CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

200535Orig1s000

REMS

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NDA 200535 Oxycodone Hydrochloride Oral Solution (20 mg/mL)

Class of Product: Opioid Agonist

Lehigh Valley Technologies, Inc.
514 North 12th Street
Allentown, PA 18102

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RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I. GOAL:

The goal of this REMS is to inform patients about the serious risks associated with the use of Oxycodone Hydrochloride Oral Solution.

II. REMS ELEMENTS:

A. Medication Guide

Lehigh Valley Technologies, Inc. (LVT) will ensure that a currently approved Medication Guide will be dispensed with each Oxycodone Hydrochloride Oral Solution prescription in accordance with 21 CFR 208.24.

B. Timetable for Submission of Assessments

LVT will submit REMS Assessments to the FDA at, 18 months, 3 years, and 7 years from the date of approval of the REMS. To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 days before the submission date for that assessment. LVT will submit each assessment so that it will be received by the FDA on or before the due date.