DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0764]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Draft Animal Feed Regulatory Program Standards

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 9, 2013.

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: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910-New and title ''Draft Animal Feed Regulatory Program Standards.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: *With regard to the information collection:* FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@fda.hhs.gov.*

With regard to the draft feed program standards: Beverly Kent, Office of Partnerships, Food and Drug Administration, 716–714–9503, *Beverly.kent@fda.hhs.gov*, or Jenny Murphy, Center for Veterinary Medicine, Food and Drug Administration, 240–453–6845, *Jenny.murphy@fda.hhs.gov.*

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.

Draft Animal Feed Regulatory Program Standards—(OMB Control Number 0910—New)

I. Background

In the United States, Federal and State government Agencies ensure the safety of animal feed. FDA is responsible for ensuring that all food and feed moving in interstate commerce, except those under the U.S. Department of Agriculture jurisdiction, are safe, wholesome, and labeled properly. States are responsible for conducting inspections and regulatory activities that help ensure food and feed produced, processed, and distributed within their jurisdictions are safe and in compliance with State laws and regulations. States primarily perform inspections under their own regulatory authority. Some States conduct inspections of feed facilities under contract with the FDA. Because jurisdictions may overlap, FDA and States collaborate and share resources to protect animal feed.

The FDA Food Safety Modernization Act passed on January 4, 2011, calls for enhanced partnerships and provides a legal mandate for developing an Integrated Food Safety System (IFSS). FDA is committed to implementing an IFSS thereby optimizing coordination of food and feed safety efforts with Federal, State, local, tribal, and territorial regulatory and public health agencies. Model standards provide a consistent, underlying foundation that is critical for uniformity across State and Federal Agencies to ensure credibility of food and feed programs within the IFSS.

At this time, model regulatory program standards exist for human food, but do not exist for animal feed. The draft Animal Feed Regulatory Program Standards (AFRPS or draft feed standards) are a major step in a long-term process of collaboration to achieve uniformity and consistency in feed safety across the nation while acknowledging State responsibilities and authorities.

II. Significance of Feed Program Standards

The AFRPS provide a uniform and consistent approach to feed regulation in the United States. Implementation of the draft feed program standards would be voluntary. States implementing the standards will identify and maintain program improvements that will strengthen the safety and integrity of the U.S. animal feed supply.

Description: These draft feed standards are the framework that each State should use to design, manage, and improve its feed program. Eleven standards describing regulatory foundation, training, inspection program, auditing, feed-related illness or death and emergency response, enforcement program, outreach activities, budget and planning, laboratory services, sampling program, and assessment and improvement of standard implementation are the basis for the draft feed standards.

Each standard has a purpose statement, requirement summary, description of program elements, projected outcomes, and a list of required documentation. When a State program voluntarily agrees to implement the draft feed standards, it must fully implement and maintain the individual program elements and documentation requirements in each standard in order to fully implement the standard. The State program must fully implement the 11 standards to achieve full implementation of the AFRPS. The draft feed standards are not intended to address the performance appraisal processes that a State agency may use to evaluate individual employee performance.

The draft feed standards have forms, worksheets, and templates to help the State program assess and meet the program elements in the standard. State programs are not obligated to use the forms, worksheets, and templates provided with the draft feed standards. Other manual or automated forms, worksheets, and templates may be used as long as the pertinent data elements are present. Records and other documents specified in the draft feed standards must be maintained in good order by the State program and must be available to verify the implementation of each standard.

In the first year of implementation, the State program uses the self-assessment worksheets to determine if the requirements for each standard are fully met, partially met, or not met. The self-assessments are used to develop an improvement plan for fully implementing the requirements of the 11 standards.

Although FDA plans to provide financial support to State programs that implement the draft feed standards, funding opportunities are contingent upon the availability of funds. Funding opportunities may be only available to State feed regulatory programs that currently have an FDA feed inspection contract. State programs receiving financial support to implement the feed standards will be audited by FDA.

