FDA has nonetheless examined the economic implications of the final rule in accordance with the Regulatory Flexibility Act and determined that the final rule will not have a significant economic impact on a substantial number of small entities. Similarly, because FDA is not required to perform a final regulatory flexibility analysis under 5 U.S.C 605(b) for the final rule, FDA is not required to issue an SECG to comply with section 212 of the Small Business Regulatory Enforcement Fairness Act (Pub. L. 104–121); nevertheless, FDA has updated this SECG to state in plain language the requirements of 21 CFR part 1, Subpart J, as amended by the final rule.

II. Paperwork Reduction Act of 1995

This guidance refers to information collection provisions found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). Except for the provision regarding access to records, the collections of information in 21 CFR part 1, Subpart J, have been approved under OMB control number 0910–0560. With regard to access to records, we conclude that these information collection provisions are exempt from OMB review under 44 U.S.C. 3518(c)(1)(B)(ii) and 5 CFR 1320.4(a)(2) as collections of information obtained during the conduct of a civil action to which the United States or any official or Agency thereof is a party, or during the conduct of an administrative action, investigation, or audit involving an Agency against specific individuals or entities. The regulations in 5 CFR 1320.3(c) provide that the exception in 5 CFR 1320.4(a)(2) applies during the entire course of the investigation, audit or action, but only after a case file or equivalent is opened with respect to a particular party. Such a case file would be opened as part of the request to access records.

III. 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://regulations.gov.*

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/RegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: April 1, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–07548 Filed 4–3–14; 8:45 am]

BILLING CODE 4160–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2013–0646; FRL–9908–71–Region 5]

Approval and Promulgation of Air Quality Implementation Plans; Michigan; PSD Rules for $PM_{2.5}$

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve revisions to Michigan's Prevention of Significant Deterioration Program rules and definitions, including revisions to Parts 1 and 18 of Michigan's Air Pollution Control Rules into Michigan's State Implementation Plan (SIP). The revised rules address the Federal requirements for significant emission levels, and definitions for fine particulate matter. The Michigan Department of Environmental Quality submitted these revisions to EPA on August 9, 2013, and September 19, 2013.

DATES: Comments must be received on or before May 5, 2014.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R05–OAR–2013–0646, by one of the following methods:

1. *www.regulations.gov:* Follow the on-line instructions for submitting comments.
2. *Email: damico.genevieve@epa.gov.*
3. *Fax:* (312) 886–0968.
4. *Mail:* Genevieve Damico, Chief, Air Permits Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604.
5. *Hand Delivery:* Genevieve Damico, Chief, Air Permits Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604. Such deliveries are only accepted during the Regional Office normal hours of operation, and special arrangements should be made for deliveries of boxed information. The Regional Office official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

Please see the direct final rule which is located in the Rules section of this **Federal Register** for detailed instructions on how to submit comments.

FOR FURTHER INFORMATION CONTACT: Constantine Blathras, Environmental Engineer, Air Permits Sections, Air Programs Branch (AR–18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–0671, *Blathras.constantine@epa.gov.*

SUPPLEMENTARY INFORMATION: In the Rules section of this **Federal Register**, EPA is approving the State's SIP submittal as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this rule, no further activity is contemplated. If EPA receives adverse comments, we will withdraw the direct final rule and will address all public comments in a subsequent final rule based on this proposed action. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule which may be severed from the remainder of the rule, EPA may adopt as final those provisions 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: March 17, 2014.

Susan Hedman,

Regional Administrator, Region 5.

[FR Doc. 2014–06827 Filed 4–3–14; 8:45 am]

BILLING CODE 6560–50–P