



November 9, 2015

Sharon Hertz, M.D.
Director, Division of Anesthesia, Analgesia and Addiction Products
Center for Drug Evaluation and Research
Food and Drug Administration
Center for Drug Evaluation and Research
5901-B Ammendale Road
Beltsville, MD 20705-1266

RE: NDA 21-038/S-010
IND 32,934 Serial No. 0584
Precedex™ (Dexmedetomidine Hydrochloride Injection)

RESPONSE TO PREA NON-COMPLIANCE LETTER

Dear Dr. Hertz:

Hospira, a Pfizer Company, hereby responds to the September 25, 2015 NOTIFICATION OF NON-COMPLIANCE WITH PREA for the above referenced new drug application. The notification indicated that the Post Marketing Requirement (PMR) for the Required Pediatric Assessment to satisfy the Pediatric Research Equity Act (PREA) requirement identified in the October 17, 2008 approval letter for NDA 21-038/S-010 had not been submitted.

The PMR final clinical study report (CSR) was submitted on August 28, 2015 prior to the August 31, 2015 deferral due date. The submission included the required, “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 to 16 years of age.” An acknowledgement notification was electronically received on August 28, 2015. (b) (4)

We note the November 6, 2015 email communication from Parinda Jani, Chief Project Management Staff, Division of Anesthesia, Analgesia, and Addiction Products which indicated that the NOTIFICATION OF NON-COMPLIANCE WITH PREA and this response would not be posted on the Agency’s website as indicated in the September 25, 2015 NOTIFICATION OF NON-COMPLIANCE WITH PREA letter.

For electronic signatures, a letter of non-repudiation for Steven Townsend is on file with the FDA. The files have been scanned for viruses using the current version of System Center Endpoint Protection virus scanning software. A copy of the information has been submitted to NDA 021038 (sequence 70 in the eCTD backbone).

Should you have any questions or require additional information, please contact Steven Townsend at 224-212-4636 or Lisa Zboril at 224-212-4654.

Sincerely,

A handwritten signature in black ink that reads "Steven Townsend".

Steven Townsend
Associate Director, Global Regulatory Affairs
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cc: c/o Matthew Bacho
Senior Regulatory Health PR
Division of Pediatric and Maternal Health
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