DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–2561]

Coordinated Development of Antimicrobial Drugs and Antimicrobial Susceptibility Test Devices; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled ''Coordinated Development of Antimicrobial Drugs and Antimicrobial Susceptibility Test Devices.'' This guidance is intended to assist drug sponsors and device manufacturers who are planning to develop new antimicrobial drugs and antimicrobial susceptibility test (AST) devices and who seek to coordinate development of these products such that the AST device could be cleared either at the time of new drug approval or shortly thereafter.

DATES: The announcement of the guidance is published in the **Federal Register** on February 1, 2019.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time 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–2016–D–2561 for ''Coordinated Development of Antimicrobial Drugs and Antimicrobial Susceptibility Test Devices.'' 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 on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Coordinated Development of Antimicrobial Drugs and Antimicrobial Susceptibility Test Devices'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002, or Office of Communications, Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Ribhi Shawar, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4604, Silver Spring, MD 20993–0002, 301–796–6694; or Joseph Toerner, Center for Drug Evaluation and Research, 10903 New Hampshire Ave., Bldg. 22, Rm. 6244, Silver Spring, MD 20993, 301–796–1400.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance is intended to assist drug sponsors and device manufacturers who are planning to develop new antimicrobial drugs and AST devices and who seek to coordinate development of these products such that the AST device could be cleared either at the time of new drug approval or shortly thereafter. Specifically, the guidance describes interactions between drug sponsors and device manufacturers for coordinated development of a new antimicrobial drug and an AST device. The guidance also explains the considerations for submitting separate applications to the Center for Drug

Evaluation and Research and the Center for Devices and Radiological Health when seeking clearance of an AST device coincident with, or soon following, antimicrobial drug approval. Finally, the guidance clarifies that the review of the new antimicrobial drug product and AST device(s) will remain independent, and that coordinated development does not influence the Medical Device User Fee Act and the Prescription Drug User Fee Act review timelines for either product.

FDA considered comments received on the draft guidance that appeared in the **Federal Register** of September 21, 2016 (81 FR 64913). FDA revised the guidance as appropriate in response to the comments.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Coordinated Development of Antimicrobial Drugs and Antimicrobial Susceptibility Test Devices.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* This guidance document is also available at *https://www.regulations.gov* or *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.* Persons unable to download an electronic copy of ''Coordinated Development of Antimicrobial Drugs and Antimicrobial Susceptibility Test Devices'' may send an email request to *CDRH-Guidance@fda.hhs.gov* or *druginfo@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1400061 and the guidance title to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in the following FDA regulations and guidance have been approved by OMB as listed in the following table:

21 CFR part or guidance	Topic	OMB control No.
807, subpart E	Premarket notification	0910–0120
812	Investigational Device Exemption	0910–0078
''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff''.	Q-submissions	0910–0756
312	Investigational New Drug Regulations	0910–0014
314	Applications for FDA Approval to Market a New Drug.	0910–0001

Dated: January 15, 2019.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2019–00569 Filed 1–31–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–4628]

Risk Evaluation and Mitigation Strategies Assessment: Planning and Reporting; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry on the assessment of risk evaluation and mitigation strategies (REMS) entitled ''REMS Assessment: Planning and Reporting; Draft Guidance for Industry.'' The draft guidance is one of several guidance documents being developed to fulfill performance goals under the fifth authorization of the prescription drug user fee program, the Prescription Drug User Fee Act V. This draft guidance describes how to develop a REMS Assessment Plan; specifically, how the REMS program goals, objectives, and REMS design may impact the selection of metrics and data sources, which will be used to assess whether the REMS is meeting its risk mitigation goals.

The draft guidance recommends assessing the REMS using both process measures and outcome measures and provides examples of metrics by assessment categories, as well as data sources that may be utilized to evaluate the performance of the REMS. The draft guidance also discusses considerations for assessing the impact of REMS on patient access to the drug or its burden to the healthcare delivery system. Finally, this draft guidance provides recommendations on a standardized approach for reporting REMS assessment findings to FDA using the REMS Assessment Report.

DATES: Submit either electronic or written comments on the draft guidance by April 2, 2019 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time 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