Coordinated Development of Antimicrobial Drugs and AST Devices

FDA Workshop

September 29, 2016

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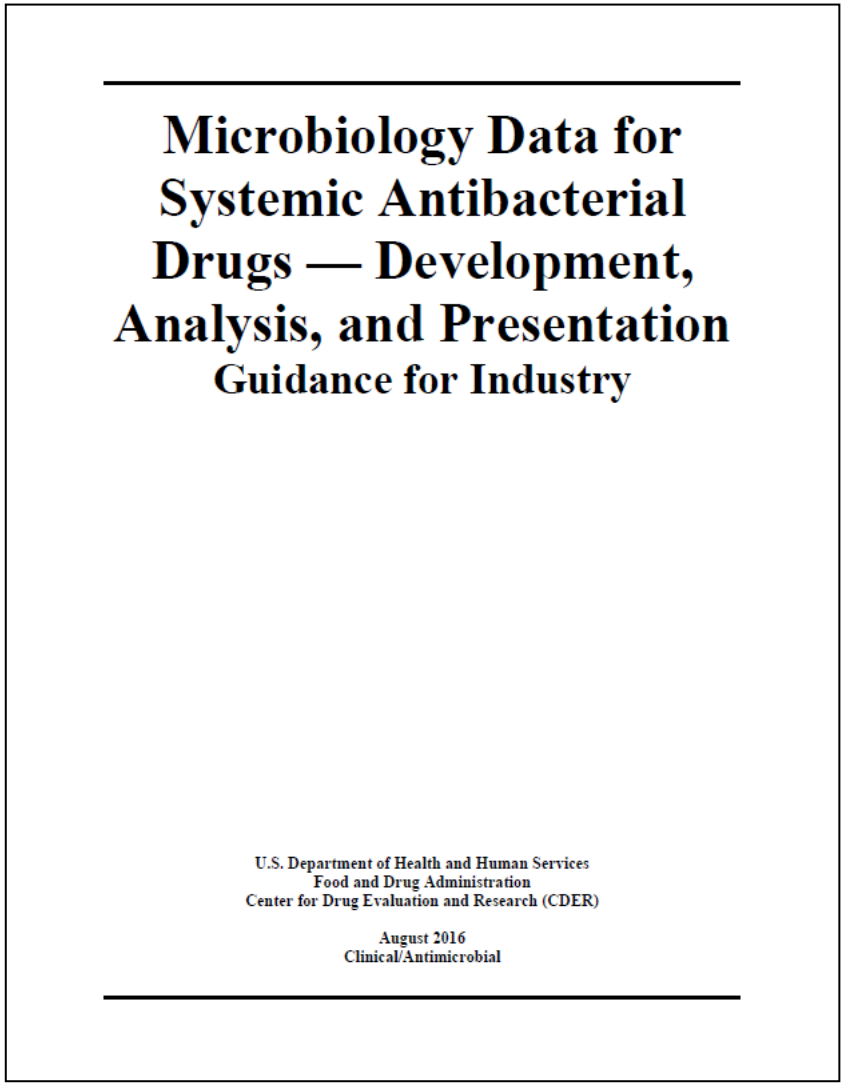
Division of Anti-Infective Products

Background

We have heard from various stakeholders (clinicians, clinical microbiology laboratories, drug and device manufacturers) that there are challenges on many fronts to make antimicrobial susceptibility testing available in a timely manner following approval of a new antibacterial drug

Today's Meeting

- Understand the challenges/bottlenecks in making antimicrobial susceptibility testing available in a timely manner following approval of new antibacterial drugs
- We hope that this meeting will provide an opportunity for a robust discussion of the issues and identify potential solutions to address the issues so that appropriate treatment can be provided to patients



Describes the overall microbiology development program needed to support development of systemic antibacterial drugs

