DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0104]

Non-Penicillin Beta-Lactam Drugs: A CGMP Framework for Preventing Cross-Contamination; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Non-Penicillin Beta-Lactam Drugs: A CGMP Framework for Preventing Cross-Contamination.'' This draft guidance describes methods, facility design elements, and controls that are important in preventing drugs from being cross-contaminated with non-penicillin beta-lactam antibacterial drugs or non-antibacterial beta-lactam compounds, and it makes recommendations for how manufacturers can be compliant with current good manufacturing practice requirements for preventing cross-contamination. This draft guidance also provides information regarding the relative health risk of, and the potential for, cross-reactivity in the classes of non-penicillin beta-lactam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 This draft guidance revises the guidance of the same title issued on April 17, 2013.

DATES: Submit either electronic or written comments on the draft guidance by August 23, 2022 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.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–2011–D–0104 for ''Non-Penicillin Beta-Lactam Drugs: A CGMP Framework for Preventing Cross-Contamination.'' 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: Carla Lankford, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 6656, Silver Spring, MD 20993–0002, 301–796–5203.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Non-Penicillin Beta-Lactam Drugs: A CGMP Framework for Preventing Cross-Contamination.'' This draft guidance describes methods, facility design elements, and controls that are important in preventing drugs from being cross-contaminated with non-penicillin beta-lactam antibacterial drugs or non-antibacterial beta-lactam compounds,[1] and it makes recommendations for how

[1] In the guidance, non-penicillin beta-lactam antibacterial drug(s) refers to any drug that is not a penicillin, has a chemical structure that includes one or more beta-lactam rings, and has an antibacterial mechanism of action. Non-antibacterial beta-lactam compound(s) refers to any compound, including an intermediate or derivative, that is not a penicillin, has a chemical structure that includes one or more beta-lactam rings, and has a mechanism of action other than an antibacterial mechanism of action.

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]

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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'').

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