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Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th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. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Joseph Toerner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6244, Silver Spring, MD 20993–0002, 301–796–1400.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance for industry entitled ''Uncomplicated Urinary Tract Infections: Developing Drugs for Treatment.'' The purpose of this guidance is to assist sponsors in the development of new drugs for the treatment of uncomplicated urinary tract infections.

This guidance finalizes the draft guidance of the same name issued May 10, 2018 (83 FR 21784). There were no comments regarding the draft guidance submitted to the public docket. We made some editorial changes made in the final guidance primarily for clarification.

Issuance of this guidance fulfills a portion of the requirements of Title VIII, section 804, of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144), which requires FDA to review and, as appropriate, revise not fewer than three guidance documents per year for the conduct of clinical trials with respect to antibacterial and antifungal drugs.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Uncomplicated Urinary Tract Infections: Developing Drugs for Treatment.'' 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 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 in 21 CFR parts 312, 314, and 601 have been approved under OMB control numbers 0910–0014, 0910–0001, and 0910–0338, respectively.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov*.

Dated: July 29, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–16423 Filed 7–31–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–3132]

General Clinical Pharmacology Considerations for Neonatal Studies for Drugs and Biological 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 ''General Clinical Pharmacology Considerations for Neonatal Studies for Drugs and Biological Products.'' This draft guidance is intended to assist sponsors of new drug applications (NDAs), biologics license applications (BLAs) for therapeutic biologics, and supplements who are planning to conduct clinical studies in neonatal populations. The issuance of this draft guidance on clinical pharmacology considerations for neonatal studies for drugs and biological products is stipulated under the FDA Reauthorization Act of 2017 (FDARA).

DATES: Submit either electronic or written comments on the draft guidance by October 30, 2019 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–

2019–D–3132 for '' General Clinical Pharmacology Considerations for Neonatal Studies for Drugs and Biological Products.'' 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 the 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: Rajnikanth Madabushi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2173, Silver Spring, MD 20993, 301–796–1537 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, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''General Clinical Pharmacology Considerations for Neonatal Studies for Drugs and Biological Products.'' This draft guidance is intended to assist sponsors of NDAs, BLAs for therapeutic biologics, and supplements who are planning to conduct clinical studies in neonatal populations. This draft guidance is adjunctive to the December 2014 draft FDA guidance entitled *General Clinical Pharmacology Considerations for Pediatric Studies for Drugs and Biological Products,* as it addresses general clinical pharmacology considerations in neonates, a pediatric subpopulation. The issuance of this draft guidance on clinical pharmacology considerations for neonatal studies for drugs and biological products is stipulated under section 505 of FDARA.

Given that most drugs used in Neonatal Intensive Care Units are used in an off-label capacity, studies of therapeutic products need to be conducted in neonates. In addition, therapies need to be developed for conditions unique to neonates. This draft guidance addresses: (1) Subgroup classifications of neonates; (2) general pharmacokinetic, pharmacodynamic, and pharmacogenomic considerations for clinical pharmacology studies in neonates; and (3) clinical pharmacology considerations for any planned studies in neonates whether the studies are conducted pursuant to the Best Pharmaceuticals for Children Act, the Pediatric Research Equity Act, or neither. This draft guidance does not discuss the timing to initiate neonatal studies. Questions regarding the appropriate timing for the initiation of neonatal studies should be discussed with the relevant FDA review division.

