CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

204803Orig1s000

RISK ASSESSMENT and RISK MITIGATION REVIEW(S)

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 Strategies (REMS) Review

Date:	January 17, 2014
Reviewer/Team Lead:	Kimberly Lehrfeld, PharmD, Risk Management Analyst
	Division of Risk Management (DRISK)
Division Director	Claudia Manzo, PharmD
	DRISK
Drug Name(s):	Posimir (SABER-Bupivacaine)
Therapeutic Class:	Local Anesthetic
Dosage and Route:	Solution for administration by instillation of 5mL directly into the surgical incision
Application Type/Number:	NDA 204803
Submission Number:	001
Applicant/sponsor:	Durect Corporation
OSE RCM #:	2013-1336, 2013-1300

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This document is to defer comment on the need for a risk evaluation and mitigation strategy (REMS) for Posimir (SABER-Bupivacaine).

On June 3, 2013, the Division of Analgesics, Anesthetics and Addiction Products (DAAAP) requested that the Division of Risk Management (DRISK) review the Risk Management Plan for Posimir (SABER-Bupivacaine) submitted with Posimir (SABER-Bupivacaine) for administration into the surgical incision to produce post-surgical analgesia.

Based on the review of clinical data submitted, the efficacy and safety Posimir (SABER-Bupivacaine) for administration into the surgical incision to produce post-surgical analgesia.cannot be established. Until the efficacy and safety profile of Posimir (SABER-Bupivacaine) is established, the benefits and risks of Posimir (SABER-Bupivacaine) cannot be adequately weighed and an appropriate risk management strategy cannot be determined. DAAAP plans to issue a Complete Response letter. Therefore, DRISK defers comment on the need for a REMS at this time.

A final discussion on the appropriate risk management strategy will be undertaken after the sponsor submits a satisfactory response to the Complete Response letter.

Please send DRISK a new consult request at such time. This memo serves to close the existing consult request for Posimir (SABER-Bupivacaine) under NDA 204803.

Please notify DRISK if you have any questions.

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/s/

KIMBERLY LEHRFELD
01/17/2014