4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-5925]

21st Century Cures Act: Annual Compilation of Notices of Updates from the Susceptibility Test Interpretive Criteria Web Page; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the availability of the Agency's annual compilation of notices of updates to the Agency's Susceptibility Test Interpretive Criteria web page. The Agency established the Susceptibility Test Interpretive Criteria web page on December 13, 2017, and since establishment has provided updates to both the format of the web pages and the susceptibility test interpretive criteria identified and recognized by FDA on the web pages. FDA is publishing this notice in accordance with procedures established by the 21st Century Cures Act (Cures Act).

DATES: This notice is published in the *Federal Register* on **[INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: You may submit either electronic or written comments and information 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 below (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-5925 for "Susceptibility Test Interpretive Criteria Recognized and Listed on the Susceptibility Test Interpretive Web Page; Request for Comments." 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.

FOR FURTHER INFORMATION CONTACT: Deborah (Wang) Kim, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6349, Silver Spring, MD 20993-0002, 301-796-9053, Deborah.Wang@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Section 511A of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360a-2), as added by section 3044 of the Cures Act (Pub. L. 114-255), was signed into law on December 13, 2016. This provision clarified FDA's authority to identify and efficiently update susceptibility test interpretive criteria, including through the recognition by FDA of standards

established by standards development organizations (SDOs). It also clarified that sponsors of antimicrobial susceptibility testing devices may rely upon listed susceptibility test interpretive criteria to support premarket authorization of their devices, provided they meet certain conditions, which allows for a more streamlined process for incorporating up-to-date information into such devices.

In the *Federal Register* notice of December 13, 2017 (82 FR 58617), FDA announced the establishment of the Susceptibility Test Interpretive Criteria web page. This web page recognizes susceptibility test interpretive criteria established by an SDO that fulfills the requirements under section 511A(b)(2)(A) of the FD&C Act; identifies when FDA does not recognize, in whole or in part, susceptibility test interpretive criteria established by an SDO; and lists susceptibility test interpretive criteria identified by FDA outside the SDO process. The susceptibility test interpretive criteria listed by FDA on the Susceptibility Test Interpretive Criteria web page is deemed to be recognized as a standard under section 514(c)(1) of the FD&C Act (21 U.S.C. 360d(c)(1)). The Susceptibility Test Interpretive Criteria web page can be found at https://www.fda.gov/STIC.

On March 1, 2018, FDA published a notice in the *Federal Register* (83 FR 8883) requesting comments on FDA's initial susceptibility test interpretive criteria recognition and listing determinations on the Susceptibility Test Interpretive Criteria web page (https://www.federalregister.gov/documents/2018/03/01/2018-04175/susceptibility-test-interpretive-criteria-recognized-and-listed-on-the-susceptibility-test). FDA may consider information provided by interested third parties as a basis for evaluating new or updated interpretive criteria standards (section 511A(c)(2)(B) of the FD&C Act); third parties should submit any information they wish to convey to the Agency to Docket No. FDA-2017-N-5925. If comments are received, FDA will review those comments and will make, as appropriate, updates to the recognized standards or susceptibility test interpretive criteria.

At least every 6 months after the establishment of the Susceptibility Test Interpretive Criteria web page, FDA is required, as appropriate to: (1) publish on that web page a notice recognizing new or updated susceptibility test interpretive criteria standards, or recognizing or declining to recognize parts of standards; (2) withdraw recognition of susceptibility test interpretive criteria standards, or parts of standards; and (3) make any other necessary updates to the lists published on the Susceptibility Test Interpretive Criteria web page (section 511A(c)(1)(A) of the FD&C Act). FDA has provided notices of updates on the Susceptibility Test Interpretive Criteria web page, which can be found here: https://www.fda.gov/drugs/development-resources/notice-updates. Interested parties may also sign up to receive emails informing them of these updates as they occur by using the link provided either on the main Susceptibility Test Interpretive Criteria web page (https://www.fda.gov/STIC) or on the updates page.

Once a year, FDA is required to compile the new notices published on the Susceptibility Test Interpretive Criteria web page, publish them in the *Federal Register,* and provide for public comment (see section 511A(c)(3) of the FD&C Act). This *Federal Register* notice satisfies that requirement. If comments are received, FDA will review them and make updates to the recognized standards or susceptibility test interpretive criteria as needed.

II. Annual Compilation of Notices, 2023: Susceptibility Test Interpretive Criteria Web Page

A. Updates to Standards Recognition

As of April 21, 2023, the following standards are no longer recognized: "Clinical and Laboratory Standards Institute (CLSI). Performance Standards for Antimicrobial Susceptibility Testing. 32nd ed. CLSI supplement M100. Wayne, PA: Clinical and Laboratory Standards Institute; 2022."

