

Errata to the FDA Open Session Briefing Document  
 Joint Meeting of the Drug Safety and Risk Management Advisory Committee (DSaRM)  
 and the Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC)  
 June 8, 2016

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

**FDA Errata to Open Session Briefing Document**

Page	Description of Error with Correction
52	Section 1B, first paragraph has been replaced by : These studies were designed to determine the extraction potential of oxycodone and naltrexone when extracted from the pellet formulations with Common Solvents A to O, under both stress and non-stress conditions. Studies used both intact and crushed pellets. The formulation was defeated in the following solvents, when extracted for 12 hours or longer using intact pellets (Common Solvents A, G, K and N). When Common Solvent K was used, 90% of oxycodone was extracted in 3 hours or more, and when Common Solvents L and M were used, about 60% of the oxycodone could be extracted from intact pellets within 30 minutes or less.
53	Section 1B, second paragraph: Common solvents A and J is replaced by Common Solvents A and G
53	Paragraph 4, sentences 4 through 8, are replaced by: Alternatively, common solvents A and K to M, are generally unable to extract oxycodone from naltrexone selectively in crushed pellets. A unique exception appears to be in use of Solvents B to D with intact tablets wherein nearly selective extraction can be achieved, in a 12 +hour period. Solvent O can selectively extract the oxycodone from intact pellets in a manner that appears dependent on the intrinsic solubility of the two APIs, not on the delayed release of the naltrexone by the sequestering membrane. This is further supported by the ability of solvent O to selectively extract oxycodone even in crushed pellets. Solvents F appears to also extract oxycodone selectively from crushed pellets.
53	Part 1C, Portion of sentence 2: Low concentrations of solvents O, B and C is replaced with Lower volumes of common solvent P.
54	Part 1D, Second Paragraph, Portion of sentence 2: Common Solvents F, G and H are replaced by Common Solvents B to E