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SUPPLEMENTARY INFORMATION: In the **Federal Register** on September 26, 2017 (82 FR 44803), FDA published a document announcing a public hearing on November 16, 2017, regarding a potential approach for device sponsors who seek to obtain marketing authorization for their products that are intended for a new use with an approved, marketed drug when the sponsor for the approved, marketed drug does not wish to pursue or collaborate on the new use. The purpose of the public hearing was to obtain comments from stakeholders on the potential approach presented in the **Federal Register** document as well as comments on public health, scientific, regulatory, or legal considerations relating to other medical products intended for new uses with approved, marketed medical products of a different type where the sponsor for the approved, marketed product does not wish to pursue or collaborate on the new use. We sought this type of public engagement because of the potential importance of the issue for public health and the need for input across the medical product industry and among public health stakeholders regarding how FDA should proceed. The comments that FDA receives in relation to this public hearing may help inform the further development of this approach.

The document stated that comments would be accepted until January 15, 2018, and that untimely comments would not be considered. Near the end of the comment period, we received a request, submitted on behalf of several potential commenters, for more time to develop comments. We have considered this request and are reopening the comment period for an additional 30 days. We believe that this reopening allows adequate time for interested persons to submit comments without delaying further Agency efforts on this topic.

Dated: January 16, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 901

[SATS No. AL-082-FOR; Docket ID: OSM-2017-0011; S1D1S SS08011000 SX064A000 189S180110; S2D2S SS08011000 SX064A000 18XS501520]

Alabama Regulatory Program

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

ACTION: Proposed rule; public comment period and opportunity for public hearing on proposed amendment.

SUMMARY: We, the Office of Surface Mining Reclamation and Enforcement (OSMRE), are announcing receipt of a proposed amendment to the Alabama regulatory program (Alabama program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). Alabama proposes revisions to its program regarding annual permit fees. Alabama revised its program at its own initiative to raise revenues sufficient to fund the Alabama Surface Mining Commission's (ASMC) share of costs to administer their coal regulatory program, including the cost of reviewing, administering, inspecting, and enforcing surface coal mining permits in Alabama.

This document gives the locations and times where the Alabama program documents and proposed amendment to that program are available for your inspection, establishes the comment period during which you may submit written comments on the amendment, and describes the procedures we will follow for the public hearing, if one is requested.

DATES: We will accept written comments on this amendment until 4:00 p.m., CST, February 21, 2018. If requested, we will hold a public hearing about the amendment on February 16, 2018. We will accept requests to speak at a hearing until 4:00 p.m., CST on February 6, 2018.

ADDRESSES: You may submit comments, identified by SATS No. AL-082-FOR, by any of the following methods:

- **Mail/Hand Delivery:** William Joseph, Acting Director, Birmingham Field Office, Office of Surface Mining Reclamation and Enforcement, 135 Gemini Circle, Suite 215, Homewood, Alabama 35209.
- **Fax:** (205) 290-7280.
- **Federal eRulemaking Portal:** The amendment has been assigned Docket ID OSM-2017-0011. If you would like to submit comments go to <http://>

www.regulations.gov. Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. For detailed instructions on submitting comments and additional information on the rulemaking process, see the "Public Comment Procedures" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to review copies of the Alabama program, this amendment, a listing of any scheduled public hearings, and all written comments received in response to this document, you must go to the address listed below during normal business hours, Monday through Friday, excluding holidays. You may receive one free copy of the amendment by contacting OSMRE's Birmingham Field Office or the full text of the program amendment is available for you to review at www.regulations.gov.

William Joseph, Acting Director, Birmingham Field Office, Office of Surface Mining Reclamation and Enforcement, 135 Gemini Circle, Suite 215, Homewood, Alabama 35209, Telephone: (205) 290-7282, email: bjoseph@osmre.gov.

In addition, you may review a copy of the amendment during regular business hours at the following location: Alabama Surface Mining Commission, 1811 Second Ave., P.O. Box 2390, Jasper, Alabama 35502-2390, Telephone: (205) 221-4130.

FOR FURTHER INFORMATION CONTACT:

William Joseph, Acting Director, Birmingham Field Office. Telephone: (205) 290-7282, email: bjoseph@osmre.gov.

SUPPLEMENTARY INFORMATION:

- I. Background on the Alabama Program
- II. Description of the Proposed Amendment
- III. Public Comment Procedures
- IV. Procedural Determinations

I. Background on the Alabama Program

Section 503(a) of the Act permits a State to assume primacy for the regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders by demonstrating that its program includes, among other things, state laws and regulations that govern surface coal mining and reclamation operations in accordance with the Act and consistent with the Federal regulations. See 30 U.S.C. 1253(a)(1) and (7). On the basis of these criteria, the Secretary of the Interior conditionally approved the Alabama program effective May 20, 1982. You can find background information on the Alabama program,

including the Secretary's findings, the disposition of comments, and the conditions of approval of the Alabama program in the May 20, 1982, **Federal Register** (47 FR 22030). You can also find later actions concerning the Alabama program and program amendments at 30 CFR 901.10, 901.15 and 901.16.

