

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

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

DRAFT AGENDA

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.

8:30 a.m.	Call to Order and Introduction of Committee	Lindsey R. Baden, MD Acting Chairperson, AMDAC
8:40 a.m.	Conflict of Interest Statement	Lauren D. Tesh, PharmD, BCPS Designated Federal Officer, AMDAC
8:45 a.m.	FDA Introductory Remarks	Sumathi Nambiar, MD, MPH Division Director Division of Anti-Infective Products (DAIP) Office of Antimicrobial Products (OAP) Office of New Drugs (OND), CDER, FDA
9:00 a.m.	SPONSOR PRESENTATIONS	Merck Sharpe & Dohme Corp.
	Bezlotoxumab Introduction	Donnette Staas, PhD Director, Regulatory Affairs Merck
	Clinical Program Overview and Efficacy	Dalya Guris, MD, MPH Executive Director, Clinical Research Merck
	Clinical Program: Safety	Yoshihiko Murata, MD, PhD Director, Clinical Research Merck
	Conclusions and Benefit-Risk	Mark Wilcox, MD 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.	BREAK	

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DRAFT AGENDA (cont.)

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**