



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Standard Development Organizations Whose Susceptibility Test Interpretive Criteria Standards May Be Recognized by the Food and Drug Administration; Request for Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Request for information.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is requesting information to assist in identifying standard development organizations (SDOs) that meet the requirements in the Federal Food, Drug, and Cosmetic Act (FD&C Act), of the 21st Century Cures Act (Cures Act), which was signed into law on December 13, 2016.

DATES: Submit either electronic or written comments on the notice by **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: You may submit comments and information as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. 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.

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 “Standard Development Organizations Whose Susceptibility Test Interpretive Criteria Standards May Be Recognized by FDA; Request for Information.” Received comments, those filed in a timely manner (see **ADDRESSES**), 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 or 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 at the concentrations of the drug that are attainable at the site of infection. Historically, susceptibility test interpretive criteria has 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 for 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 SDOs can be useful sources of information to identify and update susceptibility test interpretive criteria.

Section 511A of the FD&C Act (21 U.S.C. 360a) was added by section 3044 of the Cures Act (Pub. L. 114-255), which 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 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 provides for a more streamlined process for incorporating up-to-date information into such devices.

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 containing a list of FDA-recognized susceptibility test interpretive criteria standards, as well as other susceptibility test interpretive criteria identified by FDA. The list of standards consists of new or updated susceptibility test interpretive criteria standards with respect to legally marketed antimicrobial drugs that have been: (1) established by nationally or internationally recognized SDOs that meet the requirements under section 511A(b)(2)(A)(i) of the FD&C Act and (2) recognized, in whole or in part, by FDA, pursuant to section 511A(c) of the FD&C Act.

Section 511A(b)(2)(A)(i) of the FD&C Act requires that in order for FDA to recognize, in whole or in part, new or updated susceptibility test interpretive criteria standards established by an SDO, the SDO must: (1) be a nationally or internationally recognized SDO that establishes and maintains procedures to address potential conflicts of interest and ensure transparent decision making; (2) hold meetings to ensure that there is an opportunity for public input by interested parties, and establishes and maintains processes to ensure that such input is considered in decision making; and (3) permit its standards to be made publicly available, through the National Library of Medicine or a similar source acceptable to the Secretary of Health and Human Services.

II. Issues for Consideration and Request for Information

FDA is currently identifying SDOs that meet the requirements under section 511A(b)(2)(A)(i) of the FD&C Act and invites submission of information relevant to this task. FDA is particularly interested in publicly available information illustrating how an SDO has national or international recognition, information illustrating an SDO's established and maintained procedures on how the SDO addresses potential conflicts of interest and ensures transparent decision-making, information illustrating that an SDO holds open meetings and has established and maintained processes to ensure that public input by interested parties is considered in decision-making, and information illustrating that an SDO's standards are made publicly available through the National Institutes of Health/National Library of Medicine or a similar source. When providing this information, please provide weblinks to where this information is publicly available. This information may assist in FDA's determination of which SDOs may fulfill the statutory requirements.

Dated: October 25, 2017.

Lauren Silvis,

Chief of Staff.

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