

current regulatory framework is adequate and sufficiently flexible to appropriately regulate medical gases. FDA further explained that it can continue to work within this framework to appropriately regulate these products.

FDA issued a final rule promulgating warning statements to be included in the labeling of designated medical gases on November 18, 2016 (81 FR 81685). This final rule also imposes labeling, design, and color requirements on medical gas containers and closures to increase the likelihood that the contents of medical gas containers are accurately identified and reduce the likelihood of the wrong gas being connected to a gas supply system or container. FDA may undertake additional targeted rulemaking in the future on other specific issues if FDA determines that such issues cannot be adequately addressed by other means.

In addition to the applicable regulations, FDA relies on guidance documents (such as this one), development of appropriate inspection practices and inspector training, and interaction with industry trade associations, State regulators, and other stakeholders on an as-needed basis in regulating medical gases.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on current good manufacturing practice for medical gases. 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

This revised draft guidance includes information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). In accordance with the PRA, before publication of the final guidance document, FDA intends to solicit public comment and obtain OMB approval for any information collections recommended in this guidance that are new or that would represent material modifications to previously approved collections of information found in FDA regulations.

503(b)(4); (2) a warning statement concerning the use of the medical gas as determined by the Secretary by regulation; and (3) appropriate directions and warnings concerning storage and handling.

## 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Persons with access to the Internet may obtain the draft guidance at either 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>.

Dated: June 23, 2017.

**Anna K. Abram,**

*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

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**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2017–N–3854]

#### Antimicrobial Susceptibility and Resistance: Addressing Challenges of Diagnostic Devices; Public Workshop; Request for Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public workshop entitled “Antimicrobial Susceptibility and Resistance: Addressing Challenges of Diagnostic Devices.” The purpose of this workshop is to discuss potential scientific and regulatory challenges associated with developing traditional antimicrobial susceptibility testing (AST) devices and devices that detect antimicrobial resistance markers by molecular or novel diagnostic technologies, and to provide an overview of relevant provisions of the 21st Century Cures Act that may impact the development of such devices. Public input and feedback gained through this workshop will aid in the development of science-based approaches to regulatory decisionmaking regarding traditional and novel AST devices. Further, this workshop will explore opportunities for the efficient development and evaluation of AST devices, which may lead to better patient care and reduce antimicrobial resistance through improved antibiotic stewardship.

**DATES:** The public workshop will be held on September 13, 2017, from 8:30 a.m. to 5 p.m.

Submit either electronic or written comments on this public workshop by October 20, 2017. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

**ADDRESSES:** The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Rm. 1503 (The Great Room), Silver Spring, MD 20993. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to <http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

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 October 20, 2017. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of October 20, 2017. 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 public, 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–2017–N–3854 for “Antimicrobial Susceptibility and Resistance:

Addressing Challenges of Diagnostic Devices.” 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.

- 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.

**FOR FURTHER INFORMATION CONTACT:** Natasha Townsend, Food and Drug Administration, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, Rm. 5525, Silver Spring, MD 20993–0002, 301–796–5927, email: [natasha.townsend@fda.hhs.gov](mailto:natasha.townsend@fda.hhs.gov).

#### **SUPPLEMENTARY INFORMATION:**

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

The accurate detection of antimicrobial resistance is important due to the emergence and spread of highly resistant pathogenic bacteria. Traditional AST systems continue to provide the bulk of antimicrobial susceptibility testing. However, the spread of antimicrobial resistance has spurred the development of a range of novel diagnostic technologies (e.g., detection of molecular resistance markers) that can provide more rapid bacterial identification and susceptibility testing results than is possible with current phenotypic methods. In light of the need for accurate susceptibility information and the development of these innovative diagnostic technologies, there is a need to explore and discuss new approaches for the efficient development and evaluation of AST devices—that are important to patient care and antibiotic stewardship—to allow for the timely availability of these devices.

The purpose of the public workshop is to discuss potential scientific and regulatory challenges associated with developing traditional AST devices and devices that detect antimicrobial resistance markers by molecular or novel diagnostic technologies, and to provide an overview of relevant provisions of the 21st Century Cures Act that may impact the development of such devices. Specifically, section 3044 of the 21st Century Cures Act, entitled “Susceptibility Test Interpretive Criteria for Microorganisms; Antimicrobial Susceptibility Testing Devices,” adds section 511A to the Federal Food, Drug, and Cosmetic Act, which creates a new regulatory framework for updating AST devices with current susceptibility test interpretive criteria for approved antimicrobial drugs. Further, this workshop will explore opportunities for the efficient development and evaluation of AST devices, including new science-based approaches to regulatory decisionmaking regarding traditional and novel AST devices. In addition, FDA is considering the development of a draft guidance, and will look to the meeting to help inform

the Agency’s thinking on relevant topics. Therefore, FDA seeks input and feedback from industry, other government agencies, standard-setting organizations, clinical laboratories, and patient care professionals with an interest in the future development of AST devices.

