

Errata to the FDA Briefing Document

Joint Meeting of the Drug Safety and Risk Management
(DSaRM) Advisory Committee and Anesthetic and Analgesic
Drug Products Advisory Committee (AADPAC)

September 10-11, 2020

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

FDA Errata to Briefing Document

<ul style="list-style-type: none"> Page 1 “Oxycontin” should read “OxyContin” 	
Drug Utilization Review	
<ul style="list-style-type: none"> Page 110 	Tables 2-6 and 8 are included in the appendix; this is why only Tables 1 and 7 appear in the body of the review.
DEPI Review PMR Study 3051-1	
<ul style="list-style-type: none"> Page 118 	“6.14 Assessing Screen Changes” should read “6.14 ITS Analyses with Additional Models ”
<ul style="list-style-type: none"> Page 118 	“6.15 Model Assessments” should read “6.15 Assessing Screen Changes ”
<ul style="list-style-type: none"> Page 118 	“6.16 Comparators” should read “6.16 Model Assessments ”
<ul style="list-style-type: none"> Page 118 	“6.17 Summary Table of Published Literature Related to PMR 3051-1” should read “6.17 Comparators ”
<ul style="list-style-type: none"> Page 118 	Missing “6.18 Summary Table of Published Literature Related to PMR 3051-1 ”
<ul style="list-style-type: none"> Page 160 	“Figure 13 below” should read “Figure 12 below”
<ul style="list-style-type: none"> Page 161 	“Figure 14 depicts” should read “Figure 13 depicts”
<ul style="list-style-type: none"> Page 162 	“Figure 15 below” should read “Figure 14 below”
<ul style="list-style-type: none"> Page 163 	“Figure 16, which uses” should read “Figure 15 , which uses”
<ul style="list-style-type: none"> Page 164 	“Figure 17 below” should read “Figure 16 below”
<ul style="list-style-type: none"> Page 165 	“Figure 18 depicts” should read “Figure 17 depicts”
<ul style="list-style-type: none"> Page 167 	“Figure 19-20” should read “Figure 18-19 ”
<ul style="list-style-type: none"> Page 169 	“Figure 21-22” should read “Figure 20-21 ”
<ul style="list-style-type: none"> Page 173 	“Figure 23 (and table 22 in appendix 6.5)” should read “Figure 22 (and table 22 in appendix 6.5)”
<ul style="list-style-type: none"> Page 174 	“Figure 24 (and table 23 in appendix 6.5)” should read “Figure 23 (and table 23 in appendix 6.5)”
<ul style="list-style-type: none"> Page 177 	“Figure 25 below” should read “Figure 24 below”
<ul style="list-style-type: none"> Page 178 	“Figure 26 below” should read “Figure 25 below”
<ul style="list-style-type: none"> Page 180 	“Figure 27 (and table 28 in appendix 6.9)” should read “Figure 26 (and table 28 in appendix 6.9)”
<ul style="list-style-type: none"> Page 185 	“Figures 28 and 29 show” should read “Figures 27 and 28 show”

• Page 186	“(Figure 29)” should read “(Figure 28)”
• Page 191	“Figures 30-32 below” should read “Figures 29-31 below”
• Page 191	“Figure 30 below” should read “Figure 29 below”
• Page 193	“Figure 31 shows” should read “Figure 30 shows”
• Page 194	“Figure 32 below” should read “Figure 31 below”
• Page 198	“Figures 33-34” should read “Figures 32-33 ”
• Page 201	“Figure 35 shows” should read “Figure 34 shows”
• Page 201	“(refer to figure 32 section 3.4.8)” should read “(refer to figure 31 section 3.4.8)”
• Page 209	“are shown in figures 37-39 below” should read “are shown in figures 36-38 below”
• Page 209	“In population-based analyses (Figure 37)” should read “In population-based analyses (Figure 36)”
• Page 210	“In utilization-based analyses (Figure 38)” should read “In utilization-based analyses (Figure 37)”
• Page 211	“Figure 39 below” should read “Figure 38 below”
• Page 213	“Figure 40 shows” should read “Figure 39 shows”
• Page 214	“Figure 41 shows” should read “Figure 40 shows”
• Page 218	<p>Section 4.2.3, third sentence: “From the pre- to post-period, the percent of individuals endorsing abuse of OxyContin who reported they snorted the drug decreased from 55.2% to 33.4%, and the percent who reported injecting the drug decreased from 31.5% to 19.8%. These descriptive analyses did not formally test for statistical significance, but the estimate for the post-period did lie outside the 95% confidence interval for the pre-period estimate. In analyses looking only at those who reported abuse of original OxyContin in the pre-period or reformulated OxyContin in the post- period, the percent reporting abuse via snorting decreased from 57.3% to 27.3%, and from 30.9% to 25.4% for injection. By contrast, the percent of individuals endorsing ER morphine who reported snorting the drug increased from 22.4% to 28.1%, and the percent who reported injecting increased from 40.4% to 49.1%. For the smaller subset of sites contributing ≥ 1 assessment per quarter, the percentage of those abusing IR hydrocodone combination products who reported snorting decreased slightly from 17.2% to 14.4%, and the percent injecting remained very low, decreasing from 1.6% to 0.2%. The results from the larger set of sites contributing ≥ 1 assessment/year were qualitatively different, and showed a small increase in proportion of IR hydrocodone cases via injection reported (Figure 89, appendix 6.11).”</p> <p>should read</p>

