

*Comments:* Regardless of attendance at the public meeting, interested persons may submit electronic comments to <http://www.regulations.gov> or written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5600 Fishers Lane, rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. Identify comments with Docket No. FDA-2013-N-0260, which has previously been established to accept comments regarding this issue. In order to receive consideration in advance of the delivery of the report (discussed further in this document), comments must be received by December 16, 2013. 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://www.regulations.gov>.

*Transcripts:* Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management (see *Comments*). A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Send written requests to the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

On July 9, 2012, President Obama signed FDASIA (Pub. L. 112-144) into law. Section 1112(a) of FDASIA provides that not later than 18 months after its enactment, the Secretary, after obtaining input from medical gas manufacturers and any other interested members of the public, shall determine whether any changes to the Federal drug regulations are necessary for medical gases and submit a report regarding any such changes to the Committee on Health, Education, Labor, and Pensions of the U.S. Senate and the Committee on Energy and Commerce of the U.S. House of Representatives. Section 1112(c)(1) defines "Federal drug regulations" to mean "regulations in title 21 of the Code of Federal Regulations pertaining to drugs." Section 1112(b) provides that if the Secretary determines that changes to the Federal drug regulations are necessary for medical gases, the Secretary shall issue final regulations revising the Federal drug regulations with respect to medical gases not later than 48 months after the enactment of FDASIA.

On March 22, 2013, FDA issued a **Federal Register** notice (78 FR 17611), which established a public docket (Docket No. FDA-2013-N-0260) to request comments from medical gas manufacturers and any other interested members of the public on whether any changes to Federal drug regulations are necessary for medical gases.

##### II. Purpose and Scope of the Meeting

We are holding this meeting to provide an additional opportunity for medical gas manufacturers and any other interested members of the public to provide input on whether any changes to Federal drug regulations are needed for medical gases.

Dated: October 28, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

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#### DEPARTMENT OF THE INTERIOR

##### Bureau of Indian Affairs

##### 25 CFR Part 226

**[BIA-2013-0003; 134/A0A511010/A0A1001000]**

**RIN 1076-AF17**

##### Leasing of Osage Reservation Lands for Oil and Gas Mining

**AGENCY:** Bureau of Indian Affairs, Interior.

**ACTION:** Proposed rule; Reopening of comment period.

**SUMMARY:** In August, the Bureau of Indian Affairs (BIA) published a proposed rule in the **Federal Register** to revise regulations addressing oil and gas mining on reservation land of the Osage Nation. The public comment period for that rule closed on October 28, 2013. This notice reopens the comment period until November 18, 2013.

**DATES:** Comments on the proposed rule published August 28, 2013 (78 FR 53083) must be received by November 18, 2013.

**ADDRESSES:** You may submit comments by any of the following methods:  
—Federal rulemaking portal: The rule is listed under the agency name "Bureau of Indian Affairs" and has been assigned Docket ID "BIA-2013-0003" at <http://www.regulations.gov>.

—*Email:* [osageregneg@bia.gov](mailto:osageregneg@bia.gov). Include the number 1076-AF17 in the subject line of the message.

—*Mail or hand-delivery:* Mr. Eddie Streater, Designated Federal Officer,

Bureau of Indian Affairs, P.O. Box 8002, Muskogee, OK 74402. Include the number 1076-AF17 on the outer envelope.

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

Comments on the information collections contained in this proposed regulation are separate from those on the substance of the rule. Send comments on the information collection burden to OMB by facsimile to (202) 395-5806 or email to the OMB Desk Officer for the Department of the Interior at [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov). Please send a copy of your comments to the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

**FOR FURTHER INFORMATION CONTACT:** Mr. Eddie Streater, Designated Federal Officer, Bureau of Indian Affairs, P.O. Box 8002, Muskogee, OK 74402; telephone: (918) 781-4608; fax: (918) 718-4604; or email: [osageregneg@bia.gov](mailto:osageregneg@bia.gov). Additional information can be found at: <http://www.bia.gov/osageregneg>.

**SUPPLEMENTARY INFORMATION:** On August 28, 2013, BIA published a proposed rule revising 25 CFR 226 (78 FR 53083). The proposed rule is the result of a negotiated rulemaking and would update the leasing procedures and rental, production, and royalties requirements for oil and gas on Osage Mineral lands. The comment period for the proposed rule closed October 28, 2013. With this notice, BIA is reopening the comment period and establishing a new comment deadline of November 18, 2013.

BIA will also consider any comments that it received between the close of the original comment period on October 28, 2013, and the reopening of the comment period. If you submitted comments during this period, there is no need to resubmit them.

Dated: October 25, 2013.

**Kevin K. Washburn,**

*Assistant Secretary—Indian Affairs.*

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