##### **II. Topics for Discussion at the Public Workshop**

This public workshop will consist of brief presentations providing information to frame interactive discussions via two panel sessions. The presentations and panel discussions will focus on:

1. Industry and FDA perspectives on AST device evaluation requirements, including opportunities to streamline the premarket review processes that may allow for more rapid availability of AST devices for new antimicrobial drugs;
2. Performance review of traditional AST devices;
3. An overview of relevant provisions of the 21st Century Cures Act that may impact the development of AST devices;
4. The clinical laboratory perspective on AST result interpretation and reporting;
5. Novel technologies for detection of resistance markers;
6. Standards-setting organization perspective on reference methods and organism resources;
7. The role of new technologies for promoting antibiotic stewardship, improving patient care, aiding the selection of appropriate antimicrobial therapy, and reducing the impact of antimicrobial resistance; and
8. Direct-from-specimen testing and the challenges of the clinical use and phenotypic interpretation of genotypic results.

##### **III. Participating in the Public Workshop**

*Registration:* To register for the public workshop, please visit FDA’s Medical Devices News & Events—Workshops & Conferences calendar at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>. (Select this public workshop from the posted events list.) Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone number.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register by September 1, 2017, 4 p.m. Eastern Time. Early registration is recommended because seating is

limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted. If time and space permit, onsite registration on the day of the public meeting/public workshop will be provided beginning at 8 a.m. We will let registrants know if registration closes before the day of the public workshop.

If you need special accommodations due to a disability, please contact Susan Monahan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4321, Silver Spring, MD 20993-0002, 301-796-5661, email: [susan.monahan@fda.hhs.gov](mailto:susan.monahan@fda.hhs.gov) no later than August 30, 2017.

**Requests for Oral Presentations:** During online registration you may indicate if you wish to present during the public comment session, and which topic you wish to present. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation. Following the close of registration, we will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and begin notifying participants by September 5, 2017. All requests to make oral presentations must be received by the close of registration on September 1, 2017. If selected for presentation, any presentation materials must be emailed to Natasha Townsend (see **FOR FURTHER INFORMATION CONTACT**) no later than September 8, 2017, 5 p.m. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

**Streaming Webcast of the Public Workshop:** This public workshop will also be Webcast. Persons interested in viewing the Webcast must register online by September 8, 2017, 4 p.m. The Webcast link will be available on the registration Web page after September 8, 2017. Organizations are requested to register all participants, but to view using one connection per location.

If you have never attended a Connect Pro event before, test your connection at [https://collaboration.fda.gov/common/help/en/support/meeting\\_test.htm](https://collaboration.fda.gov/common/help/en/support/meeting_test.htm). To get a quick overview of the Connect Pro program, visit: [http://www.adobe.com/go/connectpro\\_overview](http://www.adobe.com/go/connectpro_overview). FDA has verified the Web site addresses in this document, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

**Transcripts:** Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at <https://www.regulations.gov>. It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available approximately 45 days after the public workshop on the Internet at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>. (Select this public workshop from the posted events list).

Dated: June 23, 2017.

**Anna K. Abram,**

*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2017-N-3199]

#### Program for Enhanced Review Transparency and Communication for Original 351(k) Biologics License Applications in Biosimilar User Fee Act II

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; establishment of docket; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the statement of work for an assessment of the Program for Enhanced Review Transparency and Communication for original biologics license applications (BLAs) (351(k)s) submitted under the Public Health Service Act (hereafter referred to as 351(k) applications) (hereafter referred to as the Program). The Program is part of the FDA performance commitments under the proposed reauthorization of the Biosimilar User Fee Act (BsUFA), which, if enacted into law, will allow FDA to collect user fees for the review of 351(k) applications for fiscal years (FYs) 2018-2022. As part of the FDA performance commitments described in this document, the Program will be evaluated by an independent contractor in an interim and final assessment.

**DATES:** FDA is providing a period of 30 days for public comment on the statement of work before beginning the assessment. The statement of work can be accessed at <https://www.fda.gov/downloads/ForIndustry/UserFees/>

*PrescriptionDrugUserFee/UCM559341.pdf*. Public comments will be accepted through July 31, 2017. See **ADDRESSES** section below for information about submitting comments to the public docket.

**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 July 31, 2017. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of July 31, 2017. 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:

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- 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."