As of April 21, 2023, with certain exceptions, FDA recognizes the standards published in: "Clinical and Laboratory Standards Institute (CLSI). Performance Standards for

Antimicrobial Susceptibility Testing. 33rd ed. CLSI supplement M100. Wayne, PA: Clinical and Laboratory Standards Institute; 2023."

B. Updates by Drug:

Table 1.--Notices of Updates to Recognized or Updated Susceptibility Test Interpretive Criteria (STIC) by Drug[1]

Drug	Route of Administration	Action Taken	Therapeutic Category	Date
Amikacin	Injection	FDA does not recognize MI00 standard (MIC and disk diffusion) for Enterobacterales and *Pseudomonas aeruginosa*	Antibacterial	4/21/2023
Cefepime	Injection	FDA recognizes M100 susceptible-dose dependent standard (MIC and disk diffusion) for Enterobacterales.	Antibacterial	6/21/2023
Cefiderocol	Injection	FDA recognizes M100 disk diffusion standards for Enterobacterales.	Antibacterial	1/31/2023
Colistimethate	Injection	FDA does not recognize M100 standard (MIC) for Enterobacterales, Pseudomonas aeruginosa, or Acinetobacter spp. (Rationale available at https://www.fda.gov/drugs/development-resources/fda-rationale-polymyxin-breakpoints-enterobacterales-pseudomonas-aeruginosa-and-acinetobacter-spp.)	Antibacterial	1/17/2023
Fluconazole	Injection, Oral	FDA recognizes M27M44S susceptible-dose dependent standard (MIC and disk diffusion) for *Candida* species.	Antifungal	8/10/2023
Gentamicin	Injection	FDA does not recognize MI00 standard (MIC and disk diffusion) for Enterobacterales and *Pseudomonas aeruginosa.*	Antibacterial	4/21/2023
Lefamulin	Oral, Injection	FDA recognizes M100 standard (MIC and disk diffusion) for *Staphylococcus aureus* (methicillin-susceptible isolates), *Streptococcus pneumoniae*, and *Haemophilus influenzae*.	Antibacterial	2/16/2023
Piperacillin and Tazobactam	Injection	FDA does not recognize MI00 standard (MIC and disk diffusion) for *Pseudomonas aeruginosa*.	Antibacterial	4/21/2013
Piperacillin and Tazobactam	Injection	FDA has updated STIC (MIC and disk diffusion) for Enterobacterales. FDA has recognized M100 standard for susceptible and resistant breakpoints and updated an intermediate breakpoint. FDA does not recognize M100 standard for a susceptible dose dependent breakpoint. (Rationale available at https://www.fda.gov/drugs/development-resources/fda-rationale-piperacillin-tazobactam-breakpoints-enterobacterales.)	Antibacterial	1/17/2023

Plazomicin	Injection	FDA recognizes M100 standard (MIC and disk diffusion) for Enterobacterales.	Antibacterial	4/21/2023
Polymyxin B	Injection	FDA does not recognize M100 standard (MIC) for Enterobacterales, *Pseudomonas aeruginosa*, or *Acinetobacter* spp. (Rationale available at https://www.fda.gov/drugs/development-resources/fda-rationale-polymyxin-breakpoints-enterobacterales-pseudomonas-aeruginosa-and-acinetobacter-spp.)	Antibacterial	1/17/2023
Rezafungin	Injection	FDA identified STIC (MIC and disk diffusion) for *C. albicans*, *C. glabrata*, and *C. tropicalis*. FDA has reviewed STIC (MIC) for *C. parapsilosis*, and the M27M44S standard is recognized. FDA identified STIC (disk diffusion) for *C. parapsilosis*.	Antifungal	4/18/2023
Sulbactam and Durlobactam	Injection	FDA identified STIC (MIC and disk diffusion) for *Acinetobacter baumannii-calcoaceticus* complex.	Antibacterial	5/25/2023
Tobramycin	Injection	FDA does not recognize MI00 standard (MIC and disk diffusion) for Enterobacterales and *Pseudomonas aeruginosa*.	Antibacterial	4/21/2023

[1] M100 standard in the table refers to Clinical and Laboratory Standards Institute (CLSI) Performance Standards for Antimicrobial Susceptibility Testing, 33rd ed. CLSI supplement M100; 2023.

Dated: April 4, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024-07495 Filed: 4/8/2024 8:45 am; Publication Date: 4/9/2024]