other small entities. As this rulemaking, if implemented, would impose *no* burden on small entities, the Commission hereby certifies, pursuant to section 605(b) of the RFA,[30] that the regulations proposed herein will not have a significant economic impact on a substantial number of small entities.

VI. Comment Procedures

29. The Commission invites interested persons to submit comments on the matters and issues proposed in this notice to be adopted, including any related matters or alternative proposals that commenters may wish to discuss. Comments are due June 27, 2011. Comments must refer to Docket No. RM11–12–000, and must include the commenter's name, the organization they represent, if applicable, and their address.

30. The Commission encourages commenters to file electronically via the eFiling link on the Commission's Web site at *http://www.ferc.gov.* The Commission accepts most standard word processing formats and commenters may attach additional files with supporting information in certain other file formats. Commenters filing electronically do not need to make a paper filing.

31. Commenters unable to file comments electronically must mail or hand deliver an original copys of their comments to: Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street, NE., Washington, DC, 20426. These requirements can be found on the Commission's Web site, *see, e.g.,* the "Quick Reference Guide for Paper Submissions," *available* at *http://www.ferc.gov/docs-filing/efiling.asp* or via phone from FERC Online Support at (202) 502–6652 or toll-free at 1–866–208–3676.

32. All comments will be placed in the Commission's public files and may be viewed, printed, or downloaded remotely as described in the Document Availability section below. Commenters on this proposal are not required to serve copies of their comments on other commenters.

VII. Document Availability

33. In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the Internet through FERC's Home Page (*http://www.ferc.gov*) and in FERC's Public Reference Room during normal business hours (8:30 a.m. to 5 p.m. Eastern time) at 888 First Street, NE., Room 2A, Washington, DC 20426.

34. From FERC's Home Page on the Internet, this information is available in the eLibrary. The full text of this document is available in the eLibrary both in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

35. User assistance is available for eLibrary and the FERC's Web site during our normal business hours. For assistance contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at (866) 208–3676, or for TTY, contact (202) 502–8659.

List of Subjects in 18 CFR Part 366

Electric power, and Reporting and recordkeeping requirements.

By direction of the Commission.

Kimberly D. Bose,

Secretary.

In consideration of the foregoing, the Commission proposes to revise Chapter I, Title 18, part 366 of the Code of Federal Regulations, as follows:

PART 366—BOOKS AND RECORDS

1. The authority citation for part 366 continues to read as follows:

Authority: 15 U.S.C. 717 *et seq.,* 16 U.S.C. 791a *et seq.,* and 42 U.S.C. 16451–16463.

2. In § 366.2, redesignate paragraph (d) as paragraph (e) and add a new paragraph (d) to read as follows:

§ 366.2 Commission access to books and records.

* * * * *

(d) *Electric Reliability Organization.* The Electric Reliability Organization certified by the Commission under § 39.3 of this chapter will make available to Commission staff, on an ongoing basis, access to the complete electronic tags (e-Tags), or any successor to e-Tags, used to schedule the transmission of electric power in wholesale markets. The complete e-Tag data to be made available under this section shall consist of e-Tags for interchange transactions scheduled to flow into, out of or within the United States' portion of the Eastern or Western Interconnections, or into or out of the Electric Reliability Council of Texas and into or out of the United States' portion of the Eastern or Western Interconnections.

* * * * *

[FR Doc. 2011–10119 Filed 4–26–11; 8:45 am]

BILLING CODE 6717–01–P

[30] 5 U.S.C. 605(b).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Chapter I

[Docket No. FDA–2011–N–0259]

Periodic Review of Existing Regulations; Retrospective Review Under E.O. 13563

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification for request for comment.

SUMMARY: In accordance with Executive Order 13563, "Improving Regulation and Regulatory Review," the Food and Drug Administration (FDA) is conducting a review of its existing regulations to determine, in part, whether they can be made more effective in light of current public health needs and to take advantage of and support advances in innovation. The goal of this review of existing regulations, as with our other reviews, is to help ensure that FDA's regulatory program is more effective and less burdensome in achieving its regulatory objectives. FDA is requesting comment and supporting data on which, if any, of its existing rules are outmoded, ineffective, insufficient, or excessively burdensome and thus may be good candidates to be modified, streamlined, expanded, or repealed. As part of this review, FDA also invites comment to help us review our framework for periodically analyzing existing rules.

