

**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
August 8, 2018*

AGENDA

The committee will discuss new drug applications 209816, for omadacycline tablets and 209817 for omadacycline injection, sponsored by Paratek Pharmaceuticals, Inc., for the proposed indications of community acquired bacterial pneumonia and acute bacterial skin and skin structure infections.

8:30 a.m.	Call to Order and Introduction of Committee	Lindsey R. Baden, MD Chairperson, AMDAC
8:35 a.m.	Conflict of Interest Statement	Lauren D. Tesh, PharmD, BCPS Designated Federal Officer, AMDAC
8:40 a.m.	FDA Opening Remarks	Sumathi Nambiar, MD, MPH Director Division of Anti-Infective Products (DAIP) Office of Antimicrobial Products (OAP) Office of New Drugs (OND), CDER, FDA
8:45 a.m.	APPLICANT PRESENTATIONS	Paratek Pharmaceuticals, Inc.
	Introduction	Evan Loh, MD President, Chief Operating Officer & Chief Medical Officer Paratek Pharmaceuticals
	Unmet Need	Keith S. Kaye, MD, MPH Professor of Internal Medicine Director of Clinical Research, Division of Infectious Diseases University of Michigan Medical School
	Efficacy	Anita Das, PhD Statistical Consultant
	Safety	Evan Loh, MD
	Benefit Risk	Eric Mortensen, MD, MSc Division Chief, General Internal Medicine, UConn Health Center Professor of Medicine, University of Connecticut School of Medicine
9:30 a.m.	Clarifying Questions	

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AGENDA (cont.)

9:50 a.m. **BREAK**

10:00 a.m. **FDA PRESENTATION**

Safety and Efficacy Analyses

Joseph Toerner, MD, MPH
Cross Disciplinary Team Leader
Deputy Director for Safety
DAIP, OAP, OND, CDER, FDA

10:45 a.m. Clarifying Questions

11:00 a.m. **OPEN PUBLIC HEARING**

12:00 p.m. Questions to the Committee/Committee Discussion

1:00 p.m. **ADJOURNMENT**