Errata to the FDA Briefing Document
Joint Meeting of the Drug Safety and Risk Management Advisory Committee (DSaRM)
and the Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC)
May 5, 2025

Note: Page numbers reflect the numbers at the page bottom within the document

Location in the Document	**Current Text with Deletions (~~strikethrough~~)**	**Text with Additions (bolded/underlined)**
Page 12, Table 1, row 1, column headings	Misuse % (95% CI) Abuse % (95% CI) Pain-Adjusted DSM-5-OUD~~[1]~~ % (95% CI) DSM-5-OUD~~[2]~~ % (95% CI)	Misuse % (95% CI)**[1]** Abuse % (95% CI)**[1]** Pain-Adjusted DSM-5-OUD**[2,3]** % (95% CI) DSM-5-OUD**[2,4]** % (95% CI)
Page 12, Table 1, column 1, row headings	Prospective ER/LA cohort:~~[3]~~ 12-month incidence Prospective LtOT cohort: 12-month incidence[4]	Prospective ER/LA cohort:**[5]** 12-month incidence Prospective LtOT cohort:**[6]** 12-month incidence
Page 12, Table 1, footnotes	~~[1]~~ Moderate-to-severe pain-adjusted DSM-5-OUD was defined as having four or more pain-adjusted DSM-5 criteria for OUD related to prescription opioid use *or* two or more DSM-5 criteria related to heroin use, as measured by the PRISM-5-Op. ~~[2]~~ Moderate-to-severe DSM-5-OUD was defined as having four or more standard DSM-5 criteria for OUD related to prescription opioid use *or* two or more DSM-5 criteria related to heroin use, as measured by the PRISM-5-Op.	**[1]** 12-month misuse and abuse incidence were calculated using the past-3-month measure, as assessed at 3, 6, 9, and 12 months from baseline (prospective study). Misuse and abuse prevalence was measured using the past-3-month measure at the single interview (cross-sectional study). **[2]** OUD is past-12-months for both studies (measured at 12 months after baseline in the prospective study and the single interview in the cross-sectional study).

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	[3] Includes patients who initiated an ER/LA OA that included at least 28 days' supply of an ER/LA OA within a 60-day window followed by a subsequent ER/LA OA prescription within a 7-day period, all within a 90-day period prior to the patient's baseline interview. Patients could not have used an ER/LA OA in the 6 months before the initial 28 days' supply of an ER/LA OA, but patients on IR/SA OAs during the same 6 months were still eligible for this cohort. [4] Includes patients who initiated either an ER/LA OA or a Schedule II IR/SA OA for at least 70 of the past 90 days. Patients could not have used an ER/LA OA or a Schedule II IR/SA OA in the 6 months before the initial ER/LA OA or Schedule II IR/SA OA prescription contributing to at least 70 days of use, but other prescription OA therapy would not exclude them (e.g., tramadol use).	[3] Moderate-to-severe pain-adjusted DSM-5-OUD was defined as having four or more pain-adjusted DSM-5 criteria for OUD related to prescription opioid use *or* two or more DSM-5 criteria related to heroin use, as measured by the PRISM-5-Op. [4] Moderate-to-severe DSM-5-OUD was defined as having four or more standard DSM-5 criteria for OUD related to prescription opioid use *or* two or more DSM-5 criteria related to heroin use, as measured by the PRISM-5-Op. [5] Includes patients who initiated an ER/LA OA that included at least 28 days' supply of an ER/LA OA within a 60-day window followed by a subsequent ER/LA OA prescription within a 7-day period, all within a 90-day period prior to the patient's baseline interview. Patients could not have used an ER/LA OA in the 6 months before the initial 28 days' supply of an ER/LA OA, but patients on IR/SA OAs during the same 6 months were still eligible for this cohort. [6] Includes patients who initiated either an ER/LA OA or a Schedule II IR/SA OA for at least 70 of the past 90 days. Patients could not have used an ER/LA OA or a

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		Schedule II IR/SA OA in the 6 months before the initial ER/LA OA or Schedule II IR/SA OA prescription contributing to at least 70 days of use, but other prescription OA therapy would not exclude them (e.g., tramadol use).
Page 63-64, last paragraph of page 63	...can be found in Appendix ~~Section 6.5~~. Appendix ~~Section 6.5~~ also contains the full set of fully adjusted results for any OUD…	...can be found in Appendix **Table 37**. Appendix **Table 37** also contains the full set of fully adjusted results for any OUD…
Page 71, last paragraph, second sentence	Patients were eligible for the study if they had been enrolled in the healthcare plan for at least 9 months prior to the ~~baseline period~~.	Patients were eligible for the study if they had been enrolled in the healthcare plan for at least 9 months prior to the **patient's cohort start date**.