DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Tribal Maternal, Infant, and Early Childhood Home Visiting Program: Guidance for Submitting Reports (Office of Management and Budget#: 0970–0409)

AGENCY: Office of Early Childhood Development, Administration for Children and Families, U.S. Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Administration for Children and Families (ACF), Office of Early Childhood Development (ECD) is requesting revisions to the Tribal Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Program: Guidance for Submitting Reports (Office of Management and Budget (OMB)#: 0970–0409; expiration March 31, 2026) and a 3-year extension of approval.

DATES: *Comments due* August 5, 2024. In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: You can obtain copies of the proposed collection of information and submit comments by emailing *infocollection@acf.hhs.gov*. Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: Section 511(e)(8)(A) of title V of the Social Security Act requires that grantees under the MIECHV program for states and jurisdictions submit an annual report to the Secretary of Health and Human Services regarding the program and activities carried out under the program, including such data and information as the Secretary shall require. Section 511(h)(2)(A) further states that the requirements for the MIECHV grants to Tribes, Tribal organizations, and urban Indian organizations are to be consistent, to the greatest extent practicable, with the requirements for grantees under the MIECHV program for states and jurisdictions.

ECD, in collaboration with the Health Resources and Services Administration, Maternal and Child Health Bureau awarded grants for the Tribal MIECHV Program (Tribal Home Visiting) to support cooperative agreements to conduct community needs assessments; plan for and implement high-quality, culturally relevant, evidence-based home visiting programs in at-risk Tribal communities; establish, measure, and report on progress toward meeting performance measures in six legislatively mandated benchmark areas; and participation in research and evaluation activities to build the knowledge base on home visiting among Native populations.

After the first grant year, Tribal Home Visiting grantees must comply with the requirement to submit an Annual Report to the Secretary that should feature activities carried out under the program during the past reporting period. To assist grantees with meeting these requirements, ACF created guidance for grantees to use when writing their annual reports. The guidance specifies that grantees must address the following:

- Update on the implementation of the Home Visiting Program in targeted community(ies)
- Update on the collection, reporting, and use of data
- Progress toward fidelity monitoring, program management, and improvement
- Update on contribution to MIECHV Learning Agenda through participation in research and evaluation projects
- Dissemination
- Technical Assistance Supports

Previously, the guidance included information about both the annual and the final reports from grantees. This extension request includes updates to the guidance to make it specific to just the annual reports. Guidance specific to the final report may be submitted for review and approval by OMB in the future. A comment period will accompany that request.

Respondents: Tribal Home Visiting Managers (information collection does not include direct interaction with individuals or families that receive the services).

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
Guidance for Submitting Annual reports	51	1	25	1,275

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: Title V of the Social Security Act, sections 511(e)(8)(A) and 511(h)(2)(A).

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2024–12301 Filed 6–4–24; 8:45 am]

BILLING CODE 4184–77–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–2221]

Standardized Format for Electronic Submission for Marketing Applications Content for the Planning of Bioresearch Monitoring Inspections for Center for Biologics Evaluation and Research Submissions; 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 document entitled ''Standardized Format for Electronic Submission for Marketing Applications Content for the Planning of Bioresearch Monitoring (BIMO) Inspections for Center for Biologics Evaluation and Research Submissions.'' The draft guidance document and BIMO Technical Conformance Guide provide specifications for the electronic submission of certain data and information in standardized formats. This information is used by FDA's Center for Biologics Evaluation and Research (CBER) in the planning of, and by FDA's Office of Regulatory Affairs (ORA) in the conduct of, BIMO inspections. The draft guidance addresses major (*i.e.,* pivotal) studies used to support safety and efficacy claims in biologics license applications (BLAs) and new drug applications (NDAs) regulated by CBER, as well as certain supplemental applications containing new clinical study reports. This draft guidance, when finalized, will provide additional information regarding the format to be used for electronic submission of BLA and NDA content for the planning and conduct of CBER BIMO inspections, using the electronic Common Technical Document.

