Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2022–15562 Filed 7–20–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Tribal Maternal, Infant, and Early Childhood Home Visiting Program Form 2: Grantee Performance Measures (OMB #0970–0500)

AGENCY: Office of Child Care; Administration for Children and Families; Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Administration for Children and Families (ACF) is requesting a 3-year extension of the ACF-Tribal Maternal, Infant, and Early Childhood Home Visiting (Tribal MIECHV) Program Form 2: Grantee Performance Measures (Office of Management and Budget (OMB)) #0970–0500; Expiration date February 28, 2023). There are no changes requested to the form.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of the Paperwork Reduction Act (PRA) 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: The MIECHV Program authorizes the Secretary of the Health and Human Services (HHS) (in section 511(h)(2)(A)) to award grants to Indian tribes (or a consortium of Indian tribes), tribal organizations, or urban Indian organizations to conduct an early childhood home visiting program. The legislation set aside 3 percent of the total MIECHV program appropriation for grants to tribal entities. Tribal MIECHV grants, to the greatest extent practicable, are to be consistent with the requirements of the MIECHV grants to states and jurisdictions and include conducting a needs assessment and establishing quantifiable, measurable benchmarks.

The ACF, Office of Child Care (OCC), in collaboration with the Health Resources and Services Administration (HRSA), Maternal and Child Health Bureau (MCHB), awards grants for the Tribal MIECHV Program. The Tribal MIECHV grant awards support 5-year 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; collect and report on performance measures; and participate in research and evaluation activities to build the knowledge base on home visiting among Native populations.

Specifically, the MIECHV legislation requires that State and Tribal MIECHV grantees collect performance data to measure improvements for eligible families in six specified areas (referred to as ''benchmark areas'') that encompass the major goals of the program. These include:

1. Improved maternal and newborn health;
2. Prevention of child injuries, child abuse, neglect, or maltreatment, and reduction in emergency department visits;
3. Improvement in school readiness and achievement;
4. Reduction in crime or domestic violence;
5. Improvement in family economic self-sufficiency; and
6. Improvement in the coordination and referrals for other community resources and supports.

Tribal MIECHV grantees are required to propose a plan for meeting the benchmark requirements specified in the legislation and must report on improvement in constructs under each benchmark area. The Tribal Home Visiting (HV) Form 2 provides a template for Tribal MIECHV grantees to report data on their progress in improving performance under the six benchmark areas, as stipulated in the legislation.

ACF will continue to use Tribal HV Form 2 to:

- Track and improve the quality of benchmark measures data submitted by the Tribal grantees;
- Improve program monitoring and oversight;
- Improve rigorous data analyses that help to assess the effectiveness of the programs and enable ACF to better monitor projects; and
- Ensure adequate and timely reporting of program data to relevant federal agencies and stakeholders including Congress and members of the public.

Respondents: Tribal MIECHV Program Grantees.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
Tribal MIECHV Form 2	23	1	500	11,500

Estimated Total Annual Burden Hours: 11,500.

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: The Bipartisan Budget Act of 2018 (Public Law 115–123). Section 511(h)(2)(A) of Title V of the Social Security Act.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2022–15632 Filed 7–20–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–0528]

Evaluation of Therapeutic Equivalence; 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 ''Evaluation of Therapeutic Equivalence.'' The draft guidance would explain FDA's therapeutic equivalence evaluations, including the assignment of therapeutic equivalence codes, if finalized as written. FDA's therapeutic equivalence evaluations are listed for multisource prescription drug products approved under the Federal Food, Drug, and Cosmetic Act (FD&C Act) in the active section of the Approved Drug Products With Therapeutic Equivalence Evaluations (commonly known as the Orange Book). These therapeutic equivalence evaluations have been prepared to serve as public information and advice to state health agencies, prescribers, and pharmacists to promote public education in the area of drug product selection and to foster containment of health care costs.

DATES: Submit either electronic or written comments on the draft guidance by September 19, 2022 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–2022–D–0528 for ''Evaluation of Therapeutic Equivalence.'' 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 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. 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: Susan Levine, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1674, Silver Spring, MD 20993–0002, 240–402–7936, *Susan.Levine@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Evaluation of Therapeutic Equivalence.'' The draft guidance would explain FDA's therapeutic equivalence evaluations, including the assignment of therapeutic equivalence codes. Therapeutic equivalents are approved drug products that are pharmaceutical equivalents for which bioequivalence has been demonstrated, and that can be expected to have the same clinical effect and safety profile when administered to patients under the conditions specified in the labeling.

FDA's therapeutic equivalence evaluations are listed for multisource prescription drug products approved under section 505 of the FD&C Act (21 U.S.C. 355) in the active section of the Approved Drug Products With Therapeutic Equivalence Evaluations (commonly known as the Orange Book). These therapeutic equivalence evaluations have been prepared to serve as public information and advice to state health agencies, prescribers, and pharmacists to promote public education in the area of drug product selection and to foster containment of health care costs. For example, the Orange Book can assist in the establishment of formularies that States and other entities may use in determining when drug products may be substituted for one another. If lower-cost, therapeutically equivalent drug products are available, American consumers are more likely to receive savings on these products without a sacrifice in the quality of treatment.

In the **Federal Register** of June 1, 2020 (85 FR 33165), FDA announced the establishment of a public docket to solicit comments on the Orange Book, including questions related to the presentation of information on therapeutic equivalence (*e.g.,* ''How useful is the second letter of a therapeutic equivalence evaluation code?''), which also relate to the content of this guidance. FDA is continuing to consider the comments to this docket.

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 ''Evaluation of Therapeutic Equivalence.'' 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.

II. Paperwork Reduction Act of 1995

While this draft guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this draft guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR 10.30 have been approved under OMB control number 0910–0191.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: July 18, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–15612 Filed 7–20–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0634]

Oncologic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Oncologic Drugs Advisory Committee. The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on September 22, 2022, from 9 a.m. to 6 p.m. Eastern Time and September 23, 2022, from 9 a.m. to 1:15 p.m. Eastern Time.

ADDRESSES: Please note that due to the impact of this COVID–19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2022–N–0634. The docket will close on September 21, 2022. Submit either electronic or written comments on this public meeting by September 21, 2022. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before September 21, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 21, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Comments received on or before September 8, 2022, will be provided to the committee. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is canceled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

You may submit comments 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–2022–N–0634 for ''Oncologic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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.'' FDA will review this copy, including the