information submitted by States is reviewed and results are compiled by CMS in a format intended to provide information, comparisons, and trends related to States' experiences with DUR. States benefit from the information and may enhance their programs each year based on State reported innovative practices that are compiled by CMS from the DUR annual reports.

In this 2021 collection of information request, we revised certain FFS, MCO, and Abbreviated MCO survey questions. While a few questions were added to the surveys to address GAO (U.S. Government Accountability Office) recommendations, other aspects of the survey changes include grammar and formatting edits. Overall, we are not revising our currently approved burden estimates.

Form Number: CMS–R–153 (OMB control number: 0938–0659); *Frequency:* Yearly, quarterly, and occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 51; *Total Annual Responses:* 663; *Total Annual Hours:* 41,004. (For policy questions regarding this collection contact Mike Forman at 410–786–2666.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Supporting Statement for Essential Community Provider Data Collection to Support QHP Certification for PYs 2022–2024; *Use:* Standards for Essential Community Provider (ECP) requirements are codified at 45 CFR 156.235. Issuers must contract with a certain percentage, as determined by HHS, of the available ECPs in the plan's service area. For plan years 2022–2024, Health and Human Services (HHS) will continue to solicit qualified ECPs to complete and submit the HHS ECP provider petition in order to be added to the HHS ECP list, or update required data fields to remain on the list, resulting in a more robust and accurate listing of the universe of available ECPs from which issuers select to satisfy the ECP standard. HHS will continue to collect such data directly from providers through the online ECP provider petition. *Form Number:* CMS–10561; *Frequency:* Annually; *Affected Public:* Private sector, Business or other for-profits, and Not-for-profit Institutions; *Number of Respondents:* 12,408; *Number of Responses:* 12,408; *Total Annual Hours:* 3,140. (For questions regarding this collection, contact Deborah Hunter at 443–386–3651).

3. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* The State Flexibility to Stabilize the Market Cycle I and II Grant Program Reporting; *Use:* Section 1003 of the Affordable Care Act (ACA) adds a new section 2794 to the Public Health Service Act (PHS Act) entitled, ''Ensuring That Consumers Get Value for Their Dollars.'' Specifically, section 2794(a) requires the Secretary of the Department of Health and Human Services (the Secretary) (HHS), in conjunction with the States, to establish a process for the annual review of health insurance premiums to protect consumers from unreasonable rate increases. Section 2794(c) directs the Secretary to carry out a program to award grants to States. Section 2794(c)(2)(B) specifies that any appropriated Rate Review Grant funds that are not fully obligated by the end of FY 2014 shall remain available to the Secretary for grants to States for planning and implementing the insurance market reforms and consumer protections under Part A of title XXVII of the (PHS Act. States that are awarded funds under this funding opportunity are required to provide CMS with four quarterly reports and one annual report (except for the last year of the grant) until the end of the grant period detailing the state's progression towards planning and/or implementing the pre-selected market reforms under Part A of Title XXVII of the PHS Act. A final report is due at the end of the grant period. *Form Number:* CMS–10657 (OMB control number: 0938–1366); *Frequency:* Annually and Quarterly; *Affected Public:* State, Local or Tribal Governments; *Number of Respondents:* 34; *Total Annual Responses:* 170; *Total Annual Hours:* 2,312. (For policy questions regarding this collection contact Jim Taing at *James.Taing@cms.hhs.gov*.)

Dated: December 7, 2021.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2021–26816 Filed 12–9–21; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–1518]

Development of Anti-Infective Drug Products for the Pediatric Population; 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 final guidance for industry entitled ''Development of Anti-Infective Drug Products for the Pediatric Population.'' The purpose of this guidance is to provide general recommendations on the development of anti-infective drug products for pediatric patients. The guidance addresses enrollment strategies, extrapolation of efficacy, safety database, and other considerations to help facilitate pediatric anti-infective drug product development. This guidance finalizes the draft guidance of the same title issued on June 30, 2020.

DATES: The announcement of the guidance is published in the **Federal Register** on December 10, 2021.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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–2020–D–1518 for ''Development of Anti-Infective Drug Products for the Pediatric Population.'' 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 this 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 guidance document.

FOR FURTHER INFORMATION CONTACT: Hiwot Hiruy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 240–402–0872; 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 final guidance for industry entitled ''Development of Anti-Infective Drug Products for the Pediatric Population.'' The purpose of this guidance is to provide general recommendations on the development of anti-infective drug products for pediatric patients. The guidance addresses enrollment strategies, extrapolation of efficacy, safety database, and other considerations to help facilitate pediatric anti-infective drug product development.

This guidance finalizes the draft guidance of the same title issued on June 30, 2020 (85 FR 39193). FDA provided clarifying edits to the final guidance and included additional information after considering comments received on the draft guidance. Changes from the draft to the final guidance include updates to efficacy extrapolation from adult to pediatric patients (including from one pediatric subpopulation to another), safety data collection, additional considerations for studies, and recommendations for conducting juvenile toxicology studies.

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 ''Development of Anti-Infective Drug Products for the Pediatric Population.'' 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 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 guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR parts 312 and 314 and 21 CFR 201.56 and 201.57 have been approved under OMB control numbers 0910–0014, 0910–0001, and 0910–0572, respectively.

III. Electronic Access

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

Dated: December 6, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–26737 Filed 12–9–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0918]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Labeling Requirements for Prescription Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by January 10, 2022.