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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

21st Century Cures Act: Announcing the Establishment of the Susceptibility Test Interpretive Criteria Website

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the establishment of the Susceptibility Test Interpretive Criteria Website. The Susceptibility Test Interpretive Criteria Website will help to efficiently update susceptibility test interpretive criteria for antimicrobial drugs when necessary for public health and may allow for more efficient development and evaluation of antimicrobial susceptibility test (AST) devices. These changes may lead to better patient care and reduce antimicrobial resistance through improved antibiotic stewardship. FDA is publishing this notice in accordance with procedures established by the 21st Century Cures Act (Cures Act).

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

Antimicrobial susceptibility testing is used to determine if certain microorganisms that are isolated from a patient with an infection are likely to be killed or inhibited by a particular

antimicrobial drug. It is important that the in vitro susceptibility test methods and susceptibility test interpretive criteria for systemic antibacterial or antifungal drugs be reviewed on a regular basis and updated to reflect the most current information. The development of new mechanisms of resistance in bacteria or fungi may result in decreased susceptibility to a particular drug. Decreased susceptibility may raise efficacy or safety concerns when out-of-date susceptibility test interpretive criteria are used in guiding the treatment of patients.

Historically, susceptibility test interpretive criteria have been contained in the Microbiology subsection of antimicrobial drug labeling, and there have been significant challenges associated with ensuring that this information is up-to-date in individual antimicrobial drug labels. For some time, FDA and other stakeholders have recognized that susceptibility test interpretive criteria standards established by nationally or internationally recognized standard development organizations (SDOs) can be useful sources of information to identify and update susceptibility test interpretive criteria.

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 SDOs. It also clarifies that sponsors of AST devices may rely upon listed susceptibility interpretive criteria to support premarket authorization of their devices, provided they meet certain conditions, which provides for a more streamlined process for incorporating up-to-date information into such devices.

II. Susceptibility Test Interpretive Criteria Website

Section 511A of the FD&C Act requires FDA to establish within 1 year after the date of enactment of the Cures Act an Interpretive Criteria Website that contains a list of FDA-recognized susceptibility test interpretive criteria standards, as well as other susceptibility test interpretive criteria identified by FDA. FDA is announcing the establishment of this Interpretive Criteria Website, which can be found here: https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm410971.htm.

This website 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 Interpretive Criteria Website 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 Website, FDA will publish on the Interpretive Criteria Website 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 Website. 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. In addition to this statutorily required annual notice, FDA intends to publish a *Federal Register*

notice within the next few months to allow for public comment on the initial recognition of susceptibility test interpretive criteria.

Dated: December 7, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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