

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2023-D-4045]

**Antimicrobial Susceptibility Test System Devices—Updating Breakpoints in Device Labeling; Guidance for Industry; Availability**

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

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or we) is announcing the availability of a final guidance for industry and FDA staff entitled “Antimicrobial Susceptibility Test (AST) System Devices—Updating Breakpoints in Device Labeling.” This guidance is intended to provide industry and FDA staff with information regarding updating susceptibility test interpretative criteria (STIC)/breakpoints and associated performance data in device labeling for antimicrobial susceptibility test (AST) system devices in response to breakpoint changes posted on the FDA-Recognized Antimicrobial Susceptibility Test Interpretative Criteria website (STIC website). This guidance is expected to facilitate the timely adoption of updated breakpoints in AST system devices, which helps to ensure device safety and effectiveness.

**DATES:** The announcement of the guidance is published in the **Federal Register** on September 29, 2023.

**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-2023-D-4045 for “Antimicrobial Susceptibility Test (AST) System Devices—Updating Breakpoints in Device Labeling.” 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)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled “Antimicrobial Susceptibility Test (AST) System Devices—Updating Breakpoints in Device Labeling” to the Office of Policy, Center of Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests.

**FOR FURTHER INFORMATION CONTACT:** Ribhi Shawar, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, Rm. 3218, Silver Spring, MD 20993-0002, 301-796-6698.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a guidance for industry and FDA staff entitled “Antimicrobial Susceptibility Test (AST) System Devices—Updating Breakpoints in Device Labeling.” We are issuing this guidance consistent with our good guidance practices (GGP) regulation (21 CFR 10.115). We are implementing this guidance without prior public comment because we have determined that prior public participation is not feasible or appropriate (see 21 CFR 10.115(g)(2) and section 701(h)(1)(C)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(h)(1)(C)(i))). Specifically, we are not seeking prior comment because the guidance presents a less burdensome policy consistent with the public health and the urgent public health need for sponsors to update breakpoints for legacy AST system devices. Although

this guidance document is immediately in effect, it remains subject to comment in accordance with FDA’s GGP regulation.

AST system devices are intended to determine the in vitro susceptibility of bacterial or fungal pathogens to different antimicrobial agents. Accurate results are essential for guiding the treatment of infections by clinicians and for monitoring the spread of antimicrobial resistant microorganisms. Generally, healthcare professionals rely on AST system devices to help choose an appropriate treatment, as STIC (also referred to as breakpoints) are the criteria used to interpret AST results.

Section 3044 of the 21st Century Cures Act, signed into law on December 13, 2016, added section 511A (21 U.S.C. 360a–2), “Susceptibility Test Interpretive Criteria for Microorganisms,” to the Federal Food, Drug, and Cosmetic Act and authorizes FDA to recognize, in whole or in part, a consensus standard that provides antimicrobial STIC or establish alternative STIC, and requires FDA to establish and maintain a dedicated website that contains a list of any appropriate new or updated STIC and standards.

This guidance describes approaches for AST system device sponsors to adopt updated breakpoints recognized on the STIC website (FDA-Recognized Antimicrobial Susceptibility Test Interpretative Criteria) and associated performance data in device labeling to facilitate the timely availability of devices with the most up-to-date STIC for patient care and public health. FDA believes that this guidance presents less

burdensome approaches for AST system device sponsors to utilize predetermined change control plans (PCCPs) and breakpoint change protocols to update their device labeling to include adoption of updated breakpoints recognized on FDA’s STIC website in a timely manner while helping to ensure device safety and effectiveness. This guidance provides recommendations on the marketing submission content for PCCPs for new AST system devices, describes an enforcement policy regarding applying such updates to “legacy” AST system devices (AST system devices that were reviewed and cleared by FDA and did not include a breakpoint change protocol), and clarifies the process for incorporating by reference a cleared PCCP or breakpoint change protocol into a new 510(k) submission for an AST system device.

This guidance supersedes Sections II.A and V of Updating Labeling for Susceptibility Test Information in Systemic Antibacterial Drug Products and Antimicrobial Susceptibility Testing Devices (June 2009).

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 “Antimicrobial Susceptibility Test (AST) System Devices—Updating Breakpoints in Device Labeling.” 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. Electronic Access**

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products>. This guidance document is also available at <https://www.regulations.gov> and <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>. Persons unable to download an electronic copy of “Antimicrobial Susceptibility Test (AST) System Devices—Updating Breakpoints in Device Labeling” may send an email request to [CDRH-Guidance@fda.hhs.gov](mailto:CDRH-Guidance@fda.hhs.gov) to receive an electronic copy of the document. Please use the document number GUI00007019 and complete title to identify the guidance you are requesting.

**III. Paperwork Reduction Act of 1995**

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in the following table have been approved by OMB:

21 CFR part or guidance	Topic	OMB control No.
800, 801, and 809 .....	Medical Device Labeling Regulations .....	0910–0485
807, subpart E .....	Premarket notification .....	0910–0120
820 .....	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation.	0910–0073
“Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program”.	Q-submissions; Pre-submissions .....	0910–0756

Dated: September 25, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2023–D–3788]

**Electronic Submission Template for Medical Device De Novo Requests; Draft Guidance for Industry and Food and Drug Administration Staff; 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 the draft guidance entitled “Electronic Submission Template for Medical Device De Novo Requests.” FDA is issuing this draft guidance to introduce submitters of De Novo requests to the Center for Devices and Radiological Health (CDRH) and Center for Biological Evaluation and Research (CBER) to the current resources and associated content developed and made publicly available