DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

NDA 200535/S-004

SUPPLEMENT APPROVAL
RELEASE REMS REQUIREMENT

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

Attention: William Reightler
Director QA/Regulatory Affairs

Dear Mr. Reightler:

Please refer to your Supplemental New Drug Application (sNDA) dated and received September 27, 2011, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Oxycodone Hydrochloride Oral Solution, 100 mg/5mL (20 mg/mL).

We also acknowledge receipt of your risk evaluation and mitigation strategy (REMS) assessment dated January 3, 2012.

This supplemental new drug application proposes to eliminate the requirement for the approved Oxycodone Hydrochloride Oral Solution REMS.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Oxycodone Hydrochloride Oral Solution was originally approved on October 20, 2010. The REMS consists of a Medication Guide and a timetable for submission of assessments of the REMS.

You propose that FDA no longer require a REMS for Oxycodone Hydrochloride Oral Solution.

We have determined that maintaining the Medication Guide as part of the approved labeling is adequate to address the serious and significant public health concern and meets the standard in 21 CFR 208.1. Therefore, it is no longer necessary to include the Medication Guide as an element of the approved REMS to ensure that the benefits of Oxycodone Hydrochloride Oral Solution outweigh its risks.

We agree with your proposal, and a REMS for Oxycodone Hydrochloride Oral Solution is no longer required.

We remind you that the Medication Guide will continue to be part of the approved labeling for Oxycodone Hydrochloride Oral Solution in accordance with 21 CFR 208.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Sharon Turner-Rinehardt, Senior Regulatory Health Project Manager, at (301) 796-2254 or Katherine Won, Safety Regulatory Project Manager, at (301) 796-7568.

Sincerely,

{See appended electronic signature page}

Judith A. Racoosin, M.D., M.P.H.
Deputy Director for Safety
Division of Anesthesia, Analgesia, and
Addiction Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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/s/

KATHERINE S WON
01/24/2012

JUDITH A RACOOSIN
01/25/2012