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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0001]

Coordinated Development of Antimicrobial Drugs and Antimicrobial Susceptibility Test Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing a public workshop regarding “Coordinated Development of Antimicrobial Drugs and Antimicrobial Susceptibility Test Devices (ASTs).” This public workshop is intended to facilitate discussion between drug sponsors and device manufacturers who are planning to develop new antimicrobial drugs or ASTs and who wish 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. The input from this public workshop will also help in developing topics for future discussion.

DATES: Dates and Times: The public workshop will be held on September 29, 2016, from 9 a.m. to 4 p.m. See the **SUPPLEMENTARY INFORMATION** section for registration information.

ADDRESSES: Location: The public workshop will be held at the Sheraton Silver Spring Hotel, 8777 Georgia Ave., Silver Spring, MD 20910. The hotel’s phone number is 301-589-0800.

FOR FURTHER INFORMATION CONTACT: Contact Persons: Lori Benner and/or Jessica Barnes, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6221, Silver Spring, MD 20993-0002, 301-796-1300.

Registration: Registration is free for the public workshop. Interested parties are encouraged to register early. Seating will be available on a first-come, first-served basis. To register electronically, email your registration information (including name, title, firm name, address, telephone number, and fax number) to AntimicrobialSusceptibilitytestingWorkshop2016@fda.hhs.gov. Persons without access to the Internet can call 301-796-1300 to register.

If you need special accommodations due to a disability, please contact Jessica Barnes or Lori Benner (see Contact Persons above) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: FDA is announcing a public workshop pertaining to the coordinated development of antimicrobial drugs and ASTs. Discussions will focus on assisting drug sponsors and device manufacturers who are planning to develop new antimicrobial drugs or ASTs and who seek to coordinate development of these products.

The goals of the workshop are to: (1) Outline the regulatory considerations for submitting separate applications to the Center for Drug Evaluation and Research and the Center for Devices and Radiological Health for antimicrobial drugs and ASTs, respectively; (2) identify the challenges related to obtaining data supporting the clearance of an AST device coincident with or soon after antimicrobial drug approval; and (3) discuss ideas for addressing these challenges.

The Agency encourages individuals, industry, device manufacturers, health care professionals, researchers, public health organizations and other interested persons to attend this public workshop. Workshop updates will be made available on the internet at <http://www.fda.gov/Drugs/NewsEvents/ucm512519.htm>.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD. A transcript will also be available either in hardcopy or on CD-ROM, after submission of a Freedom of Information request. The Freedom of Information office address is available on the Agency's Web site at <http://www.fda.gov>. Transcripts will also be available on the Internet at <http://www.fda.gov/Drugs/NewsEvents/ucm512519.htm> approximately 45 days after the workshop.

Dated: September 9, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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