

re-submit its capital plan to NCUA within 30 calendar days. The resubmitted capital plan must at a minimum address:

(1) NCUA-noted deficiencies in the credit union's original capital plan; and

(2) Remediation plans for unresolved supervisory issues contributing to the rejection of the credit union's original capital plan.

(e) *Supervisory actions.* Any covered credit union operating without an NCUA-approved capital plan after September 30 of the year in which the plan was submitted will be subject to supervisory actions on the part of NCUA.

(f) *Federally insured, state-chartered credit unions.* Before taking any action under this section on the capital plan of a federally insured, state-chartered credit union, NCUA will consult with the applicable state supervisory authority.

§ 702.506 Annual supervisory stress testing.

(a) *NCUA tests.* NCUA will conduct an annual stress test of each covered credit union using baseline, adverse, and severely adverse scenarios. NCUA will provide a description of those scenarios by December 1 of a calendar year and will conduct the stress test using the credit union's financial data as of September 30 of that year. NCUA stress test analysis will take into account all relevant exposures and activities of a credit union to evaluate its ability to absorb losses in specified scenarios over a 9-quarter horizon. The minimum target stress test capital ratio for covered credit unions is 5 percent.

(b) *Potential impact on capital.* In conducting a stress test under this subpart, during each quarter of the stress test horizon, NCUA will estimate the following for each scenario for each covered credit union:

(1) Pre-provision net revenues, loan and lease loss provisions, and net income; and

(2) The potential impact on the stress test capital ratio, incorporating the effects of any capital action over the stress test horizon and maintenance of an allowance for loan losses appropriate for credit exposures throughout the horizon. NCUA will conduct the stress test without assuming any risk mitigation actions on the part of the covered credit union, except those existing and identified as part of the covered credit union's balance sheet, or off-balance sheet positions, such as assets sales or derivatives positions, on the date of the stress test.

(c) *Information collection.* Upon request, the covered credit union must

provide NCUA with any relevant qualitative or quantitative information requested by NCUA to conduct the stress test under this section.

(d) *Stress test results.* NCUA will provide each covered credit union with the results of the stress test by May 31 of the year following the September 30 "as of" testing date.

(e) *Supervisory actions.* If NCUA stress tests show that covered credit union does not have the ability to maintain a stress test capital ratio of 5 percent or more on a pro forma basis under expected and stressed conditions throughout the 9-quarter horizon, the credit union must provide NCUA, within 60 days of receipt of the stress test results, a stress test capital enhancement plan showing how it will meet that target. Failure to do so will subject a covered credit union to supervisory actions on the part of NCUA.

(f) *Federally insured, state-chartered credit unions.* Before taking any action under this section against a federally insured, state-chartered credit union, NCUA will consult with the applicable state supervisory authority.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Chapter I

[Docket No. FDA-2013-N-0001]

Medical Gas Regulation Review; Announcement of Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

The Food and Drug Administration (FDA) is announcing a public meeting on whether any changes to Federal drug regulations are necessary for medical gases. The topic to be discussed is whether any changes to the Federal drug regulations are necessary for medical gases as part of the implementation of the Food and Drug Administration Safety and Innovation Act (FDASIA).

Date and Time: The meeting will be held on December 6, 2013, from 9 a.m. to 5 p.m. However, depending on the level of public participation, the meeting may be extended or may end early.

Location: The meeting will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503A),

Silver Spring, MD 20993-0002. The FDA Conference Center at the White Oak location is a Federal facility with security procedures and limited seating (please note that all visitors to the White Oak Campus must enter through Building 1). The meeting is free and seating will be on a first-come, first-served basis. Attendees who do not wish to make an oral presentation do not need to register.

Contact Persons: Mary Gross, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20903-0002, 301-796-3519, FAX: 301-847-8753, email: Mary.Gross@fda.hhs.gov; or Christine Kirk, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20903-0002, 301-796-2465, FAX: 301-847-8440, email: Christine.Kirk@fda.hhs.gov; or Urvi Desai, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, email: Urvi.Desai@fda.hhs.gov.

Registration and Requests for Oral Presentations: If you wish to make an oral presentation, you must register by submitting your name, title, firm name, address, telephone, email address, and FAX number, to Mary Gross (see *Contact Persons*) by December 2, 2013. Please also provide the type of organization you represent (e.g., industry, consumer organization), and a brief summary of your remarks (including the discussion topic(s) that will be addressed).

FDA will try to accommodate all persons who wish to make a presentation; however, the duration of each speaker's presentation may be limited by time constraints. FDA will notify registered presenters of their scheduled presentation times. Persons registered to speak should check in before the meeting and are encouraged to arrive early to ensure their designated order of presentation. Participants who are not present when called may not be permitted to speak at a later time. An agenda of the meeting will be made available at least 3 days before the meeting at <http://www.fda.gov/Drugs/NewEvents/ucm370351.htm>.

This public meeting will be Webcast and the URL will be posted at <http://www.fda.gov/Drugs/NewEvents/ucm370351.htm> at least 1 day before the meeting. A video record of the public meeting will be available at the same Web site address for 1 year. If you need special accommodations because of disability, please contact Mary Gross (see *Contact Persons*) at least 7 days in advance.

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. 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. 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. 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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