

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**

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Standard Review of Adverse Event
Presentations

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|-------------------|---|---|
| 9:30 a.m. | Cymbalta (duloxetine hydrochloride)

<i>Questions and Recommendations</i> | Amy Taylor, MD, Medical Officer
Division of Pediatric & Maternal Health (DPMH),
Office on New Drugs (OND), CDER |
| 10:15 a.m. | Quillivant XR (methylphenidate hydrochloride)

<i>Questions and Recommendations</i> | Erica Radden, MD, Medical Officer
DPMH, OND, CDER |
| 11:10 a.m. | Risperdal (risperidone)

<i>Questions and Recommendations</i> | Erica Wynn MD, MPH, Medical Officer
DPMH, OND, CDER |
| 11:40 a.m. | Lunesta (eszopiclone)

<i>Questions and Recommendations</i> | Erica Radden, MD |
| 12:00 p.m. | Lunch | |
| 1:10 p.m. | Oxtellar XR (oxcarbazepine extended-release)

<i>Questions and Recommendations</i> | Donna Snyder, MD, Medical Officer
DPMH,OND, CDER |
| 1:25 p.m. | Revatio (sildenafil)

<i>Questions and Recommendations</i> | Amy Taylor, MD |
| 1:50 p.m. | Advair HFA (fluticasone propionate/salmeterol xinafoate)

<i>Questions and Recommendations</i> | Ethan Hausman, MD, Medical Officer
DPMH, OND, CDER |
| 2:45 p.m. | <u>Designated Abbreviated Presentation</u>

Altabax Ointment (retapamulin) | Ken Towbin, MD

Michael White, MD, PhD |
| 2:50 p.m. | Break | |

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Center for Biologics Evaluation and Research (CBER)

Abbreviated Presentations

3:00 p.m. **FluMist Quadrivalent (Influenza Vaccine Live, Intranasal)** Judith U. Cope, MD, MPH

Questions and Recommendations

3:15 p.m. **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 Nathan S. Ivey, PhD, Senior Scientific Project Manager,
Questions and Recommendations 522 Postmarket Surveillance Program, OSB, CDRH,

4:10 p.m. **Liposorber LA-15 System** Véronique Li, MS, MBA, Biomedical Engineer
Initial Post-Market HDE Review Division of Reproductive, Gastro-Renal and Urological Devices (DRGUD), Renal Devices Branch, Office of Device Evaluation (ODE), CDRH

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

Questions and Recommendations Véronique Li, MS, MBA

4:50 p.m. **Adjournment** Ken Towbin, MD