DATES: Submit either electronic or written comments by June 27, 2011.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2011–N–0259, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- *Fax:* 301–827–6870.
- *Mail/Hand delivery/Courier (for paper, disk, or CD–ROM submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA–2011–N–0259 for this rulemaking. All comments received may

be posted without change to *http://www.regulations.gov*, including any personal information provided. For additional information on submitting comments, see the "Request for Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Lisa Helmanis, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3216, Silver Spring, MD 20993–0002, 301–796–9135.

SUPPLEMENTARY INFORMATION: On February 2, 2011, President Barack Obama issued Executive Order (E.O.) 13563, "Improving Regulation and Regulatory Review." One of the provisions in the new Executive order is the affirmation of retrospective reviews of existing significant regulations. FDA already has several processes in place to ensure periodic review of its existing regulations, including those that are significant, and will continue to enhance these efforts. Under E.O. 13563, FDA is reviewing this framework for retrospective review of regulations and, through this notice, is soliciting comments on ways to make this program more effective.

I. Background

FDA is responsible for protecting the public health by: (1) Ensuring the safety and efficacy of human and veterinary drugs, biological products, and medical devices; (2) ensuring the safety and security of our nation's food supply, products that emit radiation, cosmetics; and (3) regulating the manufacture, marketing, and distribution of tobacco products. FDA also promotes the public health by striving to foster innovative approaches and solutions for some of our nation's most compelling health and medical challenges.

Currently, FDA has three main mechanisms that trigger a retrospective review of an existing regulation. First, a retrospective review may occur when there is a significant change in circumstances, such as advances in technology, new data or other information, or legislative change. Second, whenever FDA is revising an existing regulation, it reviews that regulation to determine if the underlying science and policy are still valid and whether the regulations should be updated based on current science, policy, data, or technology. The third mechanism is FDA's Citizen Petition process. Under 21 CFR 10.30, FDA provides a mechanism for the public to request the Commissioner of Food and Drugs to issue, amend, or revoke a regulation by submitting a Citizen Petition.

Other ongoing mechanisms that FDA uses to target specific audiences are biannual letters to State and Local government officials and small business entities, which are also posted on FDA's Web site. These letters highlight upcoming regulations that FDA believes may have an impact on these two groups. In addition, FDA uses the Federal Government's biannual Unified Agenda of Federal Regulations (Unified Agenda) to announce reviews conducted under section 610(c) of the Regulatory Flexibility Act (RFA). In section 610(c), Federal Agencies are required within 10 years of the effective date of regulations that have a significant economic impact on a substantial number of small entities to review the regulation and seek public input on the continued need for the regulation or on possible changes to the regulation.

Since the 1980s, FDA has participated in a variety of reviews to streamline and improve its regulatory processes. For example, as previously mentioned, section 610(c) of the RFA requires Agencies to review their regulations to determine whether the rules should be continued without change, amended, or rescinded to minimize any significant economic impact on a substantial number of small entities. These reviews are announced in the Unified Agenda.

In the 1990s, FDA participated in the "Reinventing Government" initiative and met 95 percent of its goal for eliminating outdated or unnecessary regulations, and 89 percent of its goal for revising regulations. Following that initiative, FDA has undertaken other reviews of its regulations and regulatory processes including implementing new efficiencies such as withdrawing outdated proposed rules that were never finalized. The most recent withdrawal was in 2008 (73 FR 75625, December 12, 2008). We currently conduct this review of pending proposed rules about every 5 years.

Over the past 15 years, there have also been major legislative changes that have significantly reformed major program areas within FDA and added to the Agency's responsibilities. When FDA develops implementing regulations for these legislative mandates, FDA also takes the opportunity to modify or revoke related regulations as appropriate, and streamline various regulatory processes.

The Food and Drug Administration Modernization Act of 1997 and, 10 years later, the Food and Drug Administration Amendments Act of 2007 (FDAAA) both modernized certain FDA programs and created new ones, mandating numerous regulations to implement those programs. FDAAA also expanded FDA's user fee authority and charged FDA with encouraging more research and development for treatments specifically for children. In 2009, FDA saw a significant increase in its authorities with enactment of the Family Smoking Prevention and Tobacco Control Act of 2009. Finally, earlier this year, the FDA Food Safety Modernization Act was signed into law by President Obama and, when fully implemented, will enable FDA to better protect public health by helping to ensure the safety and security of the food supply.

