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 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
589.2000(e)(1)(iv); written procedures	320	1	320	14	4480

[1] 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]

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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 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–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

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: Mark Ascione, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1150, Silver Spring, MD 20993–0002, 301–796–7652, FAX: 301–847–8443.

SUPPLEMENTARY INFORMATION:

I. Background

The Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148) amended the Public Health Service Act to create an abbreviated licensure pathway for biological products that are demonstrated to be ''biosimilar'' to or ''interchangeable'' with an FDA-licensed biological product. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by BsUFA (Title IV of the Food and Drug Administration Safety and Innovation Act, Pub. L. 112–114), authorizes FDA to assess and collect fees for biosimilar biological products from October 2012 through September 2017. FDA uses these fees to expedite the review process for biosimilar biological products. Biosimilar biological products represent an important public health benefit, with the potential to offer life-saving or life-altering benefits at reduced cost to the patient. BsUFA facilitates the development of safe and effective biosimilar products for the American public.

As part of BsUFA, FDA is required to contract with an independent accounting or consulting firm to study the workload volume and full costs associated with the process for the review of biosimilar biological product applications. This notice solicits comments on the final report. The final report is described in section 744I(d) of the FD&C Act (21 U.S.C. 379j–53(d)) (*http://uscode.house.gov/view.xhtml?req=granuleid:U.S.C.-prelim-title21-section379j-53&num=0&edition=prelim*), as amended by the Food and Drug Administration Safety and Innovation Act enacted in 2012 (*http://www.gpo.gov/fdsys/pkg/PLAW-112publ144/pdf/PLAW-112publ144.pdf*). (FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.)

II. Electronic Access

The final report can be accessed at *http://www.fda.gov/ForIndustry/UserFees/BiosimilarUserFeeActBsUFA/ucm459682.htm.*

Dated: March 9, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–05720 Filed 3–14–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

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,