

**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

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. | March 2017 FDA Public Workshop Summary | 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>Pseudomonas 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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AGENDA (cont.)

10:15 a.m. **PRESENTATION BY PROFESSIONAL ORGANIZATION**

Developing Anti-infective Drugs for
Patients with Unmet Need

Trish Perl-DeLisle, MD
Chief, Division of Infectious Diseases
UT Southwestern Medical Center
Infectious Diseases Society of America Board of
Directors

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**