4. Intergovernmental Review

Executive Order 12372, Intergovernmental Review of Federal Programs, is not applicable to these grant applications.

IV. Reporting

1. MIPPA Grantees will be required to report data in the SHIP Tracking and Reporting System (STARS). STARS is the nationwide, web-based data system that facilitates reporting of activities completed by SHIP and MIPPA Grantees. All required data must be submitted accurately, completely, and on time, and in the format specified by ACL. All reports shall be completed according to instructions distributed by ACL for grantees. States using proprietary systems (and all proprietary agencies operating within a state) must submit data into a fully compliant data system reflecting STARS Data System specifications, with no unresolved errors as a condition of eligibility for continued MIPPA funding.

2. *Financial Reporting Requirements:* ACL requires the submission of the SF–425 (Federal Financial Report) semi-annually. The reporting cycle will be reflected in the Notice of Award. The annual SF–425 is due 30 days after the end of each semi-annual reporting period. The final SF–425 report is due 90 days after the end of the project period for each priority area. Grantees are required to complete the federal cash transactions portion of the SF–425 within the Payment Management System (PMS) for each priority area as identified in their award documents for the calendar quarters ending 3/31, 6/30, 9/30. And 12/31 through the life of their award. In addition, the fully completed SF–425 will be required as denoted in the Notice of Award terms and conditions.

3. *MIPPA Performance Reporting Requirements:* All successful applicants must submit a MIPPA narrative progress report twice a year to ACL. The reports shall include: A description of the progress make toward meeting each of the MIPPA objectives outlined in the funding opportunity announcement. As part of the narrative progress reports, the grantee must provide details of how the program expects to meet the goals described in their state plan submission. The narrative progress reports must be uploaded through *www.grantsolutions.gov* for each priority area. The narrative progress reports cover the following periods and due dates annually: (a) September 30 through March 31—due April 30; (b) April 1 through September 29—due October 31.

4. A final narrative report will be due at the end of the grant period. This final report will replace the last semi-annual narrative and must cover the entire life of the grant. The final narrative report is due 90 days after the end of the award (December 31, 2020).

V. Submission Information

1. Application Kits

Application kits/Program Instructions are available at *www.grantsolutions.gov*. Instructions for completing the application kit will be available on the site. For help in locating this information contact the ACL Agency Contact identified below. Note: Applicants must submit a separate SF–424 for each priority area with their application packages. Additional detailed instructions will be available in the Application Kit.

2. Submission Dates and Times

To receive consideration, applications must be submitted by 11:59 p.m. Eastern time on August 1, 2018, through *www.GrantSolutions.gov*.

VI. Agency Contacts

Direct inquiries regarding programmatic issues to U.S. Department of Health and Human Services, Administration for Community Living, Office of Healthcare Information and Counseling, Washington, DC 20201, attention: Katie Glendening or by calling 202–795–7350 or by email *Katherine.Glendening@acl.hhs.gov*.

Dated: May 30, 2018.

Mary Lazare,

Principal Deputy Administrator.

[FR Doc. 2018–12046 Filed 6–4–18; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–1922]

Formal Meetings Between the Food and Drug Administration and Sponsors or Applicants of Biosimilar User Fee Act Products; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Formal Meetings Between the FDA and Sponsors or Applicants of BsUFA Products.'' This draft guidance provides recommendations to industry on formal meetings between FDA and sponsors or applicants relating to the development and review of biosimilar or interchangeable biological products regulated by the Center for Drug Evaluation and Research (CDER) or the Center for Biologics Evaluation and Research (CBER). The previous guidance for industry entitled ''Formal Meetings Between the FDA and Biosimilar Biological Product Sponsors or Applicants,'' issued on November 18, 2015, has been withdrawn.

DATES: Submit either electronic or written comments on the draft guidance by September 4, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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–2018–D–1922 for ''Formal Meetings Between the Food and Drug Administration and Sponsors or Applicants of Biosimilar User Fee Act Products; Draft Guidance for Industry; Availability.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff 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 *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. 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: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002, or Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Neel Patel, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6468, Silver Spring, MD 20993–0002, 301–796–0970; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Formal Meetings Between the FDA and Sponsors or Applicants of BsUFA Products.'' This draft guidance provides recommendations to industry on formal meetings between FDA and sponsors or applicants relating to the development and review of biosimilar or interchangeable biological products regulated by CDER or CBER. This draft guidance does not apply to meetings associated with the development of products intended for submission in, or review of, new drug applications or abbreviated new drug applications under section 505 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), biologics license applications under section 351(a) of the Public Health Service Act, or submissions for devices under the FD&C Act. For the purposes of this draft guidance, formal meeting includes any meeting that is requested by a sponsor or applicant following the procedures provided in this draft guidance and includes meetings conducted in any format (*i.e.,* face to face, teleconference/videoconference, written response only).

The Biosimilar User Fee Act of 2012 (BsUFA I) added sections 744G and 744H to the FD&C Act, authorizing FDA to collect user fees for a 5-year period for biosimilar biological products. BsUFA was reauthorized for a 5-year period in 2017 under Title IV of the FDA Reauthorization Act of 2017 (BsUFA II), enacted on August 18, 2017. In conjunction with that reauthorization, FDA agreed to specific performance goals and procedures described in the document, ''Biosimilar Biological Product Reauthorization Performance Goals and Procedures Fiscal Years 2018 Through 2022'' (BsUFA II goals letter available at *https://www.fda.gov/downloads/forindustry/userfees/biosimilaruserfeeactbsufa/ucm521121.pdf*). The BsUFA II goals letter includes meeting management goals for formal meetings that occur between the FDA and sponsors or applicants.

