comments. Any additional comments on this ICR should be submitted to EPA and OMB within 30 days of this notice.

EPA has established a public docket for this ICR under docket ID number EPA–HQ–OECA–2008–0368, which is available for public viewing online at *http://www.regulations.gov,* in person viewing at the Enforcement and Compliance Docket in the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Avenue, NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is (202) 566–1744, and the telephone number for the Enforcement and Compliance Docket is (202) 566–1927.

Use EPA's electronic docket and comment system at *http://www.regulations.gov,* to submit or view public comments, access the index listing of the contents of the docket, and to access those documents in the docket that are available electronically. Once in the system, select ''docket search,'' then key in the docket ID number identified above. Please note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing at *http://www.regulations.gov,* as EPA receives them and without change, unless the comment contains copyrighted material, Confidential Business Information (CBI), or other information whose public disclosure is restricted by statute. For further information about the electronic docket, go to *www.regulations.gov.*

Title: NSPS for Calciners and Dryers in Mineral Industries (Renewal).

ICR Numbers: EPA ICR Number 0746.07, OMB Control Number 2060–0251.

ICR Status: This ICR is scheduled to expire on January 31, 2009. Under OMB regulations, the Agency may continue to conduct or sponsor the collection of information while this submission is pending at OMB. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register** when approved, are listed in 40 CFR part 9, and displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers in certain EPA regulations is consolidated in 40 CFR part 9.

Abstract: The New Source Performance Standards (NSPS) for Calciners and Dryers in Mineral Industries (40 CFR part 60, subpart UUU) were proposed on April 23, 1986 and promulgated on September 28, 1992.

The affected entities are subject to the General Provisions of the NSPA at 40 CFR part 60, subpart A and any changes, or additions to the General Provisions specified at 40 CFR part 60, subpart UUU.

These standards apply to new, modified and reconstructed calciners and dryers at mineral processing plants that process or produce any of the following minerals and their concentrates or any mixture of which the majority is any of the following minerals or a combination of these minerals: Alumina, ball clay, bentonite, diatomite, feldspar, fire clay, fuller's earth, gypsum, industrial sand, kaolin, lightweight aggregate, magnesium compounds, perlite, roofing granules, talc, titanium dioxide, and vermiculite. Particulate matter is the pollutant regulated under this subpart. Feed and product conveyors are not considered part of the affected facility. Facilities subject to NSPS subpart LL, Metallic Mineral Processing Plants are not subject to this standard. There are additional processes and process units at mineral processing plants listed at 60.730(b) which are not subject to the provisions of this subpart.

Owners or operators are also required to maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative. Reports, at a minimum, are required semiannually. These notifications, reports, and records are essential in determining compliance, and are required, in general, of all sources subject to NSPS.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 20 hours per response. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements which have subsequently changed; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Respondents/Affected Entities: Calciners and dryers at mineral processing plants that process or produce any of the following minerals and their concentrates or any mixture of which the majority is any of the following minerals or a combination of these minerals: Alumina, ball clay, bentonite, diatomite, feldspar, fire clay, fuller's earth, gypsum, industrial sand, kaolin, lightweight aggregate, magnesium compounds, perlite, roofing granules, talc, titanium dioxide, and vermiculite.

Estimated Number of Respondents: 167.

Frequency of Response: Initially, occasionally, and semi-annually.

Estimated Total Annual Hour Burden: 6,955.

Estimated Total Annual Cost: $674,485, which includes $561,485 in Labor costs, $4,000 in annualized capital costs, and $109,000 in Operations & Maintenance (O&M) costs.

Changes in the Estimates: There is no change in the total estimated burden currently identified in the OMB Inventory of Approved ICR Burdens.

Dated: November 12, 2008.

John Moses,

Acting Director, Collection Strategies Division.

[FR Doc. E8–27311 Filed 11–17–08; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0397]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; State Enforcement Notifications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by December 19, 2008.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to *oira__submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0275. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3794.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

State Enforcement Notifications—(OMB Control Number 0910–0275—Extension)

Section 310(b) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 337(b)) authorizes States to enforce certain sections of the act in their own names, but provides that States must notify FDA before doing so. Section 100.2(d) (21 CFR 100.2(d)) sets forth the information that a State must provide to FDA in a letter of notification when it intends to take enforcement action under the act against a particular food located in the State. The information required under § 100.2(d) will enable FDA to identify the food against which the State intends to take action and advise the State whether Federal action has been taken against it. With certain narrow exceptions, Federal enforcement action precludes State action under the act.

In the **Federal Register** of July 18, 2008 (73 FR 41360), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours Per Response	Total Hours
100.2(d)	1	1	1	10	10

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimated reporting burden for § 100.2(d) is minimal because enforcement notifications are seldom used by States. During the last 3 years, FDA has not received any new enforcement notifications; therefore, the agency estimates that one or fewer notifications will be submitted annually. Although FDA has not received any new enforcement notifications in the last 3 years, it believes these information collection provisions should be extended to provide for the potential future need of a State government to submit enforcement notifications informing FDA when it intends to take enforcement action under the act against a particular food located in the State.

Dated: November 10, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–27258 Filed 11–18–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0559]

Draft Guidance for Industry on Process Validation: General Principles and Practices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Process Validation: General Principles and Practices.'' FDA is revising its guidance for industry entitled ''Guideline on General Principles of Process Validation,'' which issued in May 1987 (the 1987 guidance). The revised draft guidance promotes a ''lifecycle'' approach to process validation that includes scientifically sound design practices, robust qualification, and process verification. When finalized, this draft guidance will replace the 1987 guidance.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comments on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by January 20, 2009.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002; or to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448; or to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Brian Hasselbalch, Center for Drug Evaluation and Research (HFD–320), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 4364, Silver Spring, MD 20993–0002, 301–796–3279;

Grace McNally, Center for Drug Evaluation and Research (HFD–320), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 4374, Silver Spring, MD 20993–0002, 301–301–796–3286;

Christopher Joneckis, Center for Biologics Evaluation and Research (HFM–1), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–0373; or

Dennis Bensley, Center for Veterinary Medicine (HFV–140), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6956.

SUPPLEMENTARY INFORMATION: