

Errata to the FDA Briefing Document
Anesthetic and Analgesic Drug Products Advisory Committee Meeting (AADPAC)
February 14 and February 15, 2018

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

FDA Errata to Briefing Document

Clinical Pharmacology Summary	
• Page 09:	Last Paragraph, Results: the 'Study 326' should read as 'Study 327'
• Page 10:	Figure 3 description, the '402-C-326' should read as '402-C-327'
• Page 10:	Last Paragraph, 'Study 326' should read as 'Study 327'
• Page 12:	Heading, 'Comparison of PK between nerve block studies' should read as 'Comparison of PK between nerve block studies for 266 mg EXPAREL'
Clinical Summary	
• Page 17	Deletion of the phrase "...which slightly favored placebo over Exparel in reducing NRS-R over 72 hours after thoracotomy."
Safety	
• Page 29	The statement "No analysis provided of the cardiac Holter monitor data[.]" should read as "A cardiac safety report for each study was included in this submission, however, the analysis was limited to a maximum of three points on Holter for each subject."