II. Description of the Proposed Amendment

By email dated August 14, 2017 (Administrative Record No. AL-0672), Alabama sent us an amendment to its program under SMCRA (30 U.S.C. 1201 *et seq.*) at its own initiative. Below is a summary of the changes proposed by Alabama. The full text of the program amendment is available for you to read at the locations listed above under **ADDRESSES**.

Alabama Administrative Code 880-X-8B-.07

Alabama proposes revisions to its program regarding annual permit fees by:

- (1) Increasing the initial acreage fee from \$35.00 per acre to \$75.00, to be paid on each acre in a permit covered by a performance bond prior to the initiation of operations on the permit (or on an increment of an acre if increments are used), and to be paid on all bonded acreage covered by a permit renewal;
- (2) Increasing the basic fee for a coal exploration permit application from \$2,000.00 to \$2,500.00;
- (3) Increasing the basic fee for a permit renewal application from \$1,000.00 to \$2,500.00;
- (4) Increasing the basic fee for a permit transfer application from \$200.00 to \$500.00;
- (5) Adding an annual acreage fee for expired permits of \$15.00, per acre, to be paid by December 31st of each year on each acre covered by a performance bond as of October 1st of the year; and
- (6) Adding the inspection of permits to the ASMC's uses for the deposited permit fees.

Alabama fully funds its share of costs to regulate the coal mining industry with fees paid by the coal industry. The proposed fee revisions are intended to provide adequate funding to pay the State's cost of operating its regulatory program. The ASMC does not expect the increase in permit fees to exceed the actual or anticipated cost of reviewing, administering, inspecting, and enforcing surface coal mining permits in Alabama.

III. Public Comment Procedures

Under the provisions of 30 CFR 732.17(h), we are seeking your comments on whether the amendment

satisfies the applicable program approval criteria of 30 CFR 732.15. If we approve the amendment, it will become part of the State plan.

Electronic or Written Comments

If you submit written comments, they should be specific, confined to issues pertinent to the proposed regulations, and explain the reason for any recommended change(s). We appreciate any and all comments, but those most useful and likely to influence decisions on the final program will be those that either involve personal experience or include citations to and analyses of SMCRA, its legislative history, its implementing regulations, case law, other pertinent State or Federal laws or regulations, technical literature, or other relevant publications.

We cannot ensure that comments received after the close of the comment period (see **DATES**) or sent to an address other than those listed (see **ADDRESSES**) will be included in the docket for this rulemaking and considered.

Public Availability of Comments

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Public Hearing

If you wish to speak at the public hearing, contact the person listed under **FOR FURTHER INFORMATION CONTACT** by 4:00 p.m., CST on February 15, 2018. If you are disabled and need reasonable accommodations to attend a public hearing, contact the person listed under **FOR FURTHER INFORMATION CONTACT**. We will arrange the location and time of the hearing with those persons requesting the hearing. If no one requests an opportunity to speak, we will not hold a hearing.

To assist the transcriber and ensure an accurate record, we request, if possible, that each person who speaks at the public hearing provide us with a written copy of his or her comments. The public hearing will continue on the specified date until everyone scheduled to speak has been given an opportunity to be heard. If you are in the audience and have not been scheduled to speak and wish to do so, you will be allowed to speak after those who have been scheduled. We will end the hearing after

everyone scheduled to speak and others present in the audience who wish to speak, have been heard.

Public Meeting

If only one person requests an opportunity to speak, we may hold a public meeting rather than a public hearing. If you wish to meet with us to discuss the amendment, please request a meeting by contacting the person listed under **FOR FURTHER INFORMATION**

CONTACT. All such meetings are open to the public and, if possible, we will post notices of meetings at the locations listed under **ADDRESSES**. We will make a written summary of each meeting a part of the administrative record.

IV. Procedural Determinations

Executive Order 12866—Regulatory Planning and Review

Pursuant to Office of Management and Budget (OMB) Guidance and dated October 12, 1993, the approval of state program amendments is exempted from OMB review under Executive Order 12866.

Other Laws and Executive Orders Affecting Rulemaking

When a State submits a program amendment to OSMRE for review, our regulations at 30 CFR 732.17(h) require us to hold a public hearing on a program amendment if it changes the objectives, scope or major policies followed, or make a finding that the State provided adequate notice and opportunity for public comment. Alabama has elected to have OSMRE publish a notice in the **Federal Register** indicating receipt of the proposed amendment and soliciting comments. We will conclude our review of the proposed amendment after the close of the public comment period and determine whether the amendment should be approved, approved in part, or not approved. At that time, we will also make the determinations and certifications required by the various laws and executive orders governing the rulemaking process and include them in the final rule.

List of Subjects in 30 CFR Part 901

Intergovernmental relations, Surface mining, Underground mining.

Dated: August 28, 2017.

Alfred L. Clayborne,
Regional Director, Mid-Continent Region.

Editorial Note: This document was received for publication by the Office of the Federal Register on January 17, 2018.

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