Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed—21 CFR 589.2000(e)(1)(iv) OMB Control Number 0910–0339—Extension

This information collection was established because epidemiological evidence gathered in the United Kingdom suggested that bovine spongiform encephalopathy (BSE), a progressively degenerative central nervous system disease, is spread to ruminant animals by feeding protein derived from ruminants infected with BSE. This regulation places general requirements on persons that manufacture, blend, process, and distribute products that contain, or may contain, protein derived from mammalian tissue, and feeds made from such products.

Specifically, this regulation requires renderers, feed manufacturers, and others involved in feed and feed ingredient manufacturing and distribution to maintain written procedures specifying the cleanout procedures or other means, and specifying the procedures for separating products that contain or may contain protein derived from mammalian tissue from all other protein products from the time of receipt until the time of shipment. These written procedures are intended to help the firm formalize their processes, and then to help inspection personnel confirm that the firm is operating in compliance with the regulation. Inspection personnel will evaluate the written procedure and confirm it is being followed when they are conducting an inspection.

These written procedures must be maintained as long as the facility is operating in a manner that necessitates the record, and if the facility makes changes to an applicable procedure or process the record must be updated. Written procedures required by this section shall be made available for inspection and copying by FDA.

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

<table>
<thead>
<tr>
<th>21 CFR section; activity</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>
</tr>
</thead>
<tbody>
<tr>
<td>589.2000(e)(1)(iv); written procedures</td>
<td>320</td>
<td>1</td>
<td>320</td>
<td>14</td>
<td>4480</td>
</tr>
</tbody>
</table>

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

We base our estimate of the number of recordkeepers on inspectional data, which reflect a decline in the number of recordkeepers. We attribute this decline to a reduction in the number of firms handling animal protein for use in animal feed.

Dated: March 9, 2016.

Leslie Kux,
Associate Commissioner for Policy.

[FR Doc. 2016–05716 Filed 3–14–16; 8:45 am]
BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0781]

Final Results of Study of Workload Volume and Full Costs Associated With Review of Biosimilar Biological Product Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the final results of a study of the workload volume and full costs associated with the process for the review of biosimilar biological product applications (final report). This study was conducted by an independent consulting firm, and it fulfills FDA’s statutory requirement under the first authorization of the Biosimilar User Fee Act of 2012 (BsUFA), which enables FDA to collect user fees for the review of biosimilar biological applications for fiscal years 2013 to 2017. This notice solicits comments on the final report.

DATES: The report will be released on or before March 17, 2016. Submit either electronic or written comments on the final report by April 14, 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 wish 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 (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–2016–N–0781 for “Final Results of the Study of Workload Volume and Full Costs Associated With Review of Biosimilar Biological Product Applications.” 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
SUMMARY: In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (HRSA) has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than April 14, 2016.

ADDRESSES: Submit your comments, including the Information Collection Request Title, to the desk officer for HRSA, either by email to OIRA_submission@omb.eop.gov or by fax to 202–395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at paperwork@hrsa.gov or call (301) 443–1984.

SUPPLEMENTARY INFORMATION: Information Collection Request Title: Maternal and Child Health Bureau Performance Measures for Discretionary Grants

OMB No.: 0915–0298—Revision

Abstract: The Maternal and Child Health Bureau’s (MCHB) Discretionary Grant Information System (DGIS) electronically captures performance measure, program, financial, and abstract data, and products and publications about these discretionary grants from the grantees. The data collected are used by MCHB project officers to monitor and assess grantee performance as well as assist in monitoring and evaluating MCHB’s programs.

Need and Proposed Use of the Information: The Health Resources and Services Administration (HRSA) proposes to continue using reporting requirements for grant programs administered by MCHB, including national performance measures as previously approved by OMB, and in accordance with the “Government Performance and Results Act (GPRA) of 1993” (Pub. L. 103–62). This Act requires the establishment of measurable goals for Federal Programs that can be reported as part of the budgetary process, thus linking funding decisions with performance. Performance measures for MCHB discretionary grants were initially approved in January 2003. Approval from OMB is being sought to continue the use of performance measures for these grants. The revised performance measures are categorized by population domains (Adolescent Health, Child Health, Children with Special Health Care Needs, Lifecourse/Crosscutting, Maternal/Women Health, and Perinatal/Infant Health) consistent with Title V,