The committee will discuss new drug application (NDA) 209904, for stannsoporfin injection, for intramuscular use, submitted by InfaCare Pharmaceutical Corporation, proposed for the treatment of neonates greater than or equal to 35 weeks of gestational age with indicators of hemolysis who are at risk of developing severe hyperbilirubinemia.

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
<th>Presenter(s)</th>
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<tbody>
<tr>
<td>8:00 a.m.</td>
<td>Call to Order and Introduction of Committee</td>
<td>F. Sessions Cole, MD, Acting Chairperson, PAC</td>
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<tr>
<td>8:10 a.m.</td>
<td>Conflict of Interest Statement</td>
<td>Jay R. Fajiculay, PharmD, Designated Federal Officer, GIDAC</td>
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<td>8:15 a.m.</td>
<td>FDA Introductory Remarks</td>
<td>Stephanie O. Omokaro, MD, Lead Medical Officer</td>
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<td>Division of Gastroenterology and Inborn Errors Products (DGIEP)</td>
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<td>Office of Drug Evaluation (ODE) III</td>
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<td>Office of New Drugs (OND), CDER, FDA</td>
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<td>8:35 a.m.</td>
<td><strong>APPLICANT PRESENTATIONS</strong></td>
<td>InfaCare Pharmaceutical Corporation</td>
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<tr>
<td></td>
<td>Introduction</td>
<td>Lawrence A. Hill, PharmD, MBA, Vice President, Clinical Development</td>
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<td>Mallinckrodt Pharmaceuticals</td>
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<td>Unmet Need</td>
<td>Jeffrey Maisels, MD, DSc, Chair Emeritus and Professor</td>
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<td>Department of Pediatrics</td>
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<td>Oakland University William Beaumont School of Medicine</td>
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<td></td>
<td>Clinical Pharmacology, Efficacy and Safety</td>
<td>Nancy Ruiz, MD, Senior Medical and Clinical Advisor</td>
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<td>InfaCare, A Mallinckrodt Pharmaceuticals Company</td>
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<td>Long-Term Neurodevelopmental Safety</td>
<td>Dawn Phillips, PT, MS, PhD, Research Scientist</td>
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<td>Outcomes Research, Evidera</td>
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<td>Risk Management Considerations</td>
<td>Lawrence A. Hill, PharmD, MBA</td>
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<td>Benefit-Risk / Clinical Perspective</td>
<td>Jeffrey Maisels, MD, DSc</td>
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<tr>
<td>9:50 a.m.</td>
<td>Clarifying Questions</td>
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10:05 a.m. **BREAK**

10:15 a.m. **FDA PRESENTATIONS**

Overview of Efficacy

Shen (Steven) Li, PhD  
Clinical Pharmacology Reviewer  
Division of Clinical Pharmacology III  
Office of Clinical Pharmacology  
Office of Translational Sciences (OTS), CDER, FDA

Feiran Jiao, PhD  
Mathematical Statistician  
Division of Biometrics III  
Office of Biostatistics, OTS, CDER, FDA

Overview of Safety

David Joseph, PhD  
Lead Pharmacologist  
DGIEP, ODE III, OND, CDER, FDA

Y. Veronica Pei, MD, MEd, MPH  
Medical Officer  
DGIEP, ODE III, OND, CDER, FDA

Potential Postmarketing Activities

Charlotte Jones, MD, PhD, MSPH  
Medical Officer  
Division of Risk Management  
Office of Medication Error Prevention and Risk Management  
Office of Surveillance and Epidemiology, CDER, FDA

11:30 a.m. Clarifying Questions

11:45 a.m. **LUNCH**

1:00 p.m. **OPEN PUBLIC HEARING**

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

3:00 p.m. **BREAK**

3:10 p.m. Questions to the Committee/Committee Discussion (cont.)

4:30 p.m. **ADJOURNMENT**