VistaPharm

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29 March 2016

Sharon Hertz, MD, Director
Division of Anesthesia, Analgesia, and Addictive Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research
Central Document Room
Food and Drug Administration
5901-B Ammendale Road
Beltsville, Maryland 20705-1266

Re: NDA 201194
Oxycodone Hydrochloride Oral Solution 5 mg/5 mL
Sequence No.: 0032: PREA Deferral Request

RESPONSE TO PREA NON-COMPLIANCE LETTER

Dear Dr. Hertz:

Reference is made to the FDA Notification of Non-Compliance dated 02/03/15, which requested pediatric assessments for PMRs 1863-1 and 2, which were deferred until January 31, 2015.

Reference is also made to IND No. 105754/Cross Reference to NDA No. 201194.

Reference is made to the January 12, 2012 approval letter for Oxycodone Hydrochloride Oral solution and to the required Pediatric Assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients. Reference is made to the IND 105753, S-0003, 5.3.1.1.1 Interim Safety Report.

Reference is made to IND 105754. S-0002, May 29, 2013, PREA Protocol Number 20120004: A Phase IV Study to Evaluate the Pharmacokinetics and Safety of Oxycodone Oral Solution in Pediatric and Adolescent Subject.

Reference is made to S-0030, March 10, 2016, section, 1.13.12 – Status of Postmarketing Study Commitment, providing summary review of study.

On December 17, 2015, FDA requested a conference call with VistaPharrn [redacted] (b) (4) (b) (4) (b) (4) FDA went on to say they would like us to amend the protocol to collect more information on when a patient is issued rescue medication to include why they need rescue medications, what medications they were given, how did they do on the new medications, as well as did they have any adverse experiences. Ms. Fields also stated they understand this is a very difficult study in which to enroll subjects and, if we need an extension on time to completion, we should file a deferral request and the FDA would grant it.

At this time, VistaPharm, Inc. is submitting a deferral request where VistaPharm hereby commits to continue to gather the data and evaluation of the study and provide the agency summaries and comments. Additionally, VistaPharm commits to a second study that is a pharmacokinetic, safety, and efficacy study in subject from birth to 2 year of age. This study is based on Pk data that will be provided for the dose justification for the patient population, therefore the protocol is pending per completion of the first study.

The approximate size of this submission is 3 megabytes and is being submitted via the gateway. An antivirus scan was conducted using, Symantec Endpoint Protection version 11.0.4000.2295. Please do not hesitate to contact me by telephone at (727) 530-1633 or by email at jlay@vistapharm.com with any questions or comments.

Sincerely,

John G. Lay
Director, Regulatory Affairs
VistaPharm, Inc.

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