4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Susceptibility Test Interpretive Criteria Recognized and Listed on the Susceptibility Test Interpretive Web Page; Reopening of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

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

SUMMARY: The Food and Drug Administration (FDA or the Agency) is reopening a docket for public comment on the susceptibility test interpretive criteria for antibacterial and antifungal drugs provided by FDA on its Susceptibility Test Interpretive Criteria web page (Interpretive Criteria web page) established on December 13, 2017. On the Interpretive Criteria web page, FDA recognizes, in whole or in part, susceptibility test interpretive criteria standards established by Standard Development Organizations (SDOs) and lists other susceptibility test interpretive criteria identified by FDA outside of the SDO process.

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 (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.

You may submit comments to the docket at any time.

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

On December 13, 2017, FDA established the Interpretive Criteria web page (https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm410971.htm) that contains a list of FDA-recognized susceptibility test interpretive criteria standards, established by an SDO that fulfills the requirements under section 511A(b)(2)(A) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360a-2(b)(2)(A)); 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 standards recognized by FDA on the Interpretive Criteria web page are deemed to be recognized as a standard under section 514(c)(1) of the FD&C Act (21 U.S.C. 360d(c)(1)).

At least every 6 months after the establishment of the Interpretive Criteria web page, FDA will publish on the Interpretive Criteria web page a notice recognizing new or updated susceptibility test interpretive criteria standards, or parts of standards; withdrawing recognition of susceptibility test interpretive criteria standards, or parts of standards; and making any other necessary updates to the lists published on the Interpretive Criteria web page. Once a year FDA

will compile the notices from that year and publish them in the *Federal Register* and provide for public comment. If comments are received, FDA will review those comments and make any updates to the recognized standards or susceptibility test interpretive criteria as needed.

II. Recommendation of New or Updated Susceptibility Test Interpretive Criteria for Listing by FDA

This *Federal Register* notice is a request for comments by interested third parties on FDA's initial susceptibility test interpretive criteria recognition and listing determinations on the Interpretive Criteria web page. FDA may consider information provided by interested third parties as a basis for updating interpretive criteria standards. This notice allows interested third parties the opportunity to comment on FDA's recognition and listing determinations before the annual compilation of notices of susceptibility test interpretive criteria changes made that year.

Interested third parties or drug sponsors may provide information that FDA could use as a basis for listing new or for updating susceptibility interpretive criteria. This information should be submitted to Docket No. FDA-2017-N-5925. If comments are received, FDA will review those comments and will make, as necessary, updates to the recognized standards or susceptibility test interpretive criteria.

If preferred, application holders may submit data supporting changes to FDA's susceptibility test interpretive criteria recognition or listing determinations through the application holder's annual report under the new drug application. If submitting this data, application holders are encouraged to identify in the cover letter of the annual report that the enclosed submission includes data supporting changes to FDA's susceptibility test interpretive criteria recognition or listing determinations. FDA will review these annual report submissions and determine whether changes or updates to the currently recognized susceptibility test

interpretive criteria are appropriate. FDA will then update the Interpretive Criteria web page to reflect these changes, as needed.

Dated: February 22, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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