	<p>“From the pre- to post-period, the percent of individuals endorsing abuse of OxyContin who reported they snorted the drug decreased from 55.9% to 32.2%, and the percent who reported injecting the drug decreased from 34.8% to 22.3%. These descriptive analyses did not formally test for statistical significance, but the estimate for the post-period did lie outside the 95% confidence interval for the pre-period estimate. In analyses looking only at those who reported abuse of original OxyContin in the pre-period or reformulated OxyContin in the post- period, the percent reporting abuse via snorting decreased from 55.9% to 25.8%, and from 34.8% to 18.8% for injection. By contrast, the percent of individuals endorsing ER morphine who reported snorting the drug changed only slightly from 33.2% to 32.1%, and the percent who reported injecting changed slightly from 54.4% to 53.6%. For the smaller subset of sites contributing ≥ 1 assessment per quarter, the percentage of those abusing IR hydrocodone combination products who reported snorting increased slightly from 14.8% to 17.9%, and the percent injecting remained very low, decreasing from 1.6% to 0.8%. The results from the larger set of sites contributing ≥ 1 assessment/year were qualitatively different, and showed a small increase in proportion of IR hydrocodone cases via injection (Figure 89, appendix 6.11).”</p>
<ul style="list-style-type: none"> • Page 315 	<p>Title for Table 39: “AIC model fit statistic values for changes in overall abuse for OxyContin relative to primary comparators, -2y/4y” should read “AIC model fit statistic values for changes in non-oral abuse for OxyContin relative to primary comparators, -2y/4y”</p>
<p>DBVII Memorandum</p>	
<ul style="list-style-type: none"> • Page 718 	<p>There is no Figure 4.</p>
<ul style="list-style-type: none"> • Page 703 	<p>The following footnote moved to the next page: “†Rate ratio is defined by a ratio between rates in pre- and post-reformulation period for a single opioid. RORR is a ratio between two rate ratios (one for OxyContin; the other for a comparator) obtained from difference-in-differences type of analysis. See Section 4 for details.”</p>
<ul style="list-style-type: none"> • Page 711 	<p>“Figure 3 shows” should read “Figure 1 shows”</p>
<ul style="list-style-type: none"> • Page 724 	<p>“Table 4 presents” should read “Table 5 presents”</p>
<ul style="list-style-type: none"> • Page 724 	<p>“Table 5 presents” should read “Table 6 presents”</p>
<ul style="list-style-type: none"> • Page 724 	<p>“Table 5 only highlights” should read “Table 6 only highlights”</p>
<ul style="list-style-type: none"> • Page 725 	<p>“Table 6 presents” should read “Table 7 presents”</p>
<ul style="list-style-type: none"> • Page 725 	<p>“Table 6 depicts” should read “Table 7 depicts”</p>
<ul style="list-style-type: none"> • Page 725 	<p>“(denoted by CIS in Table 6)” should read “(denoted by CIS in Table 7)”</p>
<ul style="list-style-type: none"> • Page 725 	<p>“(denoted by IS in Table 6)” should read “(denoted by IS in Table 7)”</p>

• Page 726	“Table 7 presents” should read “Table 8 presents”
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