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

DRAFT 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)

8:05 a.m. Agenda Overview
Robert “Skip” Nelson, MD, PhD, Deputy Director, OPT, OC

8:10 a.m. Award Presentations
Dianne Murphy, MD, FAAP, Director OPT, OC

8:15 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

8:45 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

10:00 a.m. Venofer (iron sucrose)

10:10 a.m. Invirase (saquinavir)

Questions and Recommendations

10:20 a.m. Break
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**Standard Review of Adverse Event Presentations**

<table>
<thead>
<tr>
<th>Time</th>
<th>Product Name</th>
<th>Speaker</th>
<th>Office</th>
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<tbody>
<tr>
<td>10:30 a.m.</td>
<td>Cymbalta (duloxetine hydrochloride)</td>
<td>Amy Taylor, MD, Medical Officer</td>
<td>Division of Pediatric &amp; Maternal Health (DMPH), Office on New Drugs (OND), CDER</td>
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<td>11:00 a.m.</td>
<td>Quillivant XR (methylphenidate hydrochloride)</td>
<td>Erica Radden, MD, Medical Officer</td>
<td>DMPH, OND, CDER</td>
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<td>11:30 a.m.</td>
<td>Risperdal (risperidone)</td>
<td>Erica Wynn MD, MPH, Medical Officer</td>
<td>DMPH, OND, CDER</td>
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<td>12:00 a.m.</td>
<td>Lunesta (eszopiclone)</td>
<td>Erica Radden, MD</td>
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<td>12:30 p.m.</td>
<td>Lunch</td>
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<tr>
<td>1:30 p.m.</td>
<td>Oxtellar XR (oxcarbazepine extended-release)</td>
<td>Donna Snyder, MD, Medical Officer</td>
<td>DMPH, OND, CDER</td>
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<td>2:00 p.m.</td>
<td>Revatio (sildenafil)</td>
<td>Amy Taylor, MD</td>
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<td>2:30 p.m.</td>
<td>Advair HFA (fluticasone propionate/salmeterol xinafoate)</td>
<td>Ethan Hausman, MD, Medical Officer</td>
<td>DMPH, OND, CDER</td>
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<td>3:15 p.m.</td>
<td>Designated Abbreviated Presentation</td>
<td>Ken Towbin, MD</td>
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<td>3:20 p.m.</td>
<td>Break</td>
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Center for Biologics Evaluation and Research (CBER)

Abbreviated Presentations

3:30 p.m. FluMist Quadrivalent (Influenza Vaccine Live, Intranasal) Judith U. Cope, MD, MPH

Questions and Recommendations

3:45 p.m. Fluarix Quadrivalent (Influenza Virus Vaccine) Judith U. Cope, MD, MPH

Questions and Recommendations

Center for Devices and Radiological Health (CDRH)

4:00 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

4:05 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

4:35 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

Initial Post-Market HDE Review 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

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

Véronique Li, MS, MBA

5:30 p.m. Adjournment Ken Towbin, MD