request that a drug product be included in the OTC drug monograph system and describes the process for submitting that information.

In the **Federal Register** of July 30, 2020 (85 FR 45892), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR part and activity	Number of respondents	No. of responses per respondent	Total annual responses	Average burden per response	Total hours
Time and extent application and submission of information (§ 330.14(c) and (d))	2	1	2	1,525	3,050
Safety and effectiveness data (§ 330.14(f) and (i))	2	1	2	2,350	4,700
Sponsor request for an informal conference (§ 330.14(j)(3))	1	1	1	1	1
Sponsor signed statement that submission is complete (§ 330.14(j)(4))	2	1	2	1	2
Sponsor request for FDA to withdraw TEA consideration (§ 330.14(k)(1))	1	1	1	1	1
Sponsor request for FDA not to deem the submission withdrawn (§ 330.14(k)(2))	1	1	1	2	2
Total					7,756

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: October 14, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–23357 Filed 10–21–20; 8:45 am]

BILLING CODE 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 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 October 22, 2020.

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, 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: 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, 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

Updates to Standards Recognition

As of June 10, 2019, the following standard is no longer recognized: 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.

As of June 10, 2019, with certain exceptions, FDA recognizes the standard published in: Clinical and Laboratory Standards Institute (CLSI). Performance Standards for Antimicrobial Susceptibility Testing. 29th ed. CLSI supplement M100. Wayne, PA: Clinical and Laboratory Standards Institute; 2019.

For disk diffusion, information regarding disk strength that is not included in recognized standards has been added for the following drugs: Delafloxacin, eravacycline, omadacycline, plazomicin, tigecyline.

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

Drug	Route of administration	Action taken	Therapeutic category	Date
Azithromycin	Oral, Injection	For *Neisseria gonorrhoeae,* STIC are not recognized at this time. FDA review of these STIC is ongoing.	Antibacterial	6/10/19
Cefiderocol	Injection	Added drug to antibacterial Susceptibility Test Interpretive Criteria web page. FDA identified STIC.	Antibacterial	11/18/19
Ceftaroline fosamil	Injection	Typographical error corrected	Antibacterial	8/29/19
Ceftolozane Tazobactam	Injection	For Enterobacteriaceae, an exception to the recognized standard is provided for Disk Diffusion. For *Haemophilus influenzae,* the FDA-identified STIC are provided. STIC are based on dosing regimens that differ by the serious infection being treated, and this information is provided.	Antibacterial	6/10/19
Cefuroxime	Injection	For *Neisseria gonorrhoeae,* FDA agrees with the recognized standard that it is no longer appropriate to list STIC.	Antibacterial	6/10/19
Ciprofloxacin	Oral, Injection	For Enterobacteriaceae and *Pseudomonas aeruginosa,* the updated standard is recognized.	Antibacterial	6/10/19
Colistimethate	Injection	For *Pseudomonas aeruginosa* and *Acinetobacter spp.,* FDA has reviewed these STIC and concludes that STIC cannot be recognized at this time.	Antibacterial	6/10/19
Daptomycin	Injection	For *Enterococcus* spp. (vancomycin-susceptible isolates only), an exception to the recognized standard is provided. FDA review of these STIC is ongoing.	Antibacterial	6/10/19
Delafloxacin	Injection, Tablets	FDA identified STIC	Antibacterial	10/25/19
Imipenem-Cilastatin-Relebactam.	Injection	FDA identified STIC	Antibacterial	7/18/19
Lefamulin	Oral, Injection	FDA identified STIC	Antibacterial	8/29/19
Levofloxacin	Oral, Injection	For Enterobacteriaceae and *Pseudomonas aeruginosa,* the updated standard is recognized.	Antibacterial	6/10/19
Meropenem	Injection	For *Acinetobacter* spp., the updated standard is recognized.	Antibacterial	12/23/19
Meropenem- Vaborbactam	Injection	For Enterobacteriaceae, the updated standard is recognized.	Antibacterial	6/10/19
Ofloxacin	Oral	For *Neisseria gonorrhoeae,* FDA identified STIC are provided. FDA review of these STIC is ongoing.	Antibacterial	6/10/19
Omeprazole magnesium, Amoxicillin, and Rifabutin.	Oral	Added drug to antibacterial Susceptibility Test Interpretive Criteria web page. No STIC identified at this time.	Antibacterial	11/18/19
Pretomanid	Oral	Added drug to antibacterial Susceptibility Test Interpretive Criteria web page. No STIC identified at this time.	Antibacterial	8/29/19

Dated: October 19, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–23439 Filed 10–21–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1806]

Fit for Use Pilot Program Invitation for the Clinical Data Interchange Standards Consortium for Standard for Exchange of Nonclinical Data Implementation Guide Developmental and Reproductive Toxicology: Version 1.1

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing that it intends to conduct a Fit for Use (FFU) pilot program to test the processing and analysis of nonclinical study data provided electronically for the Clinical Data Interchange Standards Consortium (CDISC) for Standard for Exchange of Nonclinical Data (SEND) Implementation Guide (IG): Developmental and Reproductive Toxicology v1.1 (SEND–DART). The Agency's Center for Drug Evaluation and Research (CDER) will test the processing and analysis of nonclinical study data provided electronically in SEND–DART format. FDA is inviting individual firms that wish to participate in this pilot program to submit participation requests via email or in writing.

DATES: To be considered for participation in the pilot program, submit electronic or written requests by February 26, 2021. See the **ADDRESSES** section for participation request instructions.

ADDRESSES: Submit electronic requests to participate in the pilot and comments regarding this pilot project to Docket No. FDA–2020–N–1806 at *https://www.regulations.gov*. Submit written requests to participate in the pilot and comments regarding the pilot to Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time by February 26, 2021. 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.