manufacturers can be compliant with current good manufacturing practice (CGMP) requirements for preventing cross-contamination. This guidance also provides information regarding the relative health risk of, and the potential for, cross-reactivity in the classes of non-penicillin beta-lactam antibacterial drugs and non-antibacterial beta-lactam compounds. This guidance recommends that manufacturers should manufacture non-penicillin beta-lactam antibacterial drugs with complete and comprehensive separation from manufacturing operations of other drugs. For manufacturers of non-antibacterial beta-lactam compounds, this guidance provides recommendations on cross-contamination prevention strategies, including examples of relevant design features and control approaches for those seeking to justify a cross-contamination prevention strategy other than complete and comprehensive separation when appropriate.

This guidance revises the guidance of the same title issued on April 17, 2013 (78 FR 22887). Significant changes from the 2013 guidance include:

- Clarifying that the scope of the guidance also includes all compounds, including intermediates or derivatives, that are not a penicillin, have a chemical structure that includes one or more beta-lactam rings, and have a mechanism of action other than an antibacterial mechanism of action;
- Providing FDA's interpretation of terms, such as *allergic reaction, cross-reactivity,* and *complete and comprehensive separation,* used in this guidance;
- Clarifying the distinction between non-penicillin beta-lactam antibacterial drug(s) and non-antibacterial beta-lactam compound(s)—in terms of the cross-contamination and patient exposure risks and the control strategies appropriate for manufacturing operations involving each category; and
- Providing recommendations for drug manufacturers that seek to justify alternative cross-contamination prevention strategies for non-antibacterial beta-lactam compounds.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will replace the 2013 guidance and represent the current thinking of FDA on ''Non-Penicillin Beta-Lactam Drugs: A CGMP Framework for Preventing Cross-Contamination.'' 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. The Paperwork Reduction Act of 1995

FDA tentatively concludes that this draft guidance contains no new collection 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. However, this draft guidance refers to previously approved FDA collections of information. These collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR parts 210 and 211 have been approved under OMB control number 0910–0139; and the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *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: June 17, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–13513 Filed 6–23–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0319]

Agency Information Collection Activities; Proposed Collection; Comment Request; Dear Healthcare Provider Letters: Improving Communication of Important Safety Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice requests comments on information collection associated with the communication of important safety information to medical practitioners.

DATES: Submit either electronic or written comments on the collection of information by August 23, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before August 23, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of August 23, 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.

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 Docket No. FDA–2010–D–0319 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Dear Healthcare Provider Letters: Improving Communication of Important Safety Information.'' 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.'' 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.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Improving Communication of Important Safety Information—21 CFR Part 200

OMB Control Number 0910–0754—Extension

This information collection supports Agency regulations and recommendations found in associated Agency guidance, as discussed below. Under section 705 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 375), the Secretary of the Department of Health and Human Services (the Secretary) may require dissemination of information for drugs in situations that involve, in the Secretary's opinion, ''imminent danger to health, or gross deception of the consumer.'' Implementing regulations are found in § 200.5 (21 CFR 200.5) and outline the general provisions for ''Dear Healthcare Provider'' (DHCP) letters that manufacturers and distributors disseminate about important drug warnings, important prescribing information, and important correction of drug information. The regulations also prescribe certain format and content instructions regarding the dissemination of covered information. Manufacturers or distributors send DHCP letters to physicians and other healthcare providers to communicate an important drug warning, a change in prescribing information, or a correction of misinformation in prescription drug promotional labeling or advertising. We developed the guidance document entitled ''Dear Healthcare Provider Letters: Improving Communication of Important Safety Information'' (January 2014), available at *https://www.fda.gov/media/79793/download,* to provide instructions and recommendations to respondents on implementing the applicable requirements. All Agency guidance documents are issued consistent with our good guidance practice regulations at 21 CFR 10.115.

In addition to the content and format recommendations for each type of DHCP letter, the guidance also includes recommendations on consulting with FDA on: (1) how to develop a DHCP letter; (2) when to send a letter; (3) what type of letter to send; and (4) how to assess the letter's impact.

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity; 21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average time per response (in hours)	Total hours
Preparation of DHCP letters; § 200.5	6	1.3	8	100	800

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We have identified 24 DHCP letters that 18 distinct sponsors submitted to FDA during the 3-year period (2019 to 2021). Based on our Document Archiving, Reporting, and Regulatory Tracking System, we estimate eight DHCP letters will be submitted annually from six application holders. Based on our experience, we assume that each letter will require 100 hours to prepare and disseminate as recommended in the guidance. Our estimate reflects a downward adjustment by five responses and 500 hours annually. We attribute this decrease to the effectiveness of the guidance and the decreased number of DHCP letters submitted for FDA review.

