L V T Lehigh Valley Technologies, Inc.

514 North 12th Street • Allentown, PA 18102
Phone: 610-782-9780 • Fax: 610-782-9781

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2 February 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 200534
Oxycodone Hydrochloride Capsules, 5 mg
Sequence No. 0061: PREA Deferral Request

Dear Dr. Hertz:

Reference is made to the Lehigh Valley Technologies, Inc. (LVT) New Drug Application (NDA) 200534 for Oxycodone Hydrochloride Capsules, 5 mg approved pursuant to Section 505(b) of the Federal Food, Drug and Cosmetic Act. The NDA approval letter included a post-approval commitment to conduct Pediatric Assessments with a timeline for providing updates as follows:

1698-1 Pharmacokinetic, safety, and efficacy study in subjects from birth to 2 years of age.

Final Protocol Submission: August 2011
Trial Completion: November 2014
Final Report Submission: November 2015

1698-2 Pharmacokinetic and safety study in subjects >2 years to <17 years of age.

Final Protocol Submission: May 2011
Trial Completion: November 2013
Final Report Submission: May 2014

LVT submitted a pediatric study protocol outline requesting FDA comments on June 16, 2011. LVT received a general advice letter dated July 20, 2011 which included nine (9) comments/recommendations regarding the protocol outline. LVT then submitted a correspondence on October 23, 2012 to request a revision of the assessment timeline for the Final Protocol Submission with the intent of meeting the original Trial Completion and Final Report Submission dates.

(b) (4)

deficiencies. The study protocol was modified to address the nine (9) comments/recommendations that LVT received from FDA in our general advice letter of July 20, 2011. (b) (4) . The pediatric plan was released for study initiation by FDA on April 19, 2013. The study was initiated in May of 2013.

LVT submitted a deferral request on February 28, 2014. The deferral request did not include a request for extension of 1698-1 (birth to 2 years) based on:

1. As per the March 27, 2013 teleconference between FDA and (b) (4) LVT, FDA requested that the study for this age group not begin until an interim analysis of the PK data and safety be evaluated from the 2 – 17 year age group.

On August 25, 2015, the interim analysis from the 2-17 year age group was submitted to FDA and a meeting was requested to discuss (b) (4) the uncompleted portion of the PK study as well as the 0-2 year efficacy study.

(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.

As per 505B (a)(3), LVT is submitting a request for a deferral extension of our PREA post marketing requirements. Included with this submission are:

Deferral Request	Module 1.9.2
Evidence that the ongoing studies are proceeding	Module 1.9.2
Lehigh Valley Technologies, Inc. Certification	Module 1.9.2

The approximate size of this submission is 3 megabytes. All files have been scanned with Trend Micro™ Office Scan™ Antivirus Eng/Ptn: 9.850.1008/12.309.00.

Please do not hesitate to contact me by telephone at (610) 782-9780 ext. 18 or by email at breightler@lvtechinc.com with any questions or comments.

Sincerely,

William Reightler
Vice President of Regulatory Affairs
Lehigh Valley Technologies, Inc.

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