Meeting of the Drug Safety and Risk Management (DSaRM) and Anesthetic and Analgesic Drug Products (AADP) Advisory Committees

Instant-Release/Abuse-Deterrent Oxycodone: MNK-812

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Food and Drug Administration
November 14, 2018

I have no financial conflicts of interest.

MNK-812: Similarities to FDA Mistakes with Opana ER

1. Opana ER Approved without abuse-deterrent label, but….

Of note, during the first cycle, the review team determined that the data submitted to support the [redacted] (b) (4) [redacted] (b) (4) While the new formulation has demonstrated a minimal improvement in resistance to tampering by crushing, thereby limiting the likelihood of abuse by crushing followed by ingestion, and by insufflation (snorting) to some degree, it can still be [redacted] (b) (4) [redacted], cut [redacted] (b) (4) rendering it readily abusable by ingestion and intravenous injection, and possibly still by insufflation; although

FDA Opana ER Summary Review for Regulatory Action, December 9, 2011, https://www.accessdata.fda.gov/drugsatfda_docs/nda/2011/201655Orig1s000SumR.pdf, PDF page 4

MNK-812: Similarities to FDA Mistakes with Opana ER

2. Elaboration on FDA's Pre-approval Opana ER concerns

appears that OPR can be prepared for insufflation (snorting) using commonly available tools and methods.[16] OPR can be readily prepared for injection, despite Endo's claim that OPR tablets have "resistance to aqueous extraction (i.e., poor syringeability)" (Petition at 4).[17] In addition, certain data suggest that OPR can more easily be prepared for injection than OP.[18]

https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndAnalgesicDrugProductsAdvisoryCommittee/UCM545760.pdf (PDF page 74)

MNK-812: Similarities to FDA Mistakes with Opana ER

3. MNK-812: Effective Small Volume Extraction and Potential IV Abuse

"With an extraction time of 2 hours or less in a variety of ingestible solvents of varying pH, approximately 80-90% of oxycodone hydrochloride will be released from intact or ground tablets at room temperature. When tested using complex extraction and isolation procedures, 87% of oxycodone free base can be recovered from MNK-812."

FDA Briefing Information, PDF page 101

MNK-812 Similarities to FDA Mistakes with Opana ER Sufficient Reason to Reject MNK-812:

4. Serious possibility of IV abuse

"The Applicant initiated studies during the review cycle to characterize the potential toxicological effects of the drug product if it were to be manipulated for intravenous abuse. *However, final study reports for several key studies have not been submitted to the NDA in time to be included in this background document and are expected late in the review cycle. As such, the Agency has not made any definitive conclusions regarding the potential risks associated with manipulation and abuse of this product via the intravenous route of administration."*

FDA Briefing Information: PDF page 99

MNK-812: Difference from FDA Mistakes with Opana ER

5. Advisory committee meeting

Opana ER: "This application was not taken to an advisory committee meeting as there were *no unusual concerns regarding the efficacy or safety* of this reformulated opioid product [Opana ER]."*

MNK-812: As with this meeting today, all AC Meetings discussing opioids must be joint AADP and DSaRM to be useful and credible.

***Summary Review in FDA Opana ER Approval Package December 9, 2011, PDF page 7**

Voting Questions for MNK-812

VOTE: If approved, should oxycodone hydrochloride immediate-release tablets (MNK-812) be labeled as an abuse-deterrent product by the nasal route of abuse? **NO**

VOTE: If approved, should oxycodone hydrochloride immediate-release tablets (MNK-812) be labeled as an abuse-deterrent product by the intravenous route of abuse? **NO**

VOTE: Should oxycodone hydrochloride immediate-release tablets (MNK-812) be approved for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate? **NO**