

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

Antimicrobial Drugs Advisory Committee (AMDAC) Meeting
College Park Marriott Hotel and Conference Center, General Vessey Ballroom
3501 University Blvd. East, Hyattsville, Maryland
January 11, 2018

AGENDA

The committee will discuss new drug application (NDA) 210693, ciprofloxacin dispersion for inhalation, sponsored by Aradigm Corp., for the proposed indication of treatment of non-cystic fibrosis bronchiectasis patients with chronic lung infections with Pseudomonas aeruginosa.

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 Opening Remarks	Thomas Smith, MD Clinical Team Leader Division of Anti-Infective Products (DAIP) Office of Antimicrobial Products (OAP) Office of New Drugs (OND), CDER, FDA
8:55 a.m.	APPLICANT PRESENTATIONS	Aradigm Corporation
	Introduction	Juergen Froehlich, MD, MBA, FCP Chief Medical Officer, Aradigm Corporation
	Unmet Medical Need / Disease Background	Gregory Tino, MD University of Pennsylvania – Perelman School of Medicine
	Efficacy	Igor Gonda, PhD CEO and President, Aradigm Corporation
		Janet Wittes, PhD President, Statistics Collaborative, Inc.
	Safety	Juergen Froehlich, MD, MBA, FCP
	Benefit / Risk	Sanjay Sethi, MD, FACP University at Buffalo, State University of New York
		James Chalmers, MD Ninewells Hospital and Medical School – Department of Respiratory Medicine Dundee
10:25 a.m.	Clarifying Questions	
10:40 a.m.	BREAK	

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AGENDA (cont.)

10:50 a.m. **FDA PRESENTATIONS**

Presentation of Efficacy Evaluation

CDR LaRee Tracy, MA, PhD

Statistical Reviewer

Division of Biometrics IV

Office of Biostatistics

Office of Translational Sciences (OTS), CDER, FDA

Presentation of Clinical Safety

Maria Allende, MD

Medical Officer

DAIP, OAP, OND, CDER, FDA

Summary Presentation

Thomas Smith, MD

Clinical Team Leader

DAIP, OAP, OND, CDER, FDA

12:20 p.m. Clarifying Questions

12:35 p.m. **LUNCH**

1:30 p.m. **OPEN PUBLIC HEARING**

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

2:40 p.m. Questions to the Committee/Committee Discussion

4:00 p.m. **ADJOURNMENT**