

**ERRATA FOR
FDA ADVISORY COMMITTEE BRIEFING DOCUMENT**

**ApadazTM
(Benzhydrocodone HCl/Acetaminophen)**

**JOINT MEETING OF THE ANESTHETIC AND ANALGESIC
DRUG PRODUCTS ADVISORY COMMITTEE AND THE DRUG
SAFETY AND RISK MANAGEMENT ADVISORY COMMITTEE**

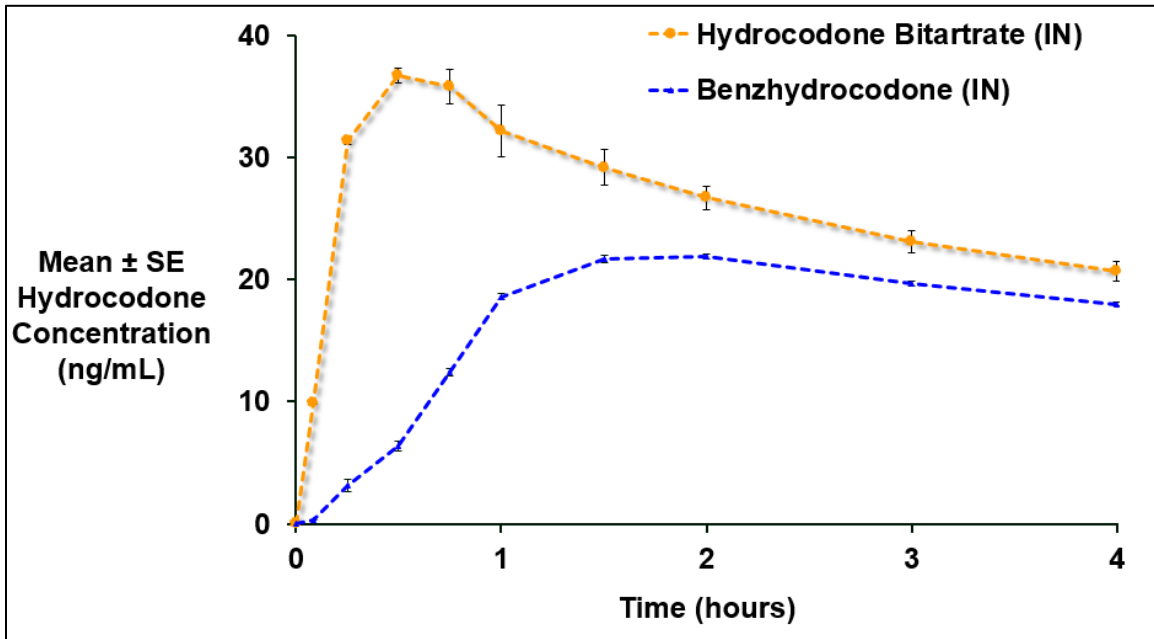
MEETING DATE: May 5, 2016

AVAILABLE FOR PUBLIC RELEASE

This errata provides one minor correction to two identical Figures contained within the briefing document to support the upcoming Joint Advisory Committee meeting on 5 May 2016. This errata is intended to provide transparency of this minor correction and does not affect the conclusions within the briefing document.

Rationale: Figure 4 (page 15) and Figure 21 (page 62) were identical figures displaying the hydrocodone plasma concentration-time profiles after intranasal administration of benzhydrocodone (the Apadaz prodrug) and hydrocodone bitartrate in Study A03. While the mean values were correct in the original briefing document, the standard errors were not correct and have been amended in the figure below.

Was:



Is amended to:

