Global Regulatory Affairs
Hospira Inc, a Pfizer company
275 North Field Drive, Bldg. H1-3S
Lake Forest, IL 60045

27 April 2021

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Division of Anesthesia and Analgesia Products
Food and Drug Administration
Center for Drug Evaluation and Research
Central Document Room
5901-B Ammendale Road
Beltsville, Maryland 20705-1266

Attention: Rigoberto Roca, MD, Director
Cc: Allison Meyer, Sr. Regulatory Health Project Manager

Re: NDA 021038/S10); IND 032934
PRECEDEX® (Dexmedetomidine HCl Injection)
RESPONSE TO PREA NON-COMPLIANCE LETTER

PMR 1772-1/Protocol C0801039 - A Phase 3/4 Randomized, Double-Blind, Dose-Ranging Study of The Safety And Efficacy Of Dexmedetomidine (Dex) Used With Propofol (Pro) As Needed For Procedural Sedation Of Pediatric Subjects ⩾1 Month To <17 Years Of Age Undergoing MRI Scans

Deferral Extension Request to 31 December 2022

Dear Dr Roca,

Hospira Inc., a Pfizer Company (Hospira), submitted a DEFERRAL EXTENSION REQUEST (dated 18 March 2021) to address Post Marketing Requirement (PMR) 1772-1 identified in the October 17, 2008 approval letter for NDA 21-038/S-010 (b) (4) Deferred pediatric study under PREA for the treatment of sedation of non-intubated patients prior to and/or during surgical and other procedures in pediatric patients 0 – 16 years of age.

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Reason for Delay

Protocol C0801039 was submitted to the Agency for review on 12 June 2018. The protocol was endorsed by the Agency on 19 September 2019 and Hospira submitted the final protocol on 23 September 2019. First Subject First Visit for study C0801039 took place on 18 February 2020 in Japan.

Completion of study C0801039 has been delayed due to the COVID-19 Pandemic. COVID-19 impacted hospital resources and study recruitment/subject enrolment with fewer sites able to continue research activities. Levels of recruitment remained low throughout 2020.

Hospira provided regular updates to FDA on the status of the study. Hospira notified FDA on 20 April 2020 (IND Serial 0595) to confirm that the study had started in February 2020, but that recruitment had been placed temporarily on hold due to the impact of the COVID-19 pandemic. The letter indicated that the PMR due date would likely need to be renegotiated.

During a telephone conversation on 06 July 2020, Lisa Zboril and Sarah Kilpatrick advised Allison Meyer, Sr. Regulatory Health Project Manager, that the study was running late due to recruitment challenges related to the COVID-19 pandemic. Ms Meyer indicated that many pharmaceutical companies were experiencing similar challenges. Additional emails relating to a strategy to increase recruitment were sent to FDA on 8 July 2020, 22 July 2020, and 11 September 2020.

Hospira submitted further updates on the status of study C0801039 on 01 September 2020 (IND Serial 0602) and 18 December 2020 (IND Serial 0607) and notified FDA that the PMR due date would need to be re-evaluated due to the recruitment challenges. Hospira indicated in those updates that it would reach out to FDA at a later date to negotiate a new PMR due date once it had more information about those recruitment challenges.

The deferral extension request was submitted on 18 March 2021 after the study had been re-baselined to take into account anticipated levels of recruitment in light of the ongoing pandemic and following the addition of new participating countries and study sites to mitigate this effect. The submission of the deferral request was delayed due to the challenges of anticipating when the study could be fully recruited and ongoing evaluation by Hospira of additional strategies to mitigate the delay to the completion of the study.

Based on the current rate of recruitment, the following projected dates are proposed:

Recruitment rates will continue to be monitored, especially in the most challenging to recruit youngest/eldest age groups. Updates will be provided to the Agency and there may be a need to further renegotiate the PREA due date, due to the ongoing challenges with recruitment during the pandemic.

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This submission has been scanned for viruses using McAfee VirusScan Enterprise Version 8.8 and is virus free. The submission is being sent via the Gateway.

Hospira considers the information submitted for NDA 021038 to be complete and ready for review. Hospira is committed to respond to the reviewers' questions promptly and to work with the Division as needed to facilitate this review.

Should you have any questions regarding this submission, please contact me via phone at 224-212-4617; or via e-mail at maria.hinklin@pfizer.com.

Sincerely,

Maria Hinklin
Associate Director
Global Regulatory Affairs

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