FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Joint Meeting of the Drug Safety and Risk Management Advisory Committee (DSaRM) and the Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC)
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
August 3, 2018

AGENDA

The committees will discuss results from assessments of the transmucosal immediate-release fentanyl (TIRF) medicines' risk evaluation and mitigation strategy (REMS), approved in December 2011. The TIRF REMS requires that healthcare providers who prescribe TIRF medicines for outpatient use are specially certified, that pharmacies that dispense TIRF medicines for inpatient and outpatient use are specially certified, and that completion of the prescriber-patient agreement form occurs prior to dispensing TIRF medicines for outpatient use. The Agency will seek the committees' assessment as to whether this REMS with elements to assure safe use (ETASU) assures safe use, is not unduly burdensome to patient access to the drugs, and to the extent practicable, minimizes the burden to the healthcare delivery system. The Agency will also seek the committees' input on any possible modifications to the TIRF REMS goals and requirements, as well as input on the adequacy of the evaluations conducted in the REMS assessments to determine whether the TIRF REMS goals are being met.

8:00 a.m.	Call to Order and Introduction of Committee	**Brian Bateman, MD, MSc** Acting Chairperson, DSaRM
8:05 a.m.	Conflict of Interest Statement	**Yinghua S. Wang, PharmD, MPH** Acting Designated Federal Officer, DSaRM
8:10 a.m.	FDA Opening Remarks	**Sharon Hertz, MD** Director Division of Anesthesia, Analgesia and Addiction Products (DAAAP) Office of Drug Evaluation II (ODE-II) Office of New Drugs (OND), CDER, FDA
8:15 a.m.	**FDA PRESENTATIONS**	
	Approval History of TIRF Medicines	**Elizabeth Kilgore, MD, MS** Medical Officer DAAAP, ODE-II, OND, CDER, FDA
	REMS Authority and TIRF REMS	**Cynthia LaCivita, PharmD** Director Division of Risk Management (DRISK) Office of Medication Error Prevention and Risk Management (OMEPRM) Office of Surveillance and Epidemiology (OSE) CDER, FDA

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Joint Meeting of the Drug Safety and Risk Management Advisory Committee (DSaRM) and the Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC)
August 3, 2018

AGENDA (cont.)

8:30 a.m.	**INDUSTRY PRESENTATIONS**	**TIRF REMS Industry Group (TRIG)**
	Introduction	**Stephen Sherman, JD, MBA** Senior Vice President Regulatory Affairs and Clinical Development Insys Therapeutics
	Breakthrough Cancer Pain and the Public Health Impact of the TIRF Medicines	**Joseph Pergolizzi, MD** Senior Partner Naples Anesthesia and Pain Associates, Inc.
	Overview of TIRF REMS Access Program	**Kyle Irwin, MBA** Associate Director, REMS Operations Teva Pharmaceuticals
	REMS Evaluation Results	**Annette Stemhagen, DrPH, FISPE** Senior Vice President, Chief Science Officer United BioSource Corporation
	RADARS Data	**Richard C. Dart, MD, PhD** Executive Director, RADARS® System Denver Health and Hospital Authority University of Colorado School of Medicine
	Effectiveness of the TIRF REMS Access Program	**Dean Mariano, DO** Senior Director Clinical Development & Medical Affairs Insys Therapeutics
	Planned Changes and Proposed Action Items	**Stephen Sherman, JD, MBA**
	Conclusions	**Stephen Sherman, JD, MBA**
10:00 a.m.	Clarifying Questions	
10:15 a.m.	**BREAK**	

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Joint Meeting of the Drug Safety and Risk Management Advisory Committee (DSaRM) and the Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC)
August 3, 2018

AGENDA (cont.)

10:30 a.m.	**FDA PRESENTATIONS**	
	FDA Review of the TIRF REMS Assessment	**Doris Auth, PharmD** Associate Director DRISK, OMEPRM, OSE, CDER, FDA
	FDA Review of the Epidemiologic and Surveillance Data	**Rose Radin, PhD, MPH** Epidemiologist Division of Epidemiology II (DEPI-II) Office of Pharmacovigilance and Epidemiology OSE, CDER, FDA
	Concluding Remarks	**Doris Auth, PharmD**
11:30 a.m.	Clarifying Questions	
11:45a.m.	**LUNCH**	
12:45 p.m.	**Yale University-Mayo Clinic Center of Excellence in Regulatory Science and Innovation (CERSI) Presentation**	
	Characterization of Potentially Unsafe Prescribing of Opioid Analgesics Requiring Prior Opioid Tolerance	**Molly Moore Jeffery, PhD** Scientific Director of Emergency Medicine Research Research Associate, Department of Health Sciences Research Mayo Clinic
1:00 p.m.	**Centers for Medicare & Medicaid Services (CMS) Presentation**	
	Effect of TIRF-REMS on Transmucosal Fentanyl Prescribing	**William Fleischman, MD, MHS** Medical Officer Center for Program Integrity, CMS
1:15 p.m.	Clarifying questions	
1:30 p.m.	**OPEN PUBLIC HEARING**	

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Joint Meeting of the Drug Safety and Risk Management Advisory Committee (DSaRM) and the Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC)
August 3, 2018

AGENDA (cont.)

2:30 p.m.	Charge to the Committees	**Claudia Manzo, PharmD** Director OMEPRM, OSE, CDER, FDA
2:35 p.m.	Questions to the Committee/Committee Discussion	
3:30 p.m.	**BREAK**	
3:45 p.m.	Questions to the Committee/Committee Discussion (cont.)	
5:00 p.m.	**ADJOURNMENT**	