II. Request for Comments

FDA is first seeking comment on how the Agency could revise its existing review framework to meet the objectives of E.O. 13563 regarding the development of a plan with a defined method and schedule for identifying certain significant rules that may be obsolete, unnecessary, unjustified, excessively burdensome, or counterproductive. Comments should address how best to evaluate and analyze regulations to expand on those that work and to modify, improve, or rescind those that do not. To be useful, comments should address how FDA can best obtain and consider accurate, objective information and data about the costs, burdens, and benefits of existing regulations and whether there are existing sources of data that FDA can use to evaluate the post-promulgation effects of regulations over time. FDA is particularly interested in how well its current processes for reviewing regulations function and how those processes might be expanded or otherwise adapted to meet the objectives of E.O. 13563. FDA is further interested in comments about factors that it should consider in selecting rules for review and prioritizing review.

Due to limited resources, FDA generally focuses its retrospective review efforts on: (1) Regulations that have a significant public health impact, (2) regulations that impose a significant burden on the Agency and/or industry, and (3) regulations that impose no significant burden on the Agency and/or industry. FDA welcomes comments

on other criteria it should be using when prioritizing its reviews of existing significant regulations.

In addition, FDA is seeking public comment on which, if any, regulations should be reviewed at this time. Please identify any regulation that should be modified, expanded, streamlined, or repealed to make our regulatory program more effective and less burdensome. Please be as specific as possible in your comments. To support its efforts to support innovation, FDA is particularly interested in comments that identify regulations that may be impediments to innovation and suggestions for how they can be improved.

Comments should focus on regulations that have demonstrated deficiencies. Comments that reiterate previously submitted arguments relating to recently issued rules will be less useful. Furthermore, the public should focus on rule changes that will achieve a broad public impact, rather than an individual personal or corporate benefit. Comments should reference a specific regulation by the Code of Federal Regulations (CFR) cite, and provide specific information on what needs fixing and why. Lastly, FDA stresses that this review is for published final rules; the public should not use this process to submit comments on proposed rules.

The most useful comments will include which specific regulations need to be changed, strengthened or clarified, or revoked. It will be most helpful to include the specific reasons explaining why the change or revocation is necessary or desired, and to provide specific ways to improve the regulation, particularly any specific language modifications.

The Agency will be able to more efficiently review and consider comments that are submitted in the format shown in table 1 of this document:

TABLE 1—FORMAT FOR SUBMITTING COMMENTS

Name of regulation	
Type of Product or FDA Center Regulating the Product.	
Statute or Code of Federal Regulations cite (if known).	
Brief Description of Problem	(For example, is it outmoded, ineffective, insufficient, or excessively burdensome? Why?)
Available Data on Cost or Economic Impact	(Quantified benefits and cost if possible. Qualitative description, if needed.)
Proposed Solution	(Include the fix and procedure to solve it. For example, what would be the best way to modify, streamline, expand, or repeal the regulation?)

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 20, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–10131 Filed 4–26–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 936

[SATS No. OK–033–FOR; Docket ID: OSM–2011–0001]

Oklahoma Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Proposed rule; public comment period and opportunity for public hearing.

SUMMARY: We, the Office of Surface Mining Reclamation and Enforcement (OSM), are announcing receipt of a proposed amendment to the Oklahoma regulatory program under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). Oklahoma proposes revisions to its program by adding size limitations for permanent impoundments; adding slope limitations affecting post-mine contours; adding a subsidence allegation reporting requirement; and adding a requirement for bond calculation at renewal. Oklahoma is proposing these additions to its program at its own initiative.

This document provides the times and locations that the Oklahoma program and proposed amendment to that program are available for public inspection, the comment period during which you may submit written comments on the amendment, and the procedures that we will follow for the public hearing, if one is requested.

DATES: We will accept written comments on this amendment until 4 p.m., c.d.t., May 27, 2011. If requested, we will hold a public hearing on the amendment on May 23, 2011. We will accept requests to speak at a hearing until 4 p.m., c.d.t. on May 12, 2011.

ADDRESSES: You may submit comments, identified by SATS No. OK–033–FOR, by any of the following methods:

- *E-mail: aclayborne@osmre.gov.* Include "SATS No. OK–033–FOR" in the subject line of the message.
- *Mail/Hand Delivery:* Alfred L. Clayborne, Director, Tulsa Field Office, Office of Surface Mining Reclamation and Enforcement, 1645 South 101st East Avenue, Suite 145, Tulsa, Oklahoma 74128–4629.
- *Fax:* (918) 581–6419.
- *Federal eRulemaking Portal:* The amendment has been assigned Docket ID OSM02011–0001. 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 Oklahoma regulations, 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,