The committees will discuss a pediatric-focused safety review of neuropsychiatric events with use of Singulair (montelukast).

8:30 a.m. Call to Order and Introduction of Committee
Kelly Wade, MD
Chairperson, PAC

Conflict of Interest Statement
Marieann R. Brill, MBA, RAC, MT
Designated Federal Officer
Pediatric Advisory Committee (PAC)
OPT, Office of Clinical Policy and Programs (OCPP)
OC, FDA

FDA Opening Remarks
Susan McCune, MD
Director
OPT, OCPP, OC, FDA

8:45 a.m. Neuropsychiatric Events with the use of Montelukast in Pediatric Patients
Katherine Clarridge, MD, MSc
Clinical Reviewer
Division of Pulmonary, Allergy, and Rheumatology (DPARP)
Office of Drug Evaluation II (ODE-II)
Office of New Drugs (OND), CDER, FDA

Pediatric Utilization Patterns Montelukast, 2014-2018
Ibrahim T Ibrahim, PharmD, MPH
Drug Utilization Analyst
Division of Epidemiology II (DEPI-II)
Office of Surveillance and Epidemiology (OSE)
CDER, FDA

Neuropsychiatric Events Associated with Montelukast: Postmarketing Experience
Ann Biehl, PharmD, MS
Safety Evaluator
Division of Pharmacovigilance I
OSE, CDER, FDA

Neuropsychiatric Adverse Events and Montelukast: Observational Safety Analyses
Veronica Sansing-Foster, PhD, MS
Epidemiologist
DEPI-II, OSE, CDER, FDA

FDA Summary and Discussion Topics
Stacy Chin, MD
Clinical Team Leader
DPARP, ODE-II, OND, CDER, FDA

10:15 a.m. BREAK
10:30 a.m.  Open Public Hearing

12:00 p.m.  Questions to the Committee/ Committee Discussion

1:51 p.m.  Adjournment  

Kelly Wade, MD
Chairperson, PAC