Dated: June 16, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–13536 Filed 6–23–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Proposed Temporary Changes in State Title V Maternal and Child Health Block Grant Allocations

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

ACTION: Notice.

SUMMARY: This notice seeks comments on proposed temporary changes to the method of calculating poverty-based allocations under Title V of the Social Security Act for HRSA's State Title V Maternal and Child Health (MCH) Block Grant. Since Fiscal Year (FY) 2017, the poverty-based allocation has been based on the U.S. Census Bureau's 3-year American Community Survey (ACS) estimates using three pooled 1-year estimates. However, due to the COVID–19 pandemic, there were disruptions in the ACS data collection in 2020 resulting in data quality issues that prevented the Census Bureau from releasing standard 1-year ACS estimates; instead, the Census Bureau released experimental estimates. HRSA proposes that the ACS 2020 experimental estimates be excluded from calculating MCH block grant allocations and that the FY 2023 funding allocation be based on the same poverty data used in the FY 2022 allocation (*i.e.,* pooled 1-year estimates for 2017, 2018, and 2019 ACS). Funding allocations for FY 2024 and FY 2025 would continue to incorporate the latest 1-year ACS data while skipping 2020 (*i.e.,* for FY 2024, the 2018, 2019, and 2021 ACS data will be used; for FY 2025, the 2019, 2021, and 2022 ACS data will be used). In FY 2026, the temporary change to the method for calculating allocations will no longer be necessary, and HRSA will resume pooling of three consecutive 1-year estimates (2021–2023).

DATES: Interested persons are invited to comment on this proposed change. Submit written comments no later than July 25, 2022. All comments received on or before this date will be considered.

ADDRESSES: All written comments concerning this notice should be submitted to Christopher Dykton, Acting Director of the Division of State and Community Health, at the contact information below.

FOR FURTHER INFORMATION CONTACT: Christopher Dykton, Acting Director of the Division of State and Community Health, Maternal and Child Health Bureau (MCHB), HRSA, Room 18N35, 5600 Fishers Lane, Rockville, Maryland 20857; telephone: (301) 433–2204; email: *MCHBlockGrant@hrsa.gov.*

SUPPLEMENTARY INFORMATION: The purpose of the Title V MCH Block Grant, administered by HRSA's MCHB, is to improve the health of the nation's mothers, infants, children, including children with special health care needs, and their families by creating federal/state partnerships that provide each state/jurisdiction with needed flexibility to respond to its individual MCH population needs. Pursuant to section 502(c) of Title V of the Social Security Act (42 U.S.C. 702(c)), for any available funding in excess of 1983 levels ($406,649,394), Title V MCH Block Grant funds are allocated to States and the District of Columbia based on the number of children living in poverty in an individual state as a proportion of the total number of children living in poverty in the U.S., using data for the number of children in poverty in each State from the U.S. Census Bureau's ACS. Incorporating the proportion of total number of children living in poverty into the state funding formula for the Title V MCH Block Grant ensures that a portion of the funding is distributed according to greatest need.

Beginning in FY 2013, data for the number of children in poverty in each state has been based on the U.S. Census Bureau's ACS.[1] In FY 2013, the allocation was based on 3-year rolling ACS estimates instead of 1-year or 5-year ACS estimates also produced at that time to strike a balance between reliability and currency of data. *See* 77 FR 65693 (October 30, 2012). However, since 2014 (for FY 2017), when the Census Bureau discontinued the release of 3-year ACS estimates, HRSA has been using three pooled ACS 1-year estimates for this purpose.

In 2020, due to the COVID–19 pandemic, there were disruptions in the ACS data collection that prevented the Census Bureau from releasing standard 1-year ACS estimates for 2020. According to the Census Bureau report, ''An Assessment of the COVID–19 Pandemic's Impact on the 2020 ACS 1-Year Data,'' [2] both survey administration methods (mailed questionnaires and interviewing in-person) were impacted beginning in March 2020. For example, no mailings were completed from April through June 2020, and when they resumed, they did not include the mailing of most of the reminder letters and postcards. Similarly, there was an abrupt switch from in-person to telephone-only interviews from March 2020 through June 2020, and the universe of addresses for which telephone numbers can be obtained is likely different than the universe of addresses obtained through in-person methods, over-representing certain types of addresses. In May, the option to complete the interview online became available. In-person

[1] Prior to this, the formula was based on poverty data from the decennial Census long-form, which was replaced with the American Community Survey.

[2] *https://www.census.gov/library/working-papers/2021/acs/2021_CensusBureau_01.html.*