

**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

DRAFT 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
	Approval History of TIRF Medicines	Elizabeth Kilgore, MD 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
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

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DRAFT AGENDA (cont.)

INDUSTRY PRESENTATIONS (CONT.)	TIRF REMS Industry Group (TRIG)
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 Stenhagen, 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	
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 (OPE) OSE, CDER, FDA

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DRAFT AGENDA (cont.)

FDA PRESENTATIONS (CONT.)

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| | 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 | |
| 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 | |