on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: Act, 42 U.S.C. 9858(c)(6).

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2019–09045 Filed 5–2–19; 8:45 am]

BILLING CODE 4184–81–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 to 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 May 3, 2019.

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 (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.

- 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: Katherine Schumann, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6242, Silver Spring, MD 20993–0002, 301–796–1182, *Katherine.Schumann@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 511A of the Federal Food, Drug, and Cosmetic Act (the 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 clarifies 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 clarifies 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/DevelopmentApprovalProcess/DevelopmentResources/ucm593952.htm.* 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 and 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: Susceptibility Test Interpretive Criteria Web Page

A. Formatting Changes to the Susceptibility Test Interpretive Criteria Web Page

On October 4, 2018, FDA updated the format of the Antifungal Susceptibility Test Interpretive Criteria web pages for clarity, in response to stakeholder feedback.

On June 26, 2018, FDA updated the format of the Antibacterial Susceptibility Test Interpretive Criteria web pages for clarity, in response to stakeholder feedback.

B. Updates to Standards Recognition

As of October 4, 2018, the following susceptibility test interpretive criteria standards are no longer recognized (for information regarding recognition of methods and quality control standards see Recognized Consensus Standards):

- Clinical and Laboratory Standards Institute (CLSI). Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeasts; Fourth Informational Supplement. CLSI document M27–S4 (2012). Clinical and Laboratory Standards Institute, 940 West Valley Rd., Suite 2500, Wayne, PA 19087, USA (CLSI M27–S4).
- Clinical and Laboratory Standards Institute (CLSI). Method for Antifungal Disk Diffusion Susceptibility Testing of Yeasts; Approved Guideline—Second Edition. CLSI document M44–S3 (2009). Clinical and Laboratory Standards Institute, 950 West Valley Rd., Suite 500, Wayne, PA 19087, USA (CLSI M44–S3).
- Clinical and Laboratory Standards Institute (CLSI). Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeasts; Fourth Informational Supplement. CLSI document M27–S3 (2008). Clinical and Laboratory Standards Institute, 940 West Valley Rd., Suite 2500, Wayne, PA 19087, USA (CLSI M27–S3).

As of October 4, 2018, with certain exceptions, FDA recognizes the following standard:

- Clinical and Laboratory Standards Institute (CLSI). Performance Standards for Antifungal Susceptibility Testing of Yeasts. 1st ed. CLSI supplement M60 (2017). Clinical and Laboratory Standards Institute, 940 West Valley Rd., Suite 2500, Wayne, PA 19087, USA (CLSI M60).

As of June 26, 2018, the following standard is no longer recognized:

- Clinical and Laboratory Standards Institute (CLSI). Performance Standards for Antimicrobial Susceptibility Testing. 27th ed. CLSI supplement M100. Wayne, PA: Clinical and Laboratory Standards Institute; 2017.

As of June 26, 2018, with certain exceptions, FDA recognizes the following standard:

- Clinical and Laboratory Standards Institute (CLSI). Performance Standards for Antimicrobial Susceptibility Testing. 28th ed. CLSI supplement M100. Wayne, PA: Clinical and Laboratory Standards Institute; 2018.

TABLE 1—NOTICES OF UPDATES TO RECOGNIZED OR UPDATED SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA BY DRUG

Drug	Route of administration	Action taken	Therapeutic category	Date
Fluconazole	Injection, Oral	FDA identifies exceptions to the recognized standard for Fluconazole. The term ''Susceptible-Dose Dependent'' is not recognized pending further clarification of the definition of the term by standards development organizations.	Antifungal	10/3/18
Flucytosine	Injection	FDA withdraws recognition of Susceptibility Test Interpretive Criteria for Flucytosine as there are not sufficient clinical or other data to support these criteria.	Antifungal	10/3/18

