

# **FDA Plan: Opioid Analgesic Education**



# **Three key areas of focus based on Advisory Committee's Advice**

- 1. Add the immediate-release (IR) opioid analgesic products to the ER/LA Opioid Analgesics REMS**
2. Expand the FDA Blueprint to incorporate pain management and educational messaging for other healthcare professionals involved in the management of patients with pain
3. Evaluate the Advisory Committee's recommendation that all opioid prescribers should be educated

**This meeting will focus on  
adding IR Opioid Analgesics**



# Current REMS

- Current ER/LA Opioid Analgesic REMS is a shared system REMS that includes:
  - approximately 34 ER/LA opioid analgesic companies
  - approximately 65 ER/LA opioid analgesic NDAs and ANDAs
- The companies have come together as a consortium of opioid manufacturers.
  - Referred to as the REMS Program Companies (RPC)

# Rationale for potentially requiring a REMS for IR Opioid Analgesics

- Continued problems of abuse, misuse, addiction overdose, and death across all opioid analgesics.
- Expansion will underscore the importance of approaching all opioid analgesics with adequate knowledge of risk and benefit.

# Adding IR Opioid Analgesics to Current REMS



- Infrastructure already exists
- RPC already has a process for adding new applicants
- Should reduce overall timeline compared to setting up new shared system for IR opioid analgesics
- A modified Blueprint that focuses on pain management could include education components relevant to ER, LA and IR products
- Reduces burden on the healthcare delivery system and application holders



# IR Opioid Analgesics Products

- An expanded “Opioid Analgesics REMS” may include all IR opioid analgesics available in dosage forms intended for outpatient treatment of pain
- Approximate number of companies ~ 50

# IR Opioids Analgesics not Impacted

- Likely not to include parenteral opioid formulations
  - Not subject to outpatient use
- Transmucosal immediate-release fentanyl (TIRF) products
  - Subject to a separate REMS with ETASU



# Details about integrating IR Opioid Analgesics



- Elaine Lippmann will be providing an overview of shared systems REMS development and FDA's expectations of all sponsors involved
- RPC will provide a presentation on recommendations for adding the IR sponsors

**Brief overview of plans for the two  
additional areas of focus -  
Blueprint Expansion and AC  
recommendation that all opioid  
prescribers should be educated**

# Rationale for Expanding Blueprint

- Consistent recommendations from advisory committees to:
  - Include all opioid analgesic products
  - Educate beyond drug specific information, including how to manage pain
  - Educate all opioid prescribers
  - Include non-prescribing healthcare team members

# Blueprint Expansion

## Key Components

- Additional background on pain
- Broad principles of acute and chronic pain management
- Non-pharmacologic treatments for pain
- Pharmacologic treatments for pain
  - Non-opioid analgesics
  - Opioid analgesics

# Blueprint Expansion

- FDA will seek stakeholder input on blueprint
- After finalization of the blueprint, sponsors will be notified to incorporate the blueprint into the REMS
- Industry expected to continue providing funding for continuing education
- Details of timing to be determined

# Approaches to Training

- Clear recommendation by advisory committees that all opioid prescribers should be educated
  - Preferable not through FDA REMS authorities
- No obvious mechanism proposed in response to HHS RFI
- Considering a public meeting to discuss the advisory committee's recommendation that all opioid prescribers should be educated

# Summary and Timeline

- Potentially new REMS to include all opioid analgesics used in outpatient setting, not already covered by another REMS (e.g. TIRF products)
- Blueprint expansion to include principles of pain management
- Timeline
  - Potential addition of IR sponsors in the RPC by fourth quarter 2017
  - FDA notifies all sponsors in first quarter 2018 of modified REMS
- Considering possible public meeting
- Plans to assess the impact of the REMS Opioid Education Plan being discussed internally

