appropriate to the product. Any advertised R-value claims must fairly reflect the results of those tests. For the purposes of this section, fenestration-related products include windows, doors, and skylights as well as attachments for those products.

■ 14. In Appendix to Part 460—Exemptions, add paragraph (d) to read as follows:

In Appendix to Part 460—Exemptions

* * * * *

(d) The requirements in §§ 460.6 through 460.21 of this part do not apply to R-value claims covered by § 460.22.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 2017–26569 Filed 1–19–18; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 15

[Docket No. FDA–2017–N–5319]

Devices Proposed for a New Use With an Approved, Marketed Drug; Public Hearing; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of public hearing; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is reopening the comment period for the document published in the **Federal Register** on September 26, 2017, announcing a public hearing on 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. In the document, in addition to seeking comments on the potential approach, FDA also welcomed 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 are reopening the comment period in response to a request for an extension to allow interested persons additional time to submit comments.

DATES: FDA is reopening the comment period on the document published on September 26, 2017 (82 FR 44803). Submit either electronic or written comments by February 21, 2018.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before February 21, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of February 21, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2017–N–5319 for ''Devices Proposed for a New Use With an Approved, Marketed Drug; Public Hearing; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: John Barlow Weiner, Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5129, Silver Spring,

MD 20993, 301–796–8930, *combination@fda.gov.*

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.

[FR Doc. 2018–00991 Filed 1–19–18; 8:45 am]

BILLING CODE 4164–01–P

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,