4164-01-P

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; 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 [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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 0910-0760. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, PRAStaff@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.

Animal Feed Regulatory Program Standards--

OMB 0910-0760--Extension

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 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.

II. Significance of Feed Program Standards

The Animal Feed Regulatory Program Standards (AFRPS) provide a uniform and consistent approach to feed regulation in the United States. Implementation of the draft feed program standards is 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.

The feed standards are the framework that each State should use to design, manage, and improve its feed program. The standards include the following: (1) Regulatory foundation; (2) training; (3) inspection program; (4) auditing; (5) feed-related illness or death and emergency response; (6) enforcement program; (7) outreach activities; (8) budget and planning; (9) assessment and improvement; (10) laboratory services; and (11) sampling program.

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 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 feed standards package includes 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 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 feed standards must be maintained in good order by the State program and must be available to verify the implementation of each standard. The feed standards are not intended to address the performance appraisal processes that a State Agency may use to evaluate individual employee performance.

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. Second and third-year assessments will provide progress evaluation.

Although FDA plans to provide financial support to State programs that implement the 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 requests for a single copy of the current feed standards from OP-PRA@fda.hhs.gov. Please note that due to editorial revisions and public comments, the final standards may differ from the copy you receive.

In the Federal Register of April 12, 2016 (81 FR 21578), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one comment. However, this comment did not address the information collection.

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

Table 1.--Estimated Annual Recordkeeping Burden[1]

Type of Respondent	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
State Employee	40	1	40	3,000	120,000

[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. This burden was determined by capturing the average amount of time for each respondent to assess the current

state of the program and work toward implementation of each of the 11 standards contained in AFRPS. FDA recognizes that full use and implementation of the feed standards by State feed programs will occur over many years and the number of years to fully implement the feed standards will vary among States.

Dated: December 8, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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