

on the day after the date of receipt of the applicant's notice of certification by the patent owner or NDA holder, whichever date is later. When the 45th day falls on Saturday, Sunday, or a Federal holiday, the 45th day will be the next day that is not a Saturday, Sunday, or Federal holiday.

(2) The ANDA applicant or 505(b)(2) applicant must notify FDA immediately in writing of the filing of any legal action for patent infringement filed within 45 days of receipt of the notice of certification. If FDA is not so notified by the ANDA or 505(b)(2) applicant, or by the patent owner or NDA holder, before the expiration of the 45-day time period or the completion of the agency's review of the application, whichever occurs later, approval of the ANDA or the 505(b)(2) application will be made effective immediately upon expiration of the 45 days or completion of the agency's review and approval of the application, whichever date is later. The notification to FDA of the legal action must include the information in paragraphs (h)(2)(i) through (h)(2)(iv) of this section and be submitted according to paragraph (h)(2)(v) of this section as follows:

(i) The ANDA or 505(b)(2) application number;

(ii) The name of the applicant;

(iii) The established name of the drug product or, if no established name exists, the name(s) of the active ingredient(s), the drug product's strength, and the dosage form;

(iv) A certification that an action for patent infringement, identified by number, has been filed in an appropriate court on a specified date; and

(v) An ANDA applicant must notify FDA's Office of Generic Drugs (HFD-600). A 505(b)(2) applicant must notify the appropriate review division in the Center for Drug Evaluation and Research or the Office of Generic Drugs if it is reviewing the application. A patent owner or NDA holder may also notify FDA of the filing of any legal action for patent infringement.

(3) If the patent owner or NDA holder waives its opportunity to file a legal action for patent infringement within 45 days of a receipt of the notice of certification and the patent owner or NDA holder submits to FDA a valid waiver before the 45 days elapse, approval of the ANDA or the 505(b)(2) application will be made effective upon completion of the agency's review and approval of the application. FDA will only accept a waiver in the following form:

(Name of patent owner or NDA holder) has received notice from (name of applicant)

under (section 505(b)(3) or (j)(2)(B) of the act) and does not intend to file an action for patent infringement against (name of applicant) concerning the drug (name of drug) before (date on which 45 days elapses). (Name of patent owner or NDA holder) waives the opportunity provided by (section 505(c)(3)(C) or (j)(2)(iii) of the act) and does not object to FDA's approval of (name of applicant)'s (505(b)(2) or ANDA) for (name of drug) with an immediate effective date on or after the date of this letter.

Dated: July 29, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99-20353 Filed 8-5-99; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 935

[OH-264-FOR]

Ohio Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Proposed rule; reopening of public comment period.

SUMMARY: OSM is reopening the public comment period on a proposed amendment to the Ohio regulatory program (Ohio program) under the surface Mining Control and Reclamation Act of 1977 (SMCRA). Ohio is proposing revisions to Section 1501:13-1-04 of the Ohio Administrative Code (OAC) as it relates to exemptions for coal extraction incidental to government-financed highway or other construction. The amendment is intended to revise the Ohio program to include counterparts to the recently promulgated "AML Enhancement Rule," which revised the Federal regulations as 30 CFR 707.5 and added a new provision, at 30 CFR 874.17.

DATES: Written comments must be received by 4:00 p.m., [E.S.T.], August 23, 1999.

ADDRESSES: Mail or hand-deliver your written comments and requests to speak at the hearing to George Rieger, Field Branch Chief, at the address listed below.

You may review copies of the Ohio program, the proposed amendment, and all written comments received in response to this document at the addresses listed below during normal business hours, Monday through Friday, excluding holidays. You may receive one free copy of the proposed

amendment by contacting OSM's Appalachian Regional Coordinating Center.

George Rieger, Field Branch Chief, Appalachian Regional Coordinating Center, Office of Surface Mining Reclamation and Enforcement, 3 Parkway Center, Pittsburgh PA 15220, Telephone: (412) 937-2153.

Ohio Division of Mines and Reclamation, 1855 Fountain Square Court, Columbus, Ohio 43244, Telephone: (614) 265-1076.

FOR FURTHER INFORMATION CONTACT: George Rieger, Field Branch Chief, Appalachian Regional Coordinating Center, Telephone: (412) 937-2153. Internet: grieger@osmre.gov.

SUPPLEMENTARY INFORMATION:

I. Background on the Ohio Program

On August 16, 1982, the Secretary of the Interior conditionally approved the Ohio program. You can find background information on the Ohio program, including the Secretary's findings, the disposition of comments, and the conditions of approval in the August 10, 1982, **Federal Register** (47 FR 34688). You can find later actions on conditions of approval and program amendments at 30 CFR 935.11, 935.15, and 935.16.

II. Description of the Proposed Amendment

By letter dated March 16, 1999 (Administrative Record No. OH-2178-00) Ohio submitted a proposed amendment to its program concerning exemptions for coal extraction incidental to government-financed highway or other construction. Ohio submitted the proposed amendment at its own initiative, in order to incorporate into its program the expanded exemption recently promulgated in the Federal regulations at 30 CFR 707.5, as part of the "AML Enhancement Rule." Under this rule, approved Title IV abandoned mine land (AML) projects under SMCRA which involve incidental coal extraction and are less than 50 percent government financed may qualify for exemption. Projects which qualify for this expanded exemption must also meet the newly promulgated requirements contained in 30 CFR 874.17. (64 FR 7470, February 12, 1999). The proposed amendment was announced in the April 16, 1999, **Federal Register** (64 FR 18857). The initial comment period closed on May 17, 1999.

