CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

203858Orig1s000

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

Risk Evaluation and Mitigation Strategy (REMS) Review Addendum

Date:	**12/21/2012**
Reviewer(s):	Amarilys Vega, M.D., M.P.H, Medical Officer Division of Risk Management (DRISK)
Team Leader:	Cynthia LaCivita, Pharm.D., Team Leader DRISK
Drug Name(s):	Lomitapide (Juxtapid™)
Therapeutic Class:	Cholesterol-lowering agent
Dosage and Route:	Starting dose is 5 mg once daily, titrated up to 60 mg as tolerated, oral administration
Application Type/Number:	NDA 203858
Supplement # and Date Received:	Email submissions dated December 20 and 21, 2012
Applicant/sponsor:	Aegerion Pharmaceuticals, Inc.
OSE RCM #:	2012-603

*** This document contains proprietary and confidential information that should not be released to the public. ***

1 INTRODUCTION

This review documents DRISK's evaluation of the amended lomitapide REMS submitted by Aegerion via email on December 20 and 21, 2012.

2 MATERIALS REVIEWED

2.1 Materials submitted by Aegerion

- REMS document
- Prescriber Training Module
- Prescriber Enrollment Form
- Prescription Authorization Form
- Dear Healthcare Provider letter
- Dear Professional Association letter
- REMS Webpages
- REMS Supporting document

3 DISCUSSION AND RECOMMENDATIONS

DRISK reviewed and provided comments on the revised lomitapide REMS submitted by Aegerion via email on December 20 in response to the Agency's comments included in DRISK review addendum from December 19, 2012. Additional comments were sent to Aegerion on December 21, 2012 followed by a teleconference between Aegerion, the Division of Metabolism and Endocrinology Products (DMEP), and DRISK.

On December 21, 2012 Aegerion submitted via email an amended version of all REMS documents addressing comments from FDA.

DRISK finds the revised lomitapide REMS and REMS Supporting Document acceptable and recommends approval (see attachments).

Initial REMS Approval: 12/2012

NDA 203858

JUXTAPID (lomitapide) capsules

Drug Class: Microsomal Triglyceride Transfer Protein Inhibitor (MTP-I)

Aegerion Pharmaceuticals, Inc. (Aegerion)

101 Main Street Suite 1850

Cambridge, MA 02142

Telephone: 617-500-7795

RISK EVALUATION AND MITIGATION STRATEGY (REMS)

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

AMARILYS VEGA
12/21/2012

CYNTHIA L LACIVITA
12/21/2012
concur

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