4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

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

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 and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection associated with the draft Animal Feed Regulatory Program Standards (AFRPS). The draft feed standards are neither final nor intended for implementation at this time.

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments on the collection of information to http://www.regulations.gov. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document. Submit written requests for single

copies of the draft feed standards to the U.S. Food and Drug Administration, Office of Regulatory Affairs, Office of Partnerships, 12420 Parklawn Dr., ELEM-3033, Rockville, MD 20857. Send one self-addressed adhesive label to assist the office in processing your request, or fax your request to 301-827-3588. See the SUPPLEMENTARY INFORMATION section for an electronic copy of the draft feed standards.

FOR FURTHER INFORMATION CONTACT:

With regard to the information collection:

Ila S. Mizrachi,

Office of Information Management,

Food and Drug Administration,

1350 Piccard Dr.,

PI50-400B,

Rockville, MD 20850,

301-796-7726,

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With regard to the draft feed program standards:

Beverly Kent,

Office of Partnerships,

Food and Drug Administration,

716-714-9503,

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Jenny Murphy,

Center for Veterinary Medicine,

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240-453-6845,

Jenny.murphy@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 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.

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 foods and feeds 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.

At this time, model regulatory program standards exist for human food, but do not exist for animal feed. The 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 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. These program standards are not intended to address the performance appraisal processes that a State agency may use to evaluate individual employee performance.

The 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 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 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.

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

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

Respondent	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	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 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 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. 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: July 3, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-16517 Filed 07/09/2013 at 8:45 am; Publication Date: 07/10/2013]