

Errata to the FDA Briefing Document  
 Anesthetic and Analgesic Drug Products Advisory Committee Meeting (AADPAC)  
 January 16, 2020

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

**FDA Errata to Briefing Document**

Division Director Memo	
<ul style="list-style-type: none"> <li>Page 01:</li> </ul>	<p>First paragraph, last line:          “The following is an excerpt from the CRL that identified the deficiencies” should read “The following is an excerpt from the CRL, issued February 12, 2014, that identified the deficiencies in the original application.”</p>
<ul style="list-style-type: none"> <li>Page 01:</li> </ul>	<p>Second paragraph, first line:          “The application does not contain sufficient information to demonstrate that POSIMIR is safe when used in the manner described in the proposed label.” should read “The original application did not contain sufficient information to demonstrate that POSIMIR is safe when used in the manner described in the proposed label.”</p>
Clinical Summary	
<ul style="list-style-type: none"> <li>Page 10:</li> </ul>	<p>First paragraph, third and fourth sentence:          “However, the studies were powered for modest improvement in mean pain intensity, of 0.4 to 0.8 difference above placebo treatment for AUC for pain 0 to 72 h using an 11-point pain scale. Therefore, the results will not be clinically meaningful.” should read “The pivotal studies in inguinal hernia repair and arthroscopic subacromial decompression demonstrated efficacy on the primary endpoints of mean pain intensity (PI) on movement AUC over the time period 1 to 72 hours post-surgery (AUC72). However, the studies demonstrated only a modest improvement in mean pain intensity, of 1.1 to 1.3 difference above SABER-placebo treatment for AUC for pain 0 to 72 h using an 11-point pain scale. It is clear from the forest plots of studies from the development program that the same or similar surgical models showed inconsistent and modest efficacy. Therefore, the clinical meaningfulness of the results are uncertain.”</p>

<ul style="list-style-type: none"><li>• Page 31:</li></ul>	<p>Last paragraph, last sentence: “Additionally, increased fibrotic tissue could may surgical re-exploration challenging with increased risk of surgical Complications” should read “Additionally, increased fibrotic tissue may make surgical re-exploration challenging with increased risk of surgical complications.”</p>
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