TABLE 1—NOTICES OF UPDATES TO RECOGNIZED OR UPDATED SUSCEPTIBILITY TEST INTERPRETIVE CRITERIA BY DRUG—Continued

Drug	Route of administration	Action taken	Therapeutic category	Date
Itraconazole	Injection, Oral	FDA identifies Susceptibility Test Interpretive Criteria for itraconazole and *Candida albicans.* The current minimum inhibitory concentration distribution data demonstrates that the sensitivity of *C. albicans* to itraconazole has not changed over time. Therefore, the in-vitro activity and clinical response data reviewed previously by FDA and described in product labeling continue to support these interpretive criteria for *C. albicans*.	Antifungal	10/3/18
Omadacycline	Injection, Oral	Added drug to antibacterial susceptibility test interpretive criteria web page. FDA identified susceptibility test interpretive criteria for omadacycline injection.	Antifungal	10/3/18
Bismuth subcitrate potassium, Metronidazole, and Tetracycline hydrochloride.	Oral	Added drug to antibacterial susceptibility test interpretive criteria web page. No susceptibility test interpretive criteria recognized or added by FDA.	Antibacterial	2/09/18
Ceftazidime Avibactam	Injection	FDA recognizes M100 standard for *Enterobacteriaceae* and *Pseudomonas aeruginosa*.	Antibacterial	6/26/18
Ceftolozane Tazobactam	Injection	FDA recognizes M100 standard for disk diffusion for *Enterobacteriaceae*.	Antibacterial	6/26/18
Clarithromycin	Oral	FDA recognizes CLSI M45 standard for clarithromycin for *Helicobacter pylori*.	Antibacterial	2/09/18
Dalbavancin	Injection	FDA recognizes M100 standard for *Staphylococcus aureus, Enterococcus* spp. (vancomycin-susceptible isolates only), *Streptococcus* spp β-Hemolytic Group, *Streptococcus* spp Viridans Group.	Antibacterial	6/26/18
Eravacycline	Injection	Added drug to antibacterial susceptibility test interpretive criteria web page. FDA identified susceptibility test interpretive criteria for eravacycline injection.	Antibacterial	8/28/18
Isoniazid, Pyrazinamide, and Rifampin.	Oral	Added drug to antibacterial susceptibility test interpretive criteria web page. No susceptibility test interpretive criteria recognized or added by FDA.	Antibacterial	2/09/18
Lansoprazole, Amoxicillin, and Clarithromycin.	Oral	Added drug to antibacterial susceptibility test interpretive criteria web page. No susceptibility test interpretive criteria recognized or added by FDA.	Antibacterial	2/09/18
Piperacillin Tazobactam	Injection	FDA recognizes revised M100 standard for anaerobes.	Antibacterial	6/26/18
Plazomicin	Injection	Added drug to antibacterial susceptibility test interpretive criteria web page. FDA identified susceptibility test interpretive criteria for plazomicin injection.	Antibacterial	6/26/18
Rifabutin	Oral	Added drug to antibacterial susceptibility test interpretive criteria web page. No susceptibility test interpretive criteria recognized or added by FDA.	Antibacterial	4/26/18
Rifapentine	Oral	Added drug to antibacterial susceptibility test interpretive criteria web page. No susceptibility test interpretive criteria recognized or added by FDA.	Antibacterial	2/09/18
Rifaximin	Oral	Added drug to antibacterial susceptibility test interpretive criteria web page. No susceptibility test interpretive criteria recognized or added by FDA.	Antibacterial	2/09/18
Tedizolid	Oral, Injection	Due to test performance concerns, FDA withdraws recognition of all disk diffusion interpretive criteria.	Antibacterial	6/26/18

Dated: April 29, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–09007 Filed 5–2–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–1619]

List of Patient Preference-Sensitive Priorities; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the availability of the list of patient preference-sensitive priorities on FDA's website entitled, ''Patient Preference-Sensitive Areas: Using Patient Preference Information (PPI) in Medical Device Evaluation.'' As part of FDA's commitments for the reauthorization of the Medical Device User Fee Amendments of 2017 (MDUFA IV), the Center for Devices and Radiological Health (CDRH) committed to publish a list of priority areas where preference-sensitive data can inform regulatory decision making. FDA is also establishing a docket to solicit public input on this list of preference-sensitive areas that may impact the design and conduct of premarket medical device clinical studies, benefit-risk assessments, and postmarket evaluation.

DATES: Submit either electronic or written comments on the notice by July 2, 2019 to ensure that the Agency considers your comment on the list of patient preference-sensitive priorities.

ADDRESSES: You may submit comments on this notice 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 Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for 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–2019–N–1619 for ''List of Patient Preference-Sensitive Priorities; Establishment of a Public Docket; Requests 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.

- 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: Anindita Saha, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5414, Silver Spring, MD 20993–0002, 301–796–2537.

SUPPLEMENTARY INFORMATION:

I. Background

In 2016, the FDA issued guidance entitled, ''Patient Preference Information—Voluntary Submission, Review in Premarket Approval Applications, Humanitarian Device Exemption Applications, and De Novo Requests, and Inclusion in Decision Summaries and Device Labeling—Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders'' (Ref. 1), outlining how stakeholders, including industry and patient advocacy organizations, can voluntarily collect and submit PPI that may be used by FDA staff in regulatory decision making.

As part of FDA's commitment for the reauthorization of MDUFA IV), FDA committed to advancing patient input and involvement and to identify patient preference-sensitive priority areas that may inform regulatory decision making (Ref. 2). FDA seeks to successfully build on our strong commitment to patients by engaging them to understand and considering their experience and perspectives, as it relates to medical device clinical studies, benefit-risk assessments, and postmarket surveillance.

As such, on December 7–8, 2017, FDA cohosted a collaborative workshop with the Centers of Excellence in Regulatory Science and Innovation entitled, ''Advancing Use of Patient Preference Information as Scientific Evidence in Medical Product Evaluation'' (Ref. 3). This workshop discussed the current progress on incorporating PPI into