Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology
Office of Medication Error Prevention and Risk Management

DEFERRAL OF RISK EVALUATION AND MITIGATION STRATEGY (REMS) REVIEW

Date:	September 2, 2015
Reviewer(s)	Danny S. Gonzalez, Pharm.D., M.S. Risk Management Analyst Division of Risk Management (DRISK)
Team Leader	Kim Lehrfeld, Pharm.D, DRISK
Deputy Division Director (Acting):	Reema Mehta, Pharm.D, M.P.H., DRISK
Subject:	Defer comment on REMS modification to the Extended-Release/Long-Acting Opioid Analgesics REMS for Butrans
Drug Name(s):	Butrans (buprenorphine transdermal system)
Therapeutic class and Dosage Form:	Opioid; transdermal system
Application Type/Number:	NDA 21306
Applicant/sponsor:	Purdue Pharma L.P.
OSE RCM #	2014-2538

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This memo is to defer Division of Risk Management (DRISK) review of a risk evaluation and mitigation strategy (REMS) modification to the Extended-Release/Long-Acting Opioid Analgesics REMS (ER/LA REMS) for Butrans (buprenorphine transdermal system), NDA 21306.

(b) (4)

Therefore, DRISK defers comment on the proposed ER/LA REMS modification for Butrans (buprenorphine transdermal system) during this review cycle.

Evaluation of a proposed REMS modification for Butrans will be undertaken by DRISK when the Applicant (b) (4). Please send DRISK a new consult request at such time.

This memo serves to close the existing consult request to DRISK for Butrans (buprenorphine transdermal system) under NDA 21306.

[1] (b) (4)

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/s/

DANNY S GONZALEZ
09/02/2015

REEMA J MEHTA
09/02/2015
I concur.