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

Anti-Infective Drugs Advisory Committee (AIDAC) Meeting
FDA White Oak Campus, 10903 New Hampshire Avenue
Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, Maryland
January 22, 2015

DRAFT AGENDA

The committee will discuss new drug applications (NDAs) 207-500 and 207-501, isavuconazonium sulfate capsules and isavuconazonium sulfate for injection, sponsored by Astellas Pharma Global Development, Inc., respectively for the proposed indications of treatment of invasive aspergillosis and mucormycosis.

8:00 a.m. Call to Order and Introduction of Committee
Thomas A. Moore, MD, FACP, FIDSA
Acting Chairperson, AIDAC

8:10 a.m. Conflict of Interest Statement
Jennifer Shepherd, RPh.
Designated Federal Officer, AIDAC

8:15 a.m. FDA Introductory Remarks
Elizabeth O’Shaughnessy, MD
Clinical Reviewer
Division of Anti-Infective Products (DAIP)
Office of Antimicrobial Products (OAP)
Office of New Drugs (OND), CDER, FDA

8:30 a.m. APPLICANT PRESENTATIONS
Astellas Pharma Global Development, Inc.

Compound Overview and Clinical Pharmacology
Bernhardt Zeiher, MD, FACP, FCCP
Executive Vice President, Global Development and Therapeutic Area Head, Immunology and Infectious Diseases
Astellas Pharma Global Development, Inc.

Disease Background and Unmet Need
Andrew Ullmann, MD
Professor of Infectious Diseases
University of Wurzburg, Germany

Efficacy
Rochelle Maher, MS
Senior Director, Global Development Project Leader, Infectious Diseases
Astellas Pharma Global Development, Inc.

Safety
Salim Mujais, MD
Vice President, Medical Head Infectious Disease/Immunology/Transplant
Astellas Pharma Global Development, Inc.
ANTHONY M. T. ZEIHER, M.D.
FACCP, FACP

9:45 a.m.  Clarifying Questions

10:00 a.m.  BREAK

10:25 a.m.  FDA PRESENTATIONS

Clinical Efficacy of Isavuconazonium for the Treatment of Invasive Aspergillosis
Cheryl Dixon, PhD
Statistical Reviewer
Division of Biometrics IV (DB IV)
Office of Biostatistics (OB)
Office of Translational Sciences (OTS)
CDER, FDA

Clinical Efficacy of Isavuconazonium for the Treatment of Invasive Mucormycosis and Overview of Safety
Edward Weinstein, MD, PhD
Medical Officer
DAIP, OAP, OND, CDER, FDA

11:25 a.m.  Clarifying Questions

12:00 p.m.  LUNCH

1:00 p.m.  Open Public Hearing

2:00 p.m.  Questions to the Committee/Committee Discussion

3:00 p.m.  BREAK

3:15 p.m.  Questions to the Committee/Committee Discussion

5:00 p.m.  ADJOURNMENT