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

• 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, Room 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.html.

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, Room
1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: FDA
PRA Staff, Office of Operations, Food
and Drug Administration, 8455
Colesville Rd., COL–14526, Silver
Spring, MD 20993–0002.

SUPPLEMENTARY INFORMATION: Under the
PRA (44 U.S.C. 3501–3520), Federal
Aguencies 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
Aguencies 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 ORA.HQ.OPITO@fda.hhs.gov. Please note that due to editorial revisions and public comments, the final standards may differ from the copy you receive.

FD网易ests the burden of this collection of information as follows:

<table>
<thead>
<tr>
<th>Type of respondent</th>
<th>Number of recordkeepers</th>
<th>Number of records per recordkeeper</th>
<th>Total annual records</th>
<th>Average burden per recordkeeping</th>
<th>Total hours</th>
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<tbody>
<tr>
<td>State Employee</td>
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<td>1</td>
<td>40</td>
<td>3,000</td>
<td>120,000</td>
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</tbody>
</table>

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.
[FR Doc. 2016–08331 Filed 4–11–16; 8:45 am]
BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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