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* 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.

[FR Doc. 2023–21407 Filed 9–28–23; 8:45 am]

BILLING CODE 4164–01–P

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 Biologics Evaluation and Research (CBER) to the current resources and associated content developed and made publicly available

to support De Novo electronic submissions to FDA. This draft guidance, when finalized, is intended to represent one of several steps in meeting FDA's commitment to the development of electronic submission templates to serve as guidance submission preparation tools for industry to improve submission consistency and enhance efficiency in the review process. This draft guidance is not final nor is it for implementation at this time.

DATES: Submit either electronic or written comments on the draft guidance by November 28, 2023 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–2023–D–3788 for ''Electronic Submission Template for Medical Device De Novo Requests.'' 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 draft guidance document entitled ''Electronic Submission Template for Medical Device De Novo Requests'' to the Office of Policy, Center for 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 request.

FOR FURTHER INFORMATION CONTACT: Rebecca Nipper, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1540, Silver Spring, MD 20993–0002, 301–796–6527 or Anne Taylor, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is issuing this draft guidance document to introduce submitters of De Novo requests [1] to CDRH and CBER to the current resources and associated content developed and made publicly available to support De Novo electronic submissions to FDA. This draft guidance is intended to represent one of several steps in meeting FDA's commitment to the development of electronic submission templates to serve as guided submission preparation tools for industry to improve submission consistency and enhance efficiency in the review process.[2] When finalized, this guidance will also facilitate the implementation of the FDA's mandate under section 745A(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 379k–1(b)), amended by section 207 of the FDA Reauthorization Act of 2017 (FDARA) (Pub. L. 115–52 [3]) to provide further standards for the submission by electronic format, a timetable for establishment of these further standards, and criteria for waivers of and exemptions from the requirements.

[1] See section 513(f)(2) of the FD&C Act (21 U.S.C. 360c(f)(2)) and 21 CFR part 860, subpart D.

[2] See 163 CONG. REC. S4729–S4736 (daily ed. August 2, 2017) (Food and Drug Administration User Fee Reauthorization), also available at *https://www.fda.gov/media/102699/download,* and 168 CONG. REC. S5194–S5203 (daily ed. September 28, 2022) (Food and Drug Administration User Fee Reauthorization), also available at *https://www.fda.gov/media/158308/download* and 168 CONG. REC. S5194–S5203 (daily ed. September 28, 2022) (Food and Drug Administration User Fee Reauthorization), also available at *https://www.fda.gov/media/158308/download.*

[3] *https://www.govinfo.gov/content/pkg/PLAW-115publ52/html/PLAW-115publ52.htm.*

FDA's guidance document ''Providing Regulatory Submissions for Medical Devices in Electronic Format—Submissions Under Section 745A(b) of the Federal Food, Drug, and Cosmetic Act'' [4] (hereafter referred to as the ''745A(b) device parent guidance'') provides a process for the development of templates to facilitate the preparation, submission, and review of regulatory submissions for medical devices solely in electronic format. As described in the 745A(b) device parent guidance, FDA plans to implement the requirements of section 745A(b)(3) of the FD&C Act with individual guidances specifying the formats for specific submissions and corresponding timetables for implementation. When finalized, this guidance will provide such information for De Novo electronic submissions solely in electronic format.

In section 745A(b) of the FD&C Act, Congress granted explicit statutory authorization to FDA to specify in guidance the statutory requirement for electronic submissions solely in electronic format by providing standards, a timetable, and criteria for waivers and exemptions. To the extent that this draft guidance provides such requirements under section 745A(b)(3) of the FD&C Act (*i.e.,* standards, timetable, criteria for waivers of and exemptions), indicated by the use of the mandatory words, such as must or required, this document is not subject to the usual restrictions in FDA's good guidance practice regulations, such as the requirement that guidances not establish legally enforceable responsibilities (see § 10.115(d) (21 CFR 10.115(d)).) To the extent that this draft guidance describes recommendations that are not standards, timetable, criteria for waivers of, or exemptions under section 745A(b)(3) of the FD&C Act, it is being issued consistent with FDA's good guidance practices regulation (§ 10.115).

The draft guidance, when finalized, will represent the current thinking of FDA on this topic. 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. This draft guidance, when finalized, will contain both binding and nonbinding provisions.

II. Electronic Access

Persons interested in obtaining a copy of the draft 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, https://www.fda.gov/regulatory-information/search-fda-guidance-documents* or *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics.* Persons unable to download an electronic copy of ''Electronic Submission Template for Medical Device De Novo Requests'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number GUI00021027 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new 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	Topic	OMB control No.
807, subpart E	Premarket notification	0910–0120
860, subpart D	De Novo classification process	0910–0844
800, 801, and 809	Medical Device Labeling Regulations	0910–0485

Dated: September 25, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–21405 Filed 9–28–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–2781]

Agency Information Collection Activities; Proposed Collection; Comment Request; Data To Support Drug Product Communications as Used by the Food and Drug Administration

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 solicits comments on a generic clearance to collect information to support communications used by FDA about drug products.

DATES: Either electronic or written comments on the collection of information must be submitted by November 28, 2023.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 28, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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

[4] *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-medical-devices-electronic-format-submissions-under-section-745ab.*