

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0764]

Agency Information Collection Activities; Proposed Collection; Comment Request; Animal Feed Regulatory Program Standards

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on FDA's Animal Feed Regulatory Program Standards (AFRPS).

DATES: Submit either electronic or written comments on the collection of information by June 13, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand delivery/Courier (for written/paper submissions):** Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2013-N-0764 for "Animal Feed Regulatory Program Standards." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION". The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper 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: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

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 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 ORAHQOPIO@fda.hhs.gov. Please note that due to editorial revisions and public comments, the final standards may differ from the copy you receive.

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

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

Type of respondent	Number of recordkeepers	Number 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: April 6, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos.: FDA-2014-E-2355; FDA-2014-E-2356; and FDA-2014-E-2357]

Determination of Regulatory Review Period for Purposes of Patent Extension; GAZYVA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for