FOOD AND DRUG ADMINISTRATION (FDA)
Office of the Commissioner (OC)

Joint Meeting of the Pediatric Advisory Committee (PAC) and the Drug Safety and Risk Management Advisory Committee (DSaRM)
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, MD
September 27, 2019

FINAL AGENDA

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**	

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FINAL AGENDA (cont.)

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