Abuse-Deterrent Opioids – Evidence Evaluation & Labeling

Medication: _____

Evaluation Date:_____   Evaluation History: [ ] Initial Version 1.0, or Version _____

Current Product Labeling established: (select one) [Prior to] or [After] publication of FDA Guidance to Industry Document (4/2015)

This is a: (Check all that apply)
 ☐New product
 ☐Existing product, new formulation
 ☐Existing product with new/updated labeling
 ☐Other: _____

Product Abuse Deterrent Property Classification: – Check all that apply
 ☐Physical / Chemical barrier
 ☐Agonist / Antagonist combination
 ☐Aversion
 ☐Delivery System
 ☐New Molecular entity or Prodrug
 ☐Combination (check combined items)
 ☐Novel Approach

Product Labeling:

 Does the product have FDA abuse deterrent labeling? [Yes] or [No]   Year obtained: _____

Abuse Deterrent Evidence provided. Summary of in-depth literature review and product evaluation based on FDA Guidance to Industry Document

 ☐Laboratory-based in vitro manipulation and extraction studies (Category 1)
  Description of Research:_____
  _____

 ☐Pharmacokinetic Studies (Category 2)
  Description of Research:_____
  _____

 ☐Clinical Abuse potential studies (Category 3)
  Description of Research:_____
  _____

 ☐Clinical Abuse potential studies (Category 3)
  Description of Research:_____
  _____

 ☐Clinical Abuse potential studies (Category 3)
  Description of Research:_____
  _____

 ☐Clinical Abuse potential studies (Category 3)
  Description of Research:_____
  _____

 ☐Additional Studies / Post Market data which assessed the impact of abuse-deterrent formulation (Category 4)
  ☐Post market
   ☐Formal studies included recommended study design features (see page 19 FDA Guidance document)
   Description of Research:_____
   _____

☐Determination if use of product results in meaningful reductions in abuse, misuse, and related adverse clinical outcomes, including addiction, overdose, and death
Description of Research:_____
_____

☐Outcome Measures and Data Interpretation in Abuse Potential Studies
    o   Standardized Instruments
        ☐Visual Analogue Scales (VAS)
        Description of Research:_____
        _____

        ☐Profile of Mood States
        Description of Research:_____
        _____

    o   Data Interpretation
        ☐Primary Analysis
        Description of Research:_____
        _____

        ☐Statistical Analysis
        Description of Research:_____
        _____

        ☐Data and dropout for non-completers
        Description of Research:_____
        _____

☐None of the above

Strength of Evidence of Abuse Deterrent Properties:

☐<u>Evidence is based on physical/chemical property, theoretical assumptions or manufacturer's claims and is not yet supported by scientifically sound outcome</u> data which demonstrates a reduction in the abuse of the product in the community setting compared to levels of abuse, overdose, and death that occurred when only formulations of the same opioid without abuse-deterrent properties were available

☐ <u>Evidence is based on physical/chemical property, clinical abuse potential studies or laboratory manipulation studies and is not yet supported by scientifically sound outcome</u> data which demonstrates a reduction in the abuse of the product in the community setting compared to levels of abuse, overdose, and death that occurred when only formulations of the same opioid without-abuse-deterrent properties were available

☐<u>There is evidence, supported by scientifically sound outcome data, which demonstrates a reduction in the abuse of the product</u> in the community setting compared to levels of abuse, overdose, and death that occurred when only formulations of the same opioid without abuse-deterrent properties were available