INCLINE THERAPEUTICS

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08 May 2013

RESPONSE TO PREA NON-COMPLIANCE LETTER

Bob A. Rappaport, MD
Director Food and Drug Administration
Center for Drug Evaluation and Research
Division of Anesthesia and Analgesia Products
5901-B Ammendale Road
Beltsville, MD 20705-1266

Re: NDA 21-338; Sequence No. 0303
IONSYS™ (fentanyl iontophoretic transdermal system)
Other: Response to PREA Non-compliance Letter;
Request for Deferral Extension for IONSYS Pediatric Study

Dear Dr. Rappaport,

Reference is made to NDA 21-338 for IONSYS™ (fentanyl iontophoretic transdermal system). Reference is also made to the Notification of Non-Compliance with PREA, dated 12 April 2013, regarding the deferred (22 May 2009) IONSYS pediatric study under PREA for the treatment of short-term management of acute post-operative pain in patients requiring opioid analgesia during hospitalization in pediatric patients ages 6 to 16 years of age.

The purpose of this submission is to respond to the Notificaton of Non-compliance with PREA and to request a deferral extension for the IONSYS pediatric study. The sponsor of the original approved product, ALZA Corporation/J&J Pharmaceutical Research and Development, did not launch or market IONSYS (b) (4). In June 2010, Incline Therapeutics, Inc. (Incline) acquired IONSYS and notified the FDA of the Transfer of Ownership of NDA 21-338 and IND (b) (4) to Incline.

In a Type C meeting on 15 February 2011 to discuss Incline's development program for IONSYS, the Agency stated that the post-marketing commitment for the pediatric study may be deferred until (b) (4) as the safety profile of IONSYS in adults must be better defined before pediatric studies can be initiated. (Please refer to the attached 15 February 2011 meeting minutes.)

(b) (4)

Therefore, at this time Incline requests a deferral extension for a pediatric study until after marketing approval of IONSYS.

If you have any questions or require any additional information, please do not hesitate to contact my colleague Deborah Ware, Director Regulatory Affairs, at deborah.ware@themedco.com, or call at (650) 241-6818.

Sincerely,

Patricia Oto, R.Ph.
Global Vice President
Regulatory Affairs and Quality Assurance
IONSYS Team
Incline Therapeutics, Inc.

cc: Please disseminate a copy of this letter to Dr. Lynne Yao of the Pediatric and Maternal Health Staff, CDER

Attachment 1 – AntiVirus Statement

DESCRIPTION OF THE ELECTRONIC SUBMISSION INCLUDING TYPE AND NUMBER OF ELECTRONIC MEDIA USED, APPROXIMATE SIZE OF THE SUBMISSION, STATEMENT THAT THE SUBMISSION IS VIRUS FREE, AND THE SOFTWARE USED TO CHECK THE FILES FOR VIRUSES

Number and Type of Electronic Media	Electronic transmission via ESG
Size of Submission	Approximately 20.0 MB
Virus Protection Statement	This submission is virus free.
Software Information	Symantec Endpoint Protection Version 11.0.5002.333

Application Point of Contact

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