

mailing address, phone/fax number, and e-mail, along with a check or money order payable to SoCRA. Please mail your payment to: SoCRA Administrative Office, 530 West Butler Ave., suite 109, Chalfont, PA 18914. Registration may be downloaded on the SoCRA Web site at <http://www.socra.org>. (FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.)

Other payment forms accepted are major credit cards (VISA, MasterCard, or American Express only). For more information on the meeting, or for questions on registration, contact the SoCRA Administrative Office (see *Contact*).

**SUPPLEMENTARY INFORMATION:** The public workshop helps fulfill the Department of Health and Human Services' and FDA's important mission to protect the public health. The public workshop will provide those engaged in FDA-regulated (human) clinical trials with information on a number of topics concerning FDA requirements related to informed consent, clinical investigation requirements, institutional review board investigations, electronic record requirements, and investigator initiated research. Topics for discussion include the following: (1) What FDA Expects in a Pharmaceutical Clinical Trial, (2) Adverse Event Reporting, (3) Part 11 Compliance—electronic signatures, (4) Informed Consent Regulations, (5) IRB Regulations and FDA Inspections, (6) Keeping Informed and Working Together, (7) FDA Conduct of Clinical Investigator Inspections, (8) Meetings with the FDA, (9) Investigator Initiated Research, (10) Medical Device Aspects of Clinical Research, (11) Working with FDA's Center for Biologics Evaluation and Research, (12) Ethical Issues in Subject Enrollment, (13) The Inspection is Over—What Happens Next? Possible FDA Compliance Actions.

FDA has made education of the drug and device manufacturing community a high priority to help ensure the quality of FDA-regulated drugs and devices. The public workshop helps to achieve objectives set forth in section 406 of the FDA Modernization Act of 1997 (21 U.S.C. 393) which includes working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. The public workshop also is consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104-121), as outreach activities by Government agencies to small businesses.

Dated: December 10, 2009.

**David Horowitz,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF THE INTERIOR

### Office of Surface Mining Reclamation and Enforcement

#### Notice of Proposed Information Collection for 1029-0089

**AGENCY:** Office of Surface Mining Reclamation and Enforcement.

**ACTION:** Notice and request for comments.

**SUMMARY:** In compliance with the Paperwork Reduction Act of 1995, the Office of Surface Mining Reclamation and Enforcement (OSM) is announcing its intention to request renewed authority for the following collection of information: 30 CFR Part 702 regarding the exemption of coal extraction incidental to the extraction of other minerals. This information collection activity was previously approved by the Office of Management and Budget (OMB), and assigned clearance number 1029-0089.

**DATES:** Comments on the proposed information collection must be received by February 16, 2010, to be assured of consideration.

**ADDRESSES:** Comments may be mailed to John Trelease, Office of Surface Mining Reclamation and Enforcement, 1951 Constitution Ave., NW., Room 202-SIB, Washington, DC 20240. Comments may also be submitted electronically to [jtrelease@osmre.gov](mailto:jtrelease@osmre.gov).

**FOR FURTHER INFORMATION CONTACT:** To request a copy of the information collection request and explanatory information contact John Trelease, at (202) 208-2783 or e-mail at the address provided above.

**SUPPLEMENTARY INFORMATION:** OMB regulations at 5 CFR 1320, which implement provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104-13), require that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities [see 5 CFR 1320.8 (d)]. This notice identifies an information collection that OSM will be submitting to OMB for approval. This collection is contained in 30 CFR part 702—Exemption for Coal Extraction Incidental to the Extraction of Other Minerals. The information submitted by respondents is required to obtain a benefit. OSM will request a 3-

year term of approval for this information collection activity.

*Comments are invited on:* (1) The need for the collection of information for the performance of the functions of the agency; (2) the accuracy of the agency's burden estimates; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the information collection burden on respondents, such as use of automated means of collection of the information. A summary of the public comments will accompany OSM's submission of the information collection request to OMB.

Before including your address, phone number, e-mail 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.

*Title:* 30 CFR Part 702 Exemption for Coal Extraction Incidental to the Extraction of Other Minerals.

*OMB Control Number:* 1029-0089.

*Summary:* This part implements the requirement in Section 701(28) of the Surface Mining Control and Reclamation Act of 1977 (SMCRA), which grants an exemption from the requirements of SMCRA to operators extracting not more than 16<sup>2</sup>/<sub>3</sub> percentage tonnage of coal incidental to the extraction of other minerals. This information will be used by the regulatory authorities to make that determination.

*Bureau Form Number:* None.

*Frequency of Collection:* Once and annually thereafter.

*Description of Respondents:* Producers of coal and other minerals and State regulatory authorities.

*Total Annual Responses:* 120.

*Total Annual Burden Hours:* 535.

*Total Non-wage Costs:* \$200.

Dated: December 11, 2009.

**Dennis G. Rice,**

*Acting Chief, Division of Regulatory Support.*

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