By letter dated July 9, 1999 (Administrative Record No. OH-2178-06) Ohio submitted a revised and final version of the proposed amendment. Ohio made this more recent submittal in

response to an OSM, July 1, 1999, issue letter (Administrative Record No. OH-2178-05). In the letter, OSM had requested that the amendment clearly restrict exemptions to projects that are AML eligible; and clearly require that the exempted reclamation project is conducted in accordance with the provisions of 30 CFR Subchapter R. The following are changes to OAC Section 1501:13-1-04 made in the final submission and not previously described in the April 16, 1999, **Federal Register** notice. Revisions concerning nonsubstantive wording, format, or organizational changes will not be described in this notice.

The last sentence of Subsection (A)(3) in the original amendment read as follows: "Funding at less than 50 percent may qualify if the construction is undertaken as an approved reclamation project under Section 1513.30 or 1513.37 of the revised code." This sentence has been revised as follows: "Funding at less than 50 percent may qualify if the project is eligible under 1513.37 of the revised code and the construction is undertaken as an approved reclamation project under Section 1513.30 or 1513.37 of the Revised Code."

Subsection (C)(4)(ii) in the original amendment read as follows: "Ensure that the reclamation project is conducted in accordance with the provision of the approved AML program and procedures." This subsection has been revised as follows: "Ensure that the reclamation project is conducted in accordance with the provisions of the AML program and procedures as approved by the U.S. Secretary Of Interior under 30 CFR Subchapter R."

III. Public Comment Procedures

According to the provisions of 30 CFR 732.17(h), we are seeking comments on whether the proposed amendment satisfies the applicable program approval criteria of 30 CFR 732.15. Specifically, we are seeking comments on the clarification to the State's amendment submitted on July 9, 1999. Comments should address whether the proposed amendment with these clarifications satisfies the applicable program approval criteria of 30 CFR 732.15. If we determine the amendment to be adequate, it will become part of the Ohio program.

Written Comments

Your written comments should be specific, pertain only to the issues proposed in this rulemaking, and include explanations in support of your recommendations. Comments received after the time indicated under **DATES** or

at locations other than the Appalachian Regional Coordinating Center will not necessarily be considered in the final rulemaking or included in the Administrative Record.

IV. Procedural Determinations

Executive Order 12866

This rule is exempt from review by the Office of Management and Budget (OMB) under Executive Order 12866 (Regulatory Planning and Review).

Executive Order 12988

The Department of the Interior has conducted the reviews required by Section 3 of Executive Order 12988 (Civil Justice Reform) and has determined that, to the extent allowed by law, this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments since each such program is drafted and promulgated by a specific State, not by OSM. Under sections 503 and 505 of SMCRA (30 U.S.C. 1253 and 1255) and 30 CFR 730.11, 732.15, and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the other requirements of 30 CFR parts 730, 731, and 732 have been met.

National Environmental Policy Act

No environmental impact statement is required for this rule since Section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that agency decisions on proposed State regulatory program provisions do not constitute major Federal actions within the meaning of section 102(2)(C) of the National Environmental Policy Act (42 U.S.C. 4332(2)(C)).

Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by OMB under the Paperwork Reduction Act (44 U.S.C. 3507 *et seq.*).

Regulatory Flexibility Act

The Department of the Interior has determined 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. 611 *et seq.*). The State submittal which is the subject of this rule is based upon counterpart Federal regulations for which an economic analysis was

prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. Accordingly, this rule will ensure that existing requirements previously promulgated by OSM will be implemented by the State. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the counterpart Federal regulations.

Unfunded Mandates

In accordance with the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*), this rule will not produce a Federal mandate of \$100 million or greater in any year, i.e., it is not a "significant regulatory action" under the Unfunded Mandates Reform Act.

List of Subjects in 30 CFR Part 935

Intergovernmental relations, Surface mining, Underground mining.

Dated: July 27, 1999.

Allen D. Klein,

Regional Director, Appalachian Regional Coordinating Center.

[FR Doc. 99-20273 Filed 8-5-99; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[MN42-01-7267; FRL-6415-2]

Approval and Promulgation of State Implementation Plans; Minnesota

AGENCY: Environmental Protection Agency.

ACTION: Proposed approval.

SUMMARY: The Environmental Protection Agency (EPA) proposes to approve an amendment to the carbon monoxide (CO) State Implementation Plan (SIP) for Minnesota. Minnesota submitted this amendment to the SIP to the EPA in four separate submittals, dated November 14, 1995, July 8, 1996, September 24, 1996, and June 30, 1999.

The submittals include revisions to the motor vehicle inspection and maintenance (I/M) program currently in operation in the Minneapolis/St. Paul CO nonattainment area. The revisions make changes to the State's I/M program, including model year coverage, vehicle waiver provisions, and other program deficiencies identified by the EPA. The revision also contains provisions for the discontinuation of the I/M program if EPA redesignates the area to attainment for CO.