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 ''General Clinical Pharmacology Considerations for Neonatal Studies for Drugs and Biological 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 found in FDA regulations. These collections of information 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 for submitting of NDAs in 21 CFR 314.50(d)(7), including pediatric use information and the submission of waiver requests in § 314.90, have been approved under OMB control number 0910–0001. The collections of information for submitting BLAs, including pediatric use information and waiver requests under 21 CFR 601.27, have been approved under OMB control number 0910–0338. The collections of information for submitting investigational new drug applications in § 312.47(b)(1)(iv), including plans for pediatric studies and the submission of waiver requests in § 312.10, have been approved under OMB control number 0910–0014. The collections of information for requesting meetings with FDA about drug development programs in §§ 312.47 and 312.82 have been approved under OMB control number 0910–0014. The collections of information for prescription drug labeling in 21 CFR 201.56 and 21 CFR 201.57 have been approved under OMB control number 0910–0572. The collections of information related to expedited review programs for serious conditions have been approved under OMB control number 0910–0765.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.* Guidance documents are also available at *https://*

www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics or *http://www.regulations.gov.*

Dated: July 26, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–16375 Filed 7–31–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Maternal, Infant, and Early Childhood Home Visiting Program Home Visiting Budget Assistance Tool, OMB No. 0906–0025—Revision

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

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR must be received no later than September 30, 2019.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, 14N136B, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Maternal, Infant, and Early Childhood Home Visiting Program Home Visiting Budget Assistance Tool, OMB No. 0906–0025—Revision.

Abstract: HRSA is requesting continued approval and revision to the Home Visiting Budget Assistance Tool (HV-BAT) based on results of the previous pilot test. The tool collects information on standardized cost metrics from programs that deliver home visiting services, as outlined in the HV-BAT. Prior to Fiscal Year (FY) 2021, entities receiving Maternal, Infant, and Early Childhood Home Visiting (MIECHV) formula funds that are states, jurisdictions, territories, and nonprofit awardees may submit cost data using the HV-BAT to HRSA. HRSA will review the data submitted for accuracy and quality control, to test the tool's capacity to support state program functions such as program planning and budgeting, and to collect data to estimate national program costs. Beginning in FY 2021, HRSA will require reporting of HV-BAT data for one-third of awardees in each year for the purpose of informing program planning and budgeting described in awardee submissions of the annual formula funding application.

MIECHV Program, authorized by section 511 of the Social Security Act, 42 U.S.C. 711, and 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, Tribal entities, and certain nonprofit organizations 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. Funding recipients may subaward grant funds to local implementing agencies (LIAs) in order to provide services to eligible families in at-risk communities.

HRSA revised the intended purpose of the data collection using the HV-BAT. Original clearance under this OMB control number was for pilot testing the reliability of a standardized cost reporting tool among evidence-based home visiting programs. HRSA revised the data collection tool to reflect findings and recommendations from the pilot study to ensure ease of use among LIAs. Changes were made to instructions and definitions based on feedback collected from participants in the pilot study. As this revision seeks to continue collection of comprehensive home visiting cost data for all LIAs in each state, the data can be aggregated to produce state and national cost estimates in addition to supporting procurement activities and sub-recipient monitoring. The burden increased as the pilot study identified a longer average amount of time to complete the tool than was originally estimated.

Need and Proposed Use of the Information: Immediately following OMB clearance, HRSA intends to make the tool available as an optional resource for all awardees. If awardees choose to immediately use the HV-BAT as an optional tool, awardees will be required to submit the data collected with the tool to HRSA. This will allow HRSA to test the feasibility of collecting comprehensive cost data at the state level; estimate national level costs for use in conducting research and analysis of home visiting costs; understand cost variation; assess how comprehensive program cost data can inform other policy priorities, such as innovative financing strategies; review the data to ensure accuracy; and analyze the data for the purpose of federal research.

Beginning in FY 2021, HRSA will require reporting of HV-BAT data for one-third of awardees in each year for the purpose of informing program planning and budgeting described in awardee submissions of the annual formula funding application. HRSA anticipates that one-third of the awardees will participate in this data collection each year and HRSA will identify which third of the awardees will be required to submit HV-BAT data in that year. This process will ease burden on awardees by requiring data collection for each awardee once every 3 years and allowing HRSA to capture a national data set every three years.

Likely Respondents: MIECHV Program awardees (n=19).

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 a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.

Total Estimated Annualized burden hours: