

Pediatric Advisory Committee Meeting
Monday-Tuesday, May 7-8, 2012
Hilton Rockville Executive Meeting Center,
1750 Rockville Pike,
Rockville, Maryland, 20852

Tuesday, May 8, 2012

FINAL AGENDA

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| 8:30 a.m. | Welcome and Introductory Remarks | Geoffrey Rosenthal, MD, PhD
Chair of PAC
Director of Pediatric & Congenital Heart Center
University of Maryland Medical Center
Hospital for Children |
| | | Walter Ellenberg, PhD
Designated Federal Official, PAC, OC, FDA |
| 8:40 a.m. | Post-marketing Monitoring of Vaccine Safety | David Martin, MD MPH, Medical Officer
CDR, U.S. Public Health Service
Director, Division of Epidemiology
Office of Biostatistics and Epidemiology
CBER, FDA |
| 9:10 a.m. | MENVEO Meningococcal (Groups A, C, Y, and W-135) Oligosaccharide Diphtheria CRM197 Conjugate Vaccine Pre-licensure Review | Margaret Bash, MD, Medical Officer, PI
CAPT, U.S. Health Service
Division of Bacterial Parasitic and Allergenic
Products, Office of Vaccines Research &
Review (OVR), CB, FDA |
| 9:35 a.m. | MENVEO Meningococcal (Groups A, C, Y, and W-135) Oligosaccharide Diphtheria CRM197 Conjugate Vaccine Post-licensure Review | Manette Niu, MD, Medical Officer
CAPT, U.S. Public Health Service
Division of Epidemiology
Office of Biostatistics & Epidemiology (OBE)
CB, FDA |
| | <i>Questions and Recommendations</i> | |
| 9:55 a.m. | GARDASIL Human Papillomavirus Quadrivalent (Types 6, 11, 16, 18) Vaccine, Recombinant Pre-licensure Review | Jeffrey Roberts, MD, Medical Officer, Team
Leader, Division of Vaccines and Related
Product Applications, OVR, CB, FDA |
| 10:05 a.m. | GARDASIL Human Papillomavirus Quadrivalent (Types 6, 11, 16, 18) Vaccine, Recombinant Post-licensure Review | Andrea Sutherland, MD, MPH, MSc
Medical Officer, Special Assistant to the
Director
Division of Epidemiology.
OBE, CB |
| | <i>Questions and Recommendations</i> | |
| 10:45 a.m. | PAC Member Designated Abbreviated Reviews
Isopto Carpine (pilocarpine hydrochloride)
Zylet (loteprednol etabonate and tobramycin)
Zymaxid (gatifloxacin) | Geoffrey Rosenthal, MD, PhD |
| 11:00 a.m. | Adjournment | Geoffrey Rosenthal, MD, PhD |