The committee will discuss biologics license application (BLA) 125545 for a proposed biosimilar to Amgen Inc.'s Epogen/Procrit (epoetin alfa), submitted by Hospira Inc., a Pfizer company. The proposed indications (uses) for this product are (1) for the treatment of anemia due to chronic kidney disease (CKD), including patients on dialysis and not on dialysis to decrease the need for red blood cell (RBC) transfusion, (2) for the treatment of anemia due to zidovudine administered at ≤ 4,200 mg/week in HIV-infected patients with endogenous serum erythropoietin levels of ≤ 500 mUnits/mL, (3) for the treatment of anemia in patients with non-myeloid malignancies where anemia is due to the effect of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of two additional months of planned chemotherapy, and (4) to reduce the need for allogeneic RBC transfusions among patients with perioperative hemoglobin > 10 to < 13 g/dL who are at high risk for perioperative blood loss from elective, noncardiac, nonvascular surgery.

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<tr>
<th>Time</th>
<th>Agenda Item</th>
<th>Presenter</th>
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| 8:00 a.m. | Call to Order and Introduction of Committee                             | Brian I. Rini, MD, FACP  
Acting Chairperson, ODAC |
| 8:05 a.m. | Conflict of Interest Statement                                            | Lauren Tesh, PharmD, BCPS  
Designated Federal Officer, ODAC |
| 8:10 a.m. | 351(k) Regulatory Pathway                                                | Leah Christl, PhD  
Associate Director for Therapeutic Biologics  
Office of New Drugs (OND)/Therapeutic Biologics and Biosimilars Staff (TBBS), CDER, FDA |
| 8:40 a.m. | Clarifying Questions to the Presenter                                     | R. Angelo de Claro, MD  
Medical Officer Team Leader  
Division of Hematology Products (DHP)  
Office of Hematology and Oncology Products (OHOP)  
Office of New Drugs (OND), CDER, FDA |
| 8:55 a.m. | Opening Remarks                                                           | Hospira Inc., a Pfizer company                |
| 9:00 a.m. | **APPLICANT PRESENTATIONS**                                               | Sumant Ramachandra, MD, PhD  
Senior VP, Research & Development Head  
Pfizer Essential Health |
|         | Introduction to Epoetin Hospira – Biosimilar to Epogen®/Procrit®          | Thomas Vanden Boom, PhD  
VP, Biosimilars Pharmaceutical Sciences  
Pfizer World Wide Research & Development |
|         | Analytical Biosimilarity Assessment                                        | Nancy Martin, MD, PharmD, FCP  
Consultant, previously VP Clinical Development, Biosimilars  
Hospira, A Pfizer Company |
FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Oncologic Drugs Advisory Committee (ODAC) Meeting
May 25, 2017

AGENDA (cont.)

Conclusion Supporting Biosimilarity and Extrapolation Across Indications

**Sumant Ramachandra, MD, PhD**

**9:45 a.m. FDA PRESENTATIONS**

“Epoetin Hospira”, a proposed biosimilar to US-licensed Epogen/Procrit - BLA 125545

Frances Namuswe, PhD
CMC Reviewer
Office of Biotechnology Products (OBP)
Office of Pharmaceutical Quality (OPQ), CDER, FDA

Chemistry, Manufacturing, and Controls (CMC)

Chao Wang, PhD
CMC Statistical Reviewer
Division of Biometrics VI (DBVI)
Office of Biostatistics (OB)
Office of Translational Sciences (OTS), CDER, FDA

Pharmacology/Toxicology

Natalie Simpson, PhD
Pharmacology/Toxicology Reviewer
Division of Hematology Oncology Toxicology
OHOP, OND, CDER, FDA

Clinical Immunogenicity

Steven Bowen, PhD
Immunogenicity Reviewer
OBP, OPQ, CDER, FDA

Clinical Pharmacology

Vicky Hsu, PhD
Clinical Pharmacology Reviewer
Division of Clinical Pharmacology V
Office of Clinical Pharmacology, OTS, CDER, FDA

Clinical Efficacy

Lola Luo, PhD
Clinical Statistical Reviewer
Division of Biometrics V (DBV)
OB, OTS, CDER, FDA

Clinical Safety

Lori Ehrlich, MD, PhD
Medical Officer
DHP, OHOP, OND, CDER, FDA

**10:30 a.m. BREAK**

**10:45 a.m. Clarifying Questions to the Presenters**

**11:15 a.m. Open Public Hearing**
12:15 p.m.  Questions to the Committee/Committee Discussion

1:30 p.m.  ADJOURNMENT