

**FOOD AND DRUG ADMINISTRATION (FDA)**  
Center for Drug Evaluation and Research (CDER)

***Antimicrobial Drugs Advisory Committee (AMDAC) Meeting***  
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)  
10903 New Hampshire Avenue, Silver Spring, Maryland  
June 9, 2016

**AGENDA**

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*The committee will discuss biologics license application (BLA) 761046, bezlotoxumab (MK-6072) injection, submitted by Merck Sharpe & Dohme Corp., for the proposed indication of prevention of Clostridium difficile infection recurrence.*

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8:30 a.m.	Call to Order and Introduction of Committee	<b>Lindsey R. Baden, MD</b> Acting Chairperson, AMDAC
8:40 a.m.	Conflict of Interest Statement	<b>Lauren D. Tesh, PharmD, BCPS</b> Designated Federal Officer, AMDAC
8:45 a.m.	FDA Introductory Remarks	<b>Sumathi Nambiar, MD, MPH</b> Division Director Division of Anti-Infective Products (DAIP) Office of Antimicrobial Products (OAP) Office of New Drugs (OND), CDER, FDA
9:00 a.m.	<b>SPONSOR PRESENTATIONS</b>	Merck Sharpe & Dohme Corp.
	Bezlotoxumab Introduction	<b>Donnette Staas, PhD</b> Director, Regulatory Affairs Merck
	Clinical Program Overview and Efficacy	<b>Dalya Guris, MD, MPH</b> Executive Director, Clinical Research Merck
	Clinical Program: Safety	<b>Yoshihiko Murata, MD, PhD</b> Director, Clinical Research Merck
	Conclusions and Benefit-Risk	<b>Mark Wilcox, MD</b> Clinical Consultant to Merck Consultant and Head of Microbiology Professor of Medical Microbiology Leeds Teaching Hospitals & University of Leeds, UK Lead on CDI, Public Health England, UK
10:30 a.m.	Clarifying Questions to the Presenters	
10:45 a.m.	<b>BREAK</b>	

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**AGENDA (cont.)**

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11:00 a.m. **FDA PRESENTATIONS**

Presentation of Clinical Efficacy

**Cheryl Dixon, PhD**  
Statistical Reviewer  
Division of Biometrics IV (DB IV)  
Office of Biostatistics (OB)  
Office of Translational Sciences (OTS)  
CDER, FDA

Presentation of Clinical Safety

**Hiwot Hiruy, MD, PhD**  
Medical Officer  
DAIP, OAP, OND, CDER, FDA

12:15 p.m. Clarifying Questions to the Presenters

12:30 p.m. **LUNCH**

1:30 p.m. Open Public Hearing

2:30 p.m. **BREAK**

2:45 p.m. Questions to the Committee/Committee Discussion

4:45 p.m. **ADJOURNMENT**