III. Electronic Access

Persons with access to the Internet may submit email requests for a single copy of the draft feed standards to *OP-ORA@fda.hhs.gov.*

In the **Federal Register** of July 10, 2013 (78 FR 41401), FDA published a 60-day notice requesting public comment on the proposed collection of

information. Four comments were received. Three comments pertain to the information collection. One comment addressed an issue unrelated to the proposed collection of information, such as pet food safety; therefore, we do not address this issue in this document.

One comment expressed concern that the estimated hours to collect the information required to implement and maintain the requirements in the draft feed standards is low. Two comments expressed concern that implementing and maintaining the draft feed standards would require more State program employees and financial support from FDA.

Regarding the comment asserting that the total estimated hours reported in Table 1 is low; we recognize the number of hours needed to implement and maintain the draft feed standards will vary among States depending on the size of the State's feed program, the number of staff, and the State's short and long term goals for implementing the draft feed standards. The burden estimates are reasonable given the variation among State programs and their current ability to implement the draft feed standards.

Regarding the comment expressing concern that the State feed programs would need additional employees and funding from FDA to implement and maintain the requirements in the draft feed standards; FDA recognizes that State feed programs may need additional resources to implement and maintain the draft feed standards. Therefore, FDA will pursue funding for the draft feed standards; however, the level of funding may vary each year and is contingent on budget approval.

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

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Respondent	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per record-keeping	Total hours
State Feed Regulatory Programs in the United States	50	1	50	3,000	150,000

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

The burden has been calculated to 3,000 hours per respondent. The estimate includes time for reviewing the draft feed standards, gathering and maintaining the data and documents for each standard, and completing and reviewing the data and documents that would be spent to fully implement the 11 standards. FDA recognizes that full use and implementation of the draft feed standards by State feed programs will occur over many years and the number of years to fully implement the draft feed standards will vary among States. This burden was determined by averaging the burden estimates received from five respondents. The five respondents are representative of the State feed programs in the United States.

Dated: November 4, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Sixth Annual Sentinel Initiative; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing the following public workshop entitled ''Sixth Annual Sentinel Initiative.'' Convened by the Engelberg Center for Health Care Reform at the Brookings Institution and supported by a cooperative agreement with FDA, this 1-day workshop will bring the stakeholder community together to discuss a variety of topics on active medical product surveillance. Topics will include an overview of the status of FDA's Sentinel Initiative and future plans, highlights from key Mini-Sentinel and related activities, and an update on active surveillance collaborations and program extensions. In addition, this workshop will engage stakeholders to discuss current and emerging Sentinel projects and facilitate stakeholder feedback and input on Sentinel projects that would be appropriate to determine the feasibility of using Sentinel to evaluate drug safety issues that may require regulatory action (e.g., labeling changes, postmarketing requirements (PMRs), or postmarketing commitments (PMCs)). This workshop satisfies an FDA commitment that is part of the fifth authorization of the Prescription Drug User Fee Act (PDUFA V).

Date and Time: The public workshop will be held on January 14, 2014, from 9 a.m. to 4 p.m.

Location: The public workshop will be held at the Washington Marriott at Metro Center, 775 12th Street NW., Washington, DC 20001. For additional travel and hotel information, please refer to *http://www.cvent.com/d/jcqhyy.* (FDA has verified the Web site addresses throughout this notice, but FDA is not responsible for subsequent changes to the Web sites after this document publishes in the **Federal Register**).

Contact Person: Carlos Bell, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6358, Silver Spring, MD 20993, 301–796–3714, FAX: 301–847–3529, email: *SentinelInitiative@fda.hhs.gov.*

Registration: To attend the public workshop, you must register before January 14, 2014, by visiting *http://www.cvent.com/d/jcqhyy.* Early registration is recommended. There will be no onsite registration. When registering, please provide the following information: Your name, title, company or organization (if applicable), postal address, telephone number, and email address. There is no registration fee for the public workshop; but because seating is limited, registration will be on a first-come, first-served basis. A 1-hour lunch break is scheduled; however, food will not be provided. There are multiple restaurants within walking distance of the hotel.

If you need special accommodations due to a disability, please contact Joanna Klatzman at the Brookings Institution (email: *jKlatzman@brookings.edu*) at least 7 days in advance.

Meeting Materials: All event materials will be available to registered attendees via email prior to the workshop and will be posted after the event on the