The committee will discuss supplemental new drug application (sNDA) 203214 supplement 18, XELJANZ (tofacitinib) tablets, submitted by Pfizer Inc., proposed for the treatment of adult patients with moderately to severely active ulcerative colitis who have demonstrated an inadequate response, loss of response, or intolerance to corticosteroids, azathioprine, 6-mercaptopurine, or tumor necrosis factor inhibitor therapy.

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<thead>
<tr>
<th>Time</th>
<th>Agenda Item</th>
<th>Presenter</th>
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<tr>
<td>8:00 a.m.</td>
<td>Call to Order and Introduction of Committee</td>
<td>Jean-Pierre Raufman, MD</td>
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<td>8:05 a.m.</td>
<td>Conflict of Interest Statement</td>
<td>Jay Fajiculay, PharmD</td>
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<td>8:10 a.m.</td>
<td>FDA Introductory Remarks</td>
<td>Tara Altepeter, MD</td>
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<td>8:20 a.m.</td>
<td><strong>APPLICANT PRESENTATIONS</strong></td>
<td>Pfizer, Inc.</td>
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<tr>
<td>8:20 a.m.</td>
<td>Introduction</td>
<td>Lou Ferrara</td>
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<td>8:20 a.m.</td>
<td>Ulcerative Colitis: A Clinician’s Perspective / Unmet Medical Need</td>
<td>William Sandborn, MD</td>
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<td>8:20 a.m.</td>
<td>Tofacitinib Ulcerative Colitis Development Program and Efficacy</td>
<td>Eric Maller, MD</td>
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<td>8:20 a.m.</td>
<td>Safety of Tofacitinib in Ulcerative Colitis Development Program</td>
<td>Chinyu Su, MD</td>
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<td>8:20 a.m.</td>
<td>Risk Management</td>
<td>Thomas Jones, MD</td>
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</table>
APPLICANT PRESENTATIONS (cont.)

Benefit:Risk and Conclusion
Michael Corbo, PhD
Senior VP, Chief Development Officer
Inflammation and Immunology, Pfizer Inc

9:50 a.m. Clarifying Questions

10:05 a.m. BREAK

10:20 a.m. FDA PRESENTATIONS

Clinical Pharmacology Findings of Tofacitinib for Treatment of Moderately to Severely Active Ulcerative Colitis (UC)
Dilara Jappar, PhD
Clinical Pharmacology Reviewer
Division of Clinical Pharmacology III
Office of Clinical Pharmacology
Office of Translational Sciences (OTS), CDER, FDA

Analyses of Efficacy Data for Proposed Dosing Regimens
Sara Jimenez, PhD
Mathematical Statistician
Division of Biostatistics III
Office of Biostatistics, OTS, CDER, FDA

Focused Tofacitinib UC Program Safety Evaluation
Lesley Hanes, MD, MSc
Medical Officer
DGIEP, ODE III, OND, CDER, FDA

Remarks About Results from Truven Marketscan®
Joel Weissfeld, MD, MPH
Medical Officer
Division of Epidemiology I
Office of Surveillance and Epidemiology, CDER, FDA

Tofacitinib Development Program: Pediatric Ulcerative Colitis
Melanie Bhatnagar, MD
Medical Officer
Division of Pediatric and Maternal Health
ODE IV, OND, CDER, FDA

11:50 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
3:15 p.m.  BREAK

3:30 p.m.  Questions to the Committee/Committee Discussion (cont.)

5:00 p.m.  ADJOURNMENT