the rule affects only one State, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act.

C. Executive Order 13045

Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997), applies to any rule that: (1) Is determined to be ''economically significant'' as defined under E.O. 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This proposed disapproval is not subject to E.O. 13045 because it does not involve decisions intended to mitigate environmental health or safety risks disproportionately on children.

D. Executive Order 13084

Under E.O. 13084, EPA may not issue a regulation that is not required by statute, that significantly affects or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide to the Office of Management and Budget, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation.

In addition, E.O. 13084 requires EPA to develop an effective process permitting elected and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.'' Today's proposed disapproval does not significantly or uniquely affect the communities of Indian tribal governments. Accordingly, the requirements of section 3(b) of E.O. 13084 do not apply to this rule.

E. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and small governmental jurisdictions.

This proposed disapproval will not have a significant impact on a substantial number of small entities. A proposed disapproval of a requested SIP revision under section 110 and subchapter I, part D of the Clean Air Act does not affect any existing Federal requirements nor does it impose new requirements. Any pre-existing Federal requirements would remain in place after this disapproval. Federal disapproval of the State submittal would not affect State-enforceability. Moreover, EPA's disapproval of the submittal would not impose any new Federal requirements. Therefore, because the proposed disapproval does not affect any existing requirements nor impose any new requirements, I certify that this action will not have a significant economic impact on a substantial number of small entities.

Moreover, due to the nature of the Federal-State relationship under the Clean Air Act, preparation of flexibility

analysis would constitute Federal inquiry into the economic reasonableness of state action. The Clean Air Act forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co.*, v. *U.S. EPA*, 427 U.S. 246, 255–66 (1976); 42 U.S.C. 7410(a)(2).

F. Unfunded Mandates

Under section 202 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act''), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated annual costs to State, local, or tribal governments in the aggregate; or to private sector, of $100 million or more. Under section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

EPA has determined that the disapproval action being proposed does not include a Federal mandate that may result in estimated annual costs of $100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. The proposed disapproval would not change existing requirements and does not impose a Federal mandate. If EPA were to disapprove the State's SIP submittal, pre-existing requirements would remain in place and State enforceability of the submittal would be unaffected. The action would impose no new requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, New source review, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Authority: 42 U.S.C. 7401–7671q.

Dated: October 22, 1999.

David A. Ullrich,

Acting Regional Administrator, Region 5.

[FR Doc. 99–29303 Filed 11–8–99; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[CA–179–0194EC; FRL–6472–5]

Approval and Promulgation of Implementation Plans; California State Implementation Plan Revision San Joaquin Valley Unified Air Pollution Control District; Extension of Comment Period

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; extension of the comment period.

SUMMARY: EPA is extending the comment period for a proposed rule published September 23, 1999 (64 FR 51489). On September 23, 1999, EPA proposed a limited approval and limited disapproval of revisions to the California State Implementation Plan controlling particulate matter (PM–10) emissions from fugitive dust sources in the San Joaquin Valley Unified Air Pollution Control District. In response to requests from the Western States Petroleum Association, Citizens Advisory Group of Industries, Independent Oil Producers' Agency, Nisei Farmers League, and California Cotton Ginners and Growers Associations, EPA is extending the comment period for 30 days.

DATES: The comment period is extended until December 8, 1999.

ADDRESSES: Comments should be submitted to: Andrew Steckel, Rulemaking Office (AIR–4), Air Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105–3901.

FOR FURTHER INFORMATION CONTACT: Karen Irwin at (415) 744–1903.

Dated: October 29, 1999.

Laura Yoshi,

Deputy, Regional Administrator, Region IX.

[FR Doc. 99–29307 Filed 11–8–99; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[FRL–6471–3]

National Oil and Hazardous Substance Pollution Contingency Plan; National Priorities List

AGENCY: Environmental Protection Agency.

ACTION: Notice of intent to delete Jacksonville Municipal Landfill Superfund site from the National Priorities List.

SUMMARY: The United States Environmental Protection Agency (EPA) Region 6 announces its intent to delete the Jacksonville Municipal Landfill Superfund Site (''the Site'') from the National Priorities List (NPL) and requests public comment on this proposed action. The NPL constitutes appendix B of 40 CFR part 300 which is the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), which the EPA promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended. The EPA and the State of Arkansas Department of Environmental Quality (ADEQ), have determined that the remedial action for the Site has been successfully completed and that no further action is warranted.

DATES: Comments on this proposed deletion may be submitted to the EPA on or before December 9, 1999.

ADDRESSES: Comments may be mailed to: Mr. Donn Walters, Community Involvement Coordinator, U.S. EPA (6SF–P), 1445 Ross Ave., Dallas, Texas 75202–2733, (214) 665–6483 or 1–800–533–3508 (Toll Free), walters.donn@epa.gov.

FOR FURTHER INFORMATION CONTACT: Ms. Kathleen Aisling, Remedial Project Manager, U.S. EPA (6SF–LT), 1445 Ross Avenue, Dallas, Texas 75202–2733, (214) 665–8509 or 1–800–533–3508 (Toll Free), aisling.kathleen@epa.gov.

SUPPLEMENTARY INFORMATION:

Information Repositories

Comprehensive information on the Site has been compiled in a public docket which is available for viewing at the Jacksonville Municipal Landfill Superfund Site information repositories:

U.S. Environmental Protection Agency, 1445 Ross Avenue, Dallas, Texas 75202–2733, (214) 665–6427, Mon.–Fri. 8:00 a.m.–4:30 p.m., (Please call in advance.)

City Hall (Administrative Record File), 1 Industrial Drive, Jacksonville, Arkansas, Mon.–Fri. 8 a.m.–5 p.m.

Base Library, Little Rock Air Force Base, Jacksonville, Arkansas, Mon.–Thurs. 10 a.m.–8 p.m., Fri. and Sat. 10 a.m.–5 p.m.

Arkansas Department of Environmental Quality (Administrative Record File), 8001 National Drive, Little Rock, Arkansas, Mon.–Fri. 8 a.m.–4:30 p.m.

Table of Contents