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FDA Drug Safety and Risk Management
and Anesthetic and Analgesic Drug Products
Advisory Committees

# Extended Release Oxycodone (IPC Oxy): Inadequately Studied

July 26, 2017
(I have no financial conflict of interest)

# FDA Discussion Questions and Votes

**The Applicant submitted only Category 1 (in vitro) studies to support labeling of Oxycodone HCl ER tablets for abuse deterrence, and is seeking labeling for abuse deterrent properties only for the IV route of abuse.**

**The product contains excipients that are intended to deter abuse by other routes. Discuss whether it is appropriate to consider labeling this product for abuse-deterrent properties for a single route without a complete assessment of all relevant routes of abuse.**

# Nine FDA-Approved Extended Release Opiates with Abuse Deterrent Labels

| Drug | Ingredients | Year ADF Label Approved | Human Abuse Potential studies |
|---|---|---|---|
| Embeda | morphine/naloxone | 2009 | yes |
| Oxycontin | oxycodone | 2012 | yes |
| Tarquiniq | oxycodone/naloxone | 2014 | yes |
| Hysingla | hydrocodone | 2014 | yes |
| Morphabond | morphine | 2015 | yes |
| Extampza | oxycodone | 2016 | yes |
| Troxyca | Oxycodone/naltrexone | 2016 | yes |
| Arymo | morphine | 2017 | yes |
| Vantrela | hydrocodone | 2017 | yes |
| | | | |
| IPC Oxy | oxycodone | ------ | no |

# Intellipharmaceutic's Promise for Postmarketing Studies if approved for IV abuse deterrence now

"In addition, if IPC Oxy is approved, IPC would work with the FDA to design a series of Category 4 post-approval epidemiologic studies to evaluate the effect of IPC Oxy on abuse in the real world. Concurrently, IPC would complete Category 2 and 3 pharmacokinetic/pharmacodynamic studies to evaluate the human abuse potential of IPC Oxy for the oral and nasal routes of abuse. Upon completion of the HAP studies, IPC would submit a supplemental NDA to the Agency to request Category 2/3 labeling if results supported abuse deterrence for additional routes of abuse."(IPC briefing document, page 51)

# Current Oxycontin® Label Warning re: Parenteral Risks of Inactive Ingredients

**“With parenteral abuse, the inactive ingredients in OXYCONTIN can be expected to result in local tissue necrosis, infection, pulmonary granulomas, and increased risk of endocarditis and valvular heart injury.”**

# FDA Discussion Questions and Votes

**Discuss any concerns you may have regarding this product and the presence of excipients that have been included to deter abuse.**

**Discuss whether it is acceptable to include excipients in this product that increase the potential risk from exposure via certain non-IV routes of abuse and have not been shown or are not intended to contribute to the proposed IV abuse-deterrent claim being sought by the Applicant. NO**

**Discuss whether it is possible to determine an acceptable level of risk for excipients that may be toxic by unintended routes of administration for this product? NO**

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| | | | |
| IPC Oxy | oxycodone | ------ | no |

# FDA Voting Questions

**VOTE:** Has the Applicant demonstrated that oxycodone extended-release tablets have properties that can be expected to deter abuse by the IV route of administration?

Clearly NO, since 1/ no human abuse potential studies of any kind have been done and 2/ there are no data on parenteral use risks of inactive ingredients or the excipients meant to deter oral or intranasal use.

**VOTE:** Are there sufficient data for this product to support inclusion of language regarding abuse-deterrent properties in the product label for the IV route of administration.

This is really a question about approval without any abuse-deterrent labeling, not apparently allowed for a new oxycodone product, thus NO