DATES: Submit either electronic or written comments on the draft guidance by August 5, 2024 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–2024–D–2221 for ''Standardized Format for Electronic Submission for Marketing Applications Content for the Planning of Bioresearch Monitoring (BIMO) Inspections for Center for Biologics Evaluation and Research Submissions.'' 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, 240–402–7500.

- 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.govinfo.gov/content/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, 240–402–7500.

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 Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), 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 the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Jessica Gillum, 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 document entitled ''Standardized Format for Electronic Submission for Marketing Applications Content for the Planning of Bioresearch Monitoring (BIMO) Inspections for Center for Biologics Evaluation and Research Submissions.'' The draft guidance document and BIMO Technical Conformance Guide [1] provide specifications for the electronic submission of certain data and information in standardized formats. This information is used by CBER in the planning of, and by ORA in the conduct of, BIMO inspections. The draft

[1] The current version of the Bioresearch Monitoring Technical Conformance Guide is available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/bioresearch-monitoring-technical-conformance-guide.*

guidance addresses major (*i.e.,* pivotal) studies used to support safety and efficacy claims in BLAs and NDAs regulated by CBER, as well as certain supplemental applications containing new clinical study reports.

To meet its review performance goals in accordance with CBER good review management principles and practices for products covered by the Prescription Drug User Fee Act, CBER generally initiates inspection planning early in the application review process (*i.e.,* during the filing determination and review planning phase). CBER's inspection planning includes the selection of clinical investigator sites and other regulated entities for onsite inspections, and the preparation of assignment memos and background packages that CBER provides to FDA's ORA, which performs FDA's BIMO inspections. CBER uses the data and information described in this guidance to plan BIMO inspections, including: (1) to facilitate the timely identification of sites for inspection and (2) to ensure the availability of information needed to conduct BIMO inspections by ORA investigators.

This draft guidance is being issued consistent with FDA's good guidance practices (GGP) regulation (21 CFR 10.115). However, in section 745A(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 379k–1(a)), Congress granted explicit authorization to FDA to specify, in guidance, the electronic format for submissions under section 505(b), (i), or (j) of the FD&C Act (21 U.S.C. 355(b), (i), or (j)) and submissions under section 351(a) or (k) of the Public Health Service Act (42 U.S.C. 262(a) or (k)). Accordingly, to the extent that this guidance, when finalized, provides such requirements, as indicated by the use of the words ''must'' or ''required'', this guidance will not be subject to the usual restrictions in FDA's GGP regulations, such as the requirement that guidances not establish legally enforceable responsibilities (see 21 CFR 10.115(d); see also the guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Submissions Under Section 745A(a) of the Federal Food, Drug, and Cosmetic Act,'' available at *https://www.fda.gov/Drugs//GuidanceCompliance/Regulatory/Information/Guidances/default.htm.*

To comply with GGP regulations and make sure that regulated entities and the public understand that guidance documents are nonbinding, FDA guidances ordinarily contain standard language explaining that guidance documents should be viewed only as recommendations unless specific regulatory or statutory requirements are cited. FDA is not including this standard language in this guidance document because it is not an accurate description of this guidance. Insofar as this guidance specifies the format for electronic submissions pursuant to section 745A(a) of the FD&C Act, when finalized, it will have binding effect.

The draft guidance, when finalized, and the BIMO Technical Conformance Guide will represent the current thinking of FDA on standardized format for electronic submission of BLA and NDA content for the planning of BIMO inspections for CBER submissions.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001; and the 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 *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: May 31, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–12354 Filed 6–4–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–5021]

Processes and Practices Applicable to Bioresearch Monitoring Inspections; 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 ''Processes and Practices Applicable to Bioresearch Monitoring Inspections.'' The draft guidance is being issued to comply with the Food and Drug Omnibus Reform Act of 2022, which directs the Agency to issue guidance describing the processes and practices applicable to inspections of sites and facilities inspected under FDA's Bioresearch Monitoring inspection program, to the extent not specified in existing publicly available FDA guides and manuals. The draft guidance is intended to cover the following: the types of records and information required to be provided, best practices for communication between FDA and industry in advance of or during an inspection or request for records or other information, and other inspections-related conduct.

DATES: Submit either electronic or written comments on the draft guidance by August 5, 2024 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'').