Purdue Pharmaceutical Products L.P.

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June 23, 2016

GENERAL CORRESPONDANCE:
RESPONSE TO PREA NON-COMPLIANCE LETTER

Sharon Hertz, M.D., Director
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Anesthesia, Analgesia,
and Addiction Products
5901-B Ammendale Road
Beltsville, MD 20705-1266

Re: Dilaudid and Dilaudid-HP® Injection (hydromorphone hydrochloride)
NDA 019034, Sequence 0067

Dear Dr. Hertz:

Reference is made to the Agency's Required Pediatric Assessment of Dilaudid Injection under the Pediatric Equity Act (PREA) received with the Approval of S-018 on April 30, 2009. (b) (4) , Purdue's February 11, 2016 Type A Meeting Request: [Written Responses Only]; FDA's April 21, 2016 Written Responses; Purdue's March 1, 2016 Deferral Extension request; FDA's April 15, 2016 Deferral Extension denied; FDA's April 21, 2016 Notification of Non-Compliance with PREA and a June 3, 2016 FDA email requesting a response to the April 21st notification.

In addition, as you are aware, Dilaudid Injection covered under NDA 019034 is no longer being manufactured (b) (4) .

Based on the FDA's Notification of Non-Compliance and FDA's June 13, 2016 email, herein we are informing FDA that it is our intent to fulfill the obligation of the PREA requirement, and as such, plan to revise the program after the September 14 - 15, 2016 Pediatric Advisory Committee Meeting on appropriate pediatric development plans for prescription opioid drugs.

As a result of this meeting, we look forward to FDA issuance of guidance, as consideration and application of the recommendations will be critical to the development of the revised program.

Purdue certifies that the submission has successfully been scanned for potential viruses and is virus free using the virus scan program NOD32. The virus signature database and virus definition files are updated on a daily basis. If you have any questions regarding the information technology aspects of this submission only, please send them by electronic mail to RegulatorySubmissions@pharma.com.

For all other questions, please do not hesitate to contact me by telephone at (203) 588-7289, or by electronic mail at beth.connelly@pharma.com.

Sincerely,

{See appended electronic signature page}

Beth Connelly
Associate Director
Regulatory Affairs

Signature Page for 2016-06-23 cover letter dillaudid inject response to non comp
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Approval	Beth Connelly beth.connelly@pharma.com Regulatory 23-Jun-2016 12:51:25 GMT+0000