The committee will discuss biologics license application (BLA)125553 for EP2006, a proposed biosimilar to Amgen Inc.’s NEUPOGEN (filgrastim), submitted by Sandoz, Inc. The proposed indications (uses) for this product are: (1) To decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever; (2) for reducing the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of adults with acute myeloid leukemia; (3) to reduce the duration of neutropenia and neutropenia-related clinical sequelae, e.g., febrile neutropenia in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by marrow transplantation; (4) for the mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis; and (5) for chronic administration to reduce the incidence and duration of sequelae of neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia.
AGENDA (cont.)

9:25 a.m. **APPLICANT PRESENTATIONS**

<table>
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<tr>
<th>Time</th>
<th>Topic</th>
<th>Presenter</th>
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| 9:25 a.m. | Introduction | Mark McCamish, MD, PhD  
Global Head of Development  
Sandoz Biopharmaceuticals |
| | Analytical Demonstration of Biosimilarity | Hansjoerg Toll, PhD  
Head Analytical Characterization  
Sandoz Biopharmaceuticals |
| | Biosimilar Clinical Development Program | Sigrid Balser, PhD  
PK/PD Expert and Global Head Biostatistics  
Sandoz Biopharmaceuticals |
| | A Clinical Perspective on Biosimilarity | Louis Weiner, MD  
Professor and Director of Lombardi  
Comprehensive Cancer Center  
Georgetown University |
| | Totality of Evidence and Concluding Remarks | Mark McCamish, MD, PhD |

10:55 a.m. **BREAK**

11:10 a.m. Clarifying Questions to the Presenters

11:25 a.m. **FDA PRESENTATIONS**

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<th>Time</th>
<th>Topic</th>
<th>Presenter</th>
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</table>
| 11:25 a.m. | Introduction to FDA Presentation | Albert Deisseroth, MD, PhD  
Medical Officer Team Leader  
Division of Hematology Products (DHP)  
Office of Hematology and Oncology Products (OHOP), OND, CDER, FDA |
| | Chemistry, Manufacturing, and Controls | Maria-Teresa Gutierrez-Lugo, PhD  
Chemistry Reviewer  
Office of Biotechnology Products (OBP)  
Office of Pharmaceutical Quality (OPQ)  
CDER, FDA |
FDA PRESENTATIONS (cont.)

EP2006 Statistical Equivalence Testing for Bioactivity and Content  
**Xiaoyu (Cassie) Dong, PhD**  
CMC Biostatistics Reviewer  
Division of Biometrics VI (DB VI)  
Office of Biostatistics (OB)  
Office of Translational Sciences (OTS), CDER, FDA

Pharmacology and Toxicology  
**Chris Sheth, PhD**  
Pharmacology/Toxicology Reviewer  
Division of Hematology Oncology Toxicology (DHOT), OHOP, OND, CDER, FDA

Clinical Pharmacology  
**Sarah J. Schrieber, PharmD**  
Clinical Pharmacology Reviewer  
Division of Clinical Pharmacology V (DCP V)  
Office of Clinical Pharmacology (OCP)  
OTS, CDER, FDA

EP2006 Immunogenicity Data  
**Susan Kirshner, PhD**  
Review Chief  
Office of Biotechnology Products (OBP)  
Office of Pharmaceutical Quality (OPQ)  
CDER, FDA

Clinical Trial Review  
**Donna Przepiorka, MD, PhD**  
Clinical Reviewer  
DHP, OHOP, OND, CDER, FDA

Summary of FDA Findings  
**Albert Deisseroth, MD, PhD**

12:55 p.m.  LUNCH

1:55 p.m.  Clarifying Questions to the Presenters

2:15 p.m.  Open Public Hearing

3:15 p.m.  BREAK
3:30 p.m. Questions to the Committee and Committee Discussion

5:00 p.m. ADJOURNMENT