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

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8:30 a.m.  INDUSTRY PRESENTATIONS

Introduction  TIRF REMS Industry Group (TRIG)
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
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

11:45 a.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