Abuse-Deterrent Opioids – Evidence Evaluation & Labeling

Medication: Zohydro® (hydrocodone extended-release capsule)

Evaluation Date: 06/02/2016 Evaluation History: ☒ Initial Version 1.0, or ☐ Version _____

Current Product Labeling established: ☐ 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: the manufacturer was unable to supply any clinical abuse potential studies or *in vitro* laboratory manipulation and extraction studies. Review of the Supplemental New Drug Application for reformulated Zohydro ER® (hydrocodone extended-release) with BeadTek™ revealed no information pertinent to the potential abuse-deterrent properties.
- ☐ Pharmacokinetic Studies (Category 2)
  Description of Research: _____
  _____
- ☐ Clinical Abuse potential studies (Category 3)
  Description of Research: _____
  _____
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  _____
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  _____
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  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

- Standardized Instruments
  - ☐ Visual Analogue Scales (VAS)
    Description of Research: _____
    _____

  - ☐ Profile of Mood States
    Description of Research: _____
    _____

- 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:

☒ Evidence is based on physical/chemical property, theoretical assumptions or manufacturer's claims and is not yet supported by scientifically sound outcome 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 (Category III)

☐ Evidence is based on physical/chemical property, clinical abuse potential studies or laboratory manipulation studies and is not yet supported by scientifically sound outcome 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 (Category II)

☐ There is evidence, supported by scientifically sound outcome 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 (Category I)