In the BsUFA II goals letter, FDA committed to issuing this draft guidance. This draft guidance discusses the principles of good meeting management practices and describes standardized procedures for requesting, preparing, scheduling, conducting, and documenting formal meetings between FDA and sponsors or applicants of BsUFA products.

The previous guidance for industry entitled ''Formal Meetings Between the FDA and Biosimilar Biological Product Sponsors or Applicants,'' issued on November 18, 2015, has been withdrawn.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on formal meetings between the FDA and sponsors or applicants of BsUFA products. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information referred to in the guidance for industry entitled ''Formal Meetings Between the FDA and Biosimilar Biological Product Sponsors or Applicants'' have been approved under OMB control number 0910–0802. The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014 and collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm*, or *https://www.regulations.gov.*

Dated: May 31, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–12027 Filed 6–4–18; 8:45 am]

BILLING CODE 4164–01–P

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; The Maternal, Infant, and Early Childhood Home Visiting Program Performance Measurement Information System, OMB No. 0906–0017—Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. A 60-day **Federal Register** Notice was published in the **Federal Register** on February 9, 2018 (83 FR 5791). There were 23 public comments. 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 July 5, 2018.

ADDRESSES: Submit your comments, including the ICR 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 Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: The Maternal, Infant, and Early Childhood Home Visiting Program Performance Measurement Information System.

OMB No. 0906–0017—Revision.

Abstract: This clearance request is for continued approval of the Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Program Performance Measurement Information System. The MIECHV Program, administered by HRSA in partnership with the Administration for Children and Families, supports voluntary, evidence-based home visiting services during pregnancy and to parents with young children up to kindergarten entry. States, certain non-profit organizations, and Tribal entities are eligible to receive funding from the MIECHV Program and have the flexibility to tailor the program to serve the specific needs of their communities. After taking into consideration public comments in response to the 60-day Notice published in the **Federal Register** on February 9, 2018 (83 FR 5791), HRSA is proposing final revisions to the data collection forms for the MIECHV Program by making the following changes:

- *Form 1:* Update Tables 4–14, 16, and 18–20 to include specific guidance to account for and report missing data.
- *Form 1, Tables 1 and 2:* Update table titles to reflect ''participants served by MIECHV.''
- *Form 1, Table 5:* Update to reflect correct age categories of ''<1 year,'' ''1–2 years,'' ''3–4 years,'' ''5–6 years,'' and ''Unknown/Did not Report.''
- *Form 1, Table 8:* Revise the category of ''Never Married'' to read ''Never Married (excluding not married but living together with partner).''
- *Form 1, Table 10:* Delete.
- *Form 1, Table 18:* Delete.
- *Form 1, Table 22:* Revise to only include children greater than or equal to 12 months of age. Title will be updated to ''Index Children (≥12 months of age) by Usual Source of Dental Care.''
- *Form 1, Notes:* Revise to include Table-specific notes.
- *Form 1, Definition of Key Terms:* Update definitions for Tables 1, 3, 5, 12, 13, 15, 20, 21, and 22.
- *Form 2:* Update all measures to include specific guidance to account for and report missing data.
- *Form 2, Measure 3:* Update denominator to reflect correct inclusion criteria.
- *Form 2, Measure 7:* Update numerator to read ''. . . without bed sharing and without soft bedding.''
- *Form 2, Measure 8:* Update numerator to clarify that nonfatal injury-related visits to the ED must have occurred within the reporting period.
- *Form 2, Measure 9:* Update numerator to clarify that investigated cases of maltreatment must have occurred within the reporting period.
- *Form 2, Measure 13:* Update numerator and denominator to clarify that only postnatal home visits should be included.
- *Form 2, Measure 14:* Update measure to reflect current terminology and the timing within which screenings should be reported.
- *Form 2, Measure 15:* Update measure and numerator to include primary caregivers enrolled in middle school.
- *Form 2, Measure 17:* Update denominator to reflect correct inclusion criteria.
- *Form 2, Measure 19:* Update denominator to reflect correct inclusion criteria.
- *Form 2, Definitions of Key Terms:* Update definitions for measures 1, 2, 4, 5, 18, and 19.

HRSA is also requesting an extension of this information collection request through November 30, 2021.

Need and Proposed Use of the Information: HRSA uses performance information to demonstrate program accountability with legislative and programmatic requirements and continuously monitor and provide oversight to MIECHV Program awardees. The information is also used to provide quality improvement guidance and technical assistance to awardees and help inform the development of early childhood systems at the national, state, and local level. HRSA is seeking to revise demographic, service utilization, and select clinical indicators for participants enrolled in home visiting services. In addition, HRSA will collect a set of standardized performance and outcome indicators that correspond with the statutorily identified benchmark areas.

In the future, HRSA anticipates that MIECHV funding decisions may be allocated, in part, based on awardee performance, including on benchmark performance areas.

Likely Respondents: MIECHV Program awardees.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to