

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

Antimicrobial Drugs Advisory Committee (AMDAC) Meeting

Tommy Douglas Conference Center
10000 New Hampshire Avenue, Silver Spring, Maryland
April 13, 2017

DRAFT AGENDA

*The committee will discuss the development of antibacterial drugs that treat a single species of bacteria when the target species infrequently causes infections; examples of such drugs include those that are only active against *Pseudomonas aeruginosa* or *Acinetobacter baumannii*.*

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| 8:30 a.m. | Call to Order and Introduction of Committee | Lindsey R. Baden, MD
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 | Edward Cox MD MPH
Director
Office of Antimicrobial Products (OAP)
Office of New Drugs (OND), CDER, FDA |
| 9:00 a.m. | FDA PRESENTATIONS

Regulatory Background | Sumathi Nambiar MD MPH
Director
Division of Anti-Infective Products (DAIP)
Office of Antimicrobial Products (OAP)
Office of New Drugs (OND), CDER, FDA |
| 9:20 a.m. | Summary of March 1 Workshop | Yuliya Yasinskaya MD
Medical Team Leader, DAIP
Office of Antimicrobial Products (OAP)
Office of New Drugs (OND), CDER, FDA |
| 9:40 a.m. | INDUSTRY PRESENTATION

Challenges with Clinical Trial Design for a Drug Targeting a Single Species of Bacteria: <i>Acinetobacter baumannii</i> | Robin Isaacs MD
Chief Medical Officer
Entasis Therapeutics |
| | FDA PRESENTATION

Example of a Development Program Targeting <i>P. aeruginosa</i> | Peter Kim MD MS
Medical Officer, DAIP
Office of Antimicrobial Products (OAP)
Office of New Drugs (OND), CDER, FDA |
| 10:00 a.m. | BREAK | |

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DRAFT AGENDA (cont.)

- 10:15 a.m. **PRESENTATION BY PROFESSIONAL ORGANIZATION** **Infectious Diseases Society of America (IDSA)**
- 11:00 a.m. Clarifying Questions
- 12:00 p.m. **LUNCH**
- 1:00 p.m. **OPEN PUBLIC HEARING**
- 2:00 p.m. **BREAK**
- 2:15 p.m. Questions to the Committee/Committee Discussion
- 5:00 p.m. **ADJOURNMENT**