http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm182288.pdf

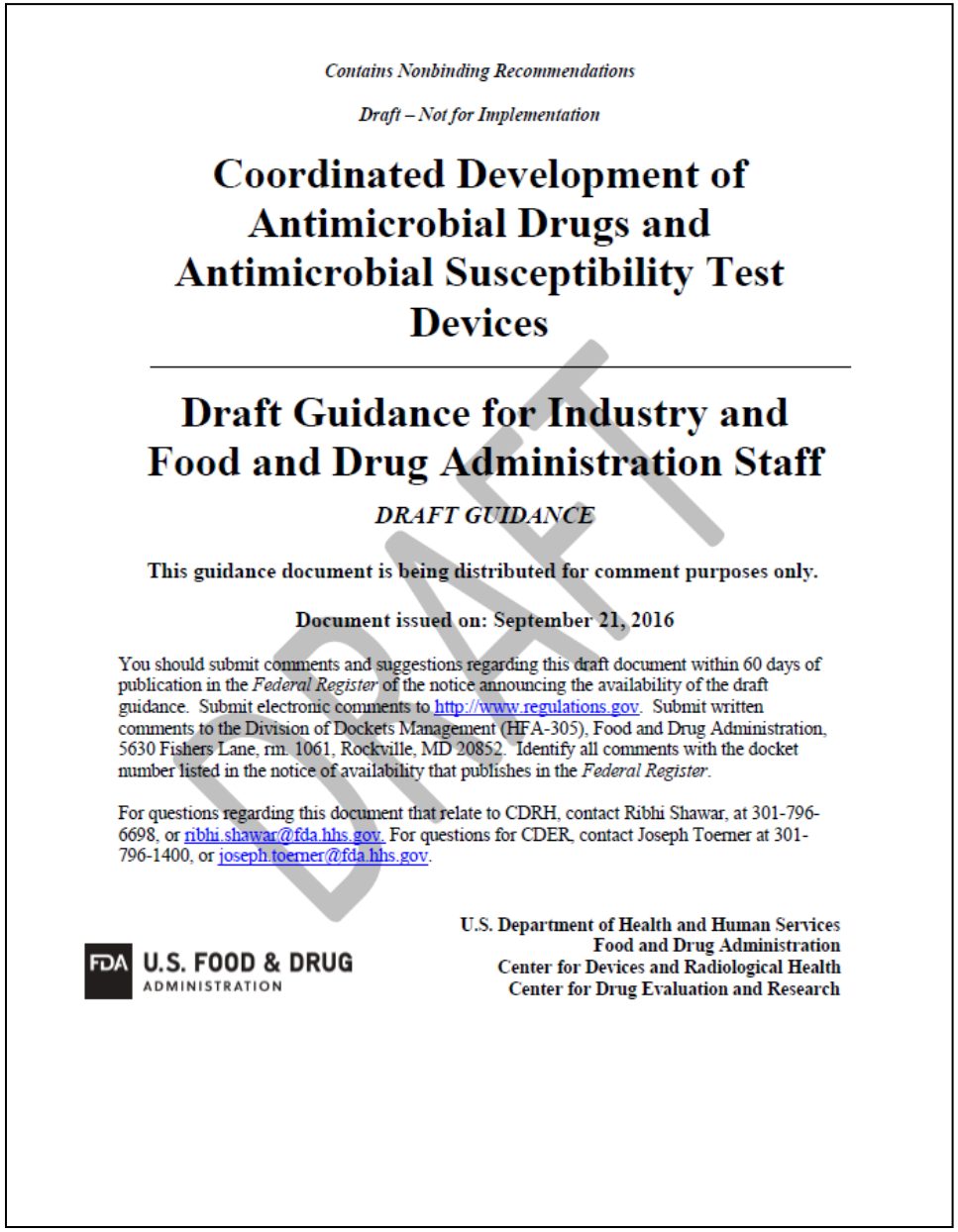
Labeling

- Subsection 12.4 of labeling (Microbiology) describes the relevant microbiology data for the drug (mechanism of action, resistance, interaction with other antimicrobials)
- Two lists are included to describe the antimicrobial spectrum of activity (first and second lists)
- Microorganisms included in the first list are associated with a labeled indication
- For microorganisms included in the second list efficacy of the drug in treating clinical infections caused by the microorganism has not been established; the microorganisms should be relevant to a labeled indication

Labeling

Susceptibility test interpretive criteria are included in the Microbiology subsection

	Minimum Inhibitory Concentration (mcg/mL)			Disk diffusion (Zone diameters in mm)		
Pathogen	S	I	R	S	I	R
Organism #1	< #	#-#	>#	< #	#-#	>#
Organism #2	< #	#-#	>#	< #	#-#	>#



Contains Nonbinding Recommendations

Draft – Not for Implementation

Coordinated Development of Antimicrobial Drugs and Antimicrobial Susceptibility Test Devices

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Document issued on: September 21, 2016

You should submit comments and suggestions regarding this draft document within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this document that relate to CDRH, contact Ribhi Shawar, at 301-796-6698, or ribhi.shawar@fda.hhs.gov. For questions for CDER, contact Joseph Toerner at 301-796-1400, or joseph.toerner@fda.hhs.gov.

FDA U.S. FOOD & DRUG ADMINISTRATION

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Drug Evaluation and Research

DRAFT

http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm521421.pdf

Key Messages

- Facilitate interactions between drug sponsors and device manufacturers for coordinated development of a new antimicrobial drug and an AST device
- Joint meetings with the drug sponsor and device manufacturer will be attended by representatives from CDER and CDRH
- Meetings can be requested by an AST device manufacturer or by drug sponsors
- Review of the new antimicrobial drug product and AST device(s) will remain independent; review timelines for either product will not be affected

Agenda

Time	Topic	Presenter(s)
9:15 AM-9:30 AM	FDA Perspective on Antimicrobial Susceptibility Test Development	Ribhi Shawar, CDRH, FDA
9:30 AM-10:00 AM	Clinical and Laboratory Perspective	Amy Mathers, University of Virginia Romney Humphries, UCLA
10:00 AM-10:45 AM	Pharmaceutical Company Experience and Perspective	Mary Motyl, Merck Kevin Krause, Achaogen
10:45 AM-11:00 AM	**Break**	
11:00 AM-11:45 AM	Diagnostic Device Manufacturer Experience and Perspective	Bill Brasso, BD Diagnostic Systems Darcie (Roe) Carpenter, Beckman Coulter
11:45 AM-12:30 PM	Clarifying Questions from Audience/Panelists	
12:30 PM-1:30 PM	**Lunch**	
1:30 PM-2:00 PM	Roles and Resources in Coordinated Development	Melissa Miller, ASM Committee on Lab Practice Jean Patel, CLSI
2:00 PM-2:30 PM	Clarifying Questions from Audience/Panelists	
2:30 PM-2:45 PM	Public Comments	
2:45 PM-3:45 PM	**Panel Discussion**	
3:45 PM-4:00 PM	Concluding Remarks	Ed Cox, CDER, FDA Steve Gitterman, CDRH, FDA

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Introduction of Panelists/Speakers