

blood components. The revised requirements were implemented in order to assure the safety of the blood supply and to protect donor health. The final rule became effective on May 23, 2016.

FDA has developed the guidance in response to feedback from blood establishments regarding the donor eligibility requirements for blood pressure and pulse in 21 CFR 630.10 and the corresponding requirements for medical supervision in 21 CFR 630.5. The guidance describes the circumstances in which FDA does not intend to take regulatory action for a blood establishment's failure to comply with certain regulations for determining the eligibility of blood donors with blood pressure or pulse measurements outside of the specified limits.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on "Blood Pressure and Pulse Donor Eligibility Requirements: Compliance Policy." 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 part 601 have been approved under OMB control number 0910–0338; the collections of information in 21 CFR parts 606 and 630 have been approved under OMB control number 0910–0116.

## III. Electronic Access

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

Dated: May 18, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2013–D–0744]

#### **Antibacterial Therapies for Patients With an Unmet Medical Need for the Treatment of Serious Bacterial Diseases—Questions and Answers (Revision 1); 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 "Antibacterial Therapies for Patients With an Unmet Medical Need for the Treatment of Serious Bacterial Diseases—Questions and Answers (Revision 1)." The purpose of this draft guidance is to assist sponsors in the clinical development of new antibacterial drugs, and it provides updates to the options for development programs, given the availability of some new therapeutic options. This draft guidance will provide necessary updates to the final guidance entitled "Antibacterial Therapies for Patients With an Unmet Medical Need for the Treatment of Serious Bacterial Diseases" published on August 2, 2017.

**DATES:** Submit either electronic or written comments on the draft guidance by July 25, 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–2013–D–0744 for "Antibacterial Therapies for Patients With an Unmet Medical Need for the Treatment of Serious Bacterial Diseases—Questions and Answers (Revision 1)." 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:** Peter Kim, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-0741.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of a draft guidance for industry entitled “Antibacterial Therapies for Patients With an Unmet Medical Need for the Treatment of Serious Bacterial Diseases—Questions and Answers (Revision 1).” This draft guidance will provide necessary updates to the final guidance entitled “Antibacterial Therapies for Patients With an Unmet Medical Need for the Treatment of Serious Bacterial Diseases” published on August 2, 2017 (82 FR 35973).

The purpose of this draft guidance is to assist sponsors in the clinical development of new antibacterial drugs. Specifically, the draft guidance explains FDA’s current thinking about possible development programs and clinical trial designs for antibacterial drugs to treat

serious bacterial diseases in patients with an unmet medical need. Since the 2017 final guidance was issued, there have been some new drug approvals that have activity against certain drug-resistant organisms. Therefore, it is now possible to conduct noninferiority (NI) trials that include subjects with infections caused by certain drug-resistant organisms because an effective active control can be provided. In addition to clarifying edits, more detail was provided for the currently used NI trial designs that may be used with a wider NI margin, including cases in which the trial population is enriched for subjects with infections caused by certain drug-resistant organisms.

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 “Antibacterial Therapies for Patients With an Unmet Medical Need for the Treatment of Serious Bacterial Diseases” and will replace the guidance with that name issued in 2017. 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 part 312 have been approved under OMB control numbers 0910-0014. The collections of information in 21 CFR part 314 have been approved under OMB control number 0910-0001. The collections of information in 21 CFR part 601 have been approved under OMB control number 0910-0338. The collections of information in 21 CFR 201.56 and 201.57 have been approved under OMB control number 0910-0572.

##### **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: May 17, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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#### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**[Document Identifier: OS-0990-0279]**

#### **Agency Information Collection Request; 30-Day Public Comment Request**

**AGENCY:** Office of the Secretary, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

**DATES:** Comments on the ICR must be received on or before June 23, 2022.

**ADDRESSES:** Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to [www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain). Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

**FOR FURTHER INFORMATION CONTACT:** Sherrette Funn, [Sherrette.Funn@hhs.gov](mailto:Sherrette.Funn@hhs.gov) or (202) 795-7714. When submitting comments or requesting information, please include the document identifier 0990-0279-30D and project title for reference.

**SUPPLEMENTARY INFORMATION:** Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency’s functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**Title of the Collection:** Department of Health and Human Services (HHS) Registration of an Institutional Review Board Form.

**Type of Collection:** Reinstatement without change.

**OMB No.:** 0990-0279.