Pediatric Advisory Committee Meeting, Tuesday, March 24, 2015
Double Tree by Hilton Hotel
8727 Colesville Road, Silver Spring, MD 20910
FINAL AGENDA

8:00 a.m. Welcome and Introductory Remarks
Ken Towbin, MD
Chair of Pediatric Advisory Committee (PAC)
Chief, Clinical and Adolescent Psychiatry, Mood
and Disorders Program, National Institute of
Mental Health

Walter Ellenberg, PhD
Designated Federal Official, PAC
Office of Pediatric Therapeutics (OPT), Office of
the Commissioner (OC)

8:15 a.m. Agenda Overview
Robert “Skip” Nelson, MD, PhD, Deputy Director,
OPT, OC

8:20 a.m. Award Presentations
Dianne Murphy, MD, FAAP, Director
OPT, OC

8:25 a.m. Ethics Subcommittee Update
Robert “Skip” Nelson, MD, PhD

Center for Drug Evaluation and Research (CDER)

8:30 a.m. Dymista (azelastine hydrochloride &
fluticasone propionate)
Judith U. Cope, MD, MPH
OPT, OC

Questions and Recommendations

8:40 a.m. QNASL (beclomethasone dipropionate)
Judith U. Cope, MD, MPH

Questions and Recommendations

9:00 a.m. Open Public Hearing
Walt Ellenberg, PhD

Justified Abbreviated Presentations
Judith Cope, MD, MPH

9:05 a.m. Venofer (iron sucrose)
9:10 a.m. Invirase (saquinavir)

Questions and Recommendations

9:20 a.m. Break
### Final Agenda

#### Standard Review of Adverse Event Presentations

<table>
<thead>
<tr>
<th>Time</th>
<th>Drug</th>
<th>Presenter</th>
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<tbody>
<tr>
<td>9:30 a.m.</td>
<td>Cymbalta (duloxetine hydrochloride)</td>
<td>Amy Taylor, MD, Medical Officer</td>
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<td>Questions and Recommendations</td>
<td>Division of Pediatric &amp; Maternal Health (DPMH), Office on New Drugs (OND), CDER</td>
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<td>10:15 a.m.</td>
<td>Quillivant XR (methylphenidate hydrochloride)</td>
<td>Erica Radden, MD, Medical Officer</td>
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<td>Questions and Recommendations</td>
<td>DPMH, OND, CDER</td>
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<td>11:10 a.m.</td>
<td>Risperdal (risperidone)</td>
<td>Erica Wynn MD, MPH, Medical Officer</td>
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<td>Questions and Recommendations</td>
<td>DPMH, OND, CDER</td>
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<td>11:40 a.m.</td>
<td>Lunesta (eszopiclone)</td>
<td>Erica Radden, MD</td>
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<td>Questions and Recommendations</td>
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<td>12:00 p.m.</td>
<td>Lunch</td>
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<td>1:10 p.m.</td>
<td>Oxtellar XR (oxcarbazepine extended-release)</td>
<td>Donna Snyder, MD, Medical Officer</td>
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<td>Questions and Recommendations</td>
<td>DPMH, OND, CDER</td>
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<td>1:25 p.m.</td>
<td>Revatio (sildenafil)</td>
<td>Amy Taylor, MD</td>
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<td>Questions and Recommendations</td>
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<td>1:50 p.m.</td>
<td>Advair HFA (fluticasone propionate/salmeterol xinafoate)</td>
<td>Ethan Hausman, MD, Medical Officer</td>
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<td>Questions and Recommendations</td>
<td>DPMH, OND, CDER</td>
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<td>2:45 p.m.</td>
<td>Designated Abbreviated Presentation</td>
<td>Ken Towbin, MD</td>
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<td>2:50 p.m.</td>
<td>Break</td>
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**Center for Biologics Evaluation and Research (CBER)**

**Abbreviated Presentations**

3:00 p.m. **Abbreviated Presentations**

FluMist Quadrivalent (Influenza Vaccine Live, Intranasal)  
Judith U. Cope, MD, MPH

3:15 p.m. **Abbreviated Presentations**

Fluarix Quadrivalent (Influenza Virus Vaccine)  
Judith U. Cope, MD, MPH

**Questions and Recommendations**

**Center for Devices and Radiological Health (CDRH)**

3:20 p.m. **Notification of Conversion to 510K from HDE for the Vertical Expandable Prosthetic Titanium Rib (VEPTR) – Informational Report to the Chair**

Amber Ballard, PhD, Biomedical Engineer  
Product Evaluation Branch III, Division of Postmarket Surveillance, Office of Surveillance and Biometrics (OSB), CDRH

3:25 p.m. **Medtronic Activa Dystonia Therapy**

Amber Ballard, PhD

**Second Post-Market HDE Review**

Questions and Recommendations  
Nathan S. Ivey, PhD, Senior Scientific Project Manager, 522 Postmarket Surveillance Program, OSB, CDRH

4:10 p.m. **Liposorber LA-15 System**

Véronique Li, MS, MBA, Biomedical Engineer  
Division of Reproductive, Gastro-Renal and Urological Devices (DRGUD), Renal Devices Branch, Office of Device Evaluation (ODE), CDRH

Questions and Recommendations  
Doug Silverstein, MD, Medical Officer  
DRGUD, Renal Devices Branch, ODE, CDRH

Allison O’Neill, MA, Epidemiologist  
Division of Epidemiology, Evaluation & Research Branch 3, OSB, CDRH

Cynthia Bushee, BSN, RN, Nurse Consultant  
Division of Postmarket Surveillance I, OSB, CDRH

Véronique Li, MS, MBA

4:50 p.m. **Adjournment**

Ken Towbin, MD