

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

203858Orig1s000

CHEMISTRY REVIEW(S)

NDA 203-858

(Lomitapide mesylate) Capsules

Aegerion Pharmaceuticals

Xavier Ysern, PhD

ONDQA/ DNDQA III/ Branch VII

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CHEMISTRY REVIEW



Chemistry Review Data Sheet

Chemistry Review Data Sheet

1. NDA 203-585
2. REVIEW #: 3
3. REVIEW DATE: 03-Dec-2012
4. REVIEWER: Xavier Ysem, PhD
5. PREVIOUS DOCUMENTS:

Previous Documents

Document Date

Original		29-Feb-2012
Amendment Request for Proprietary Name Review	(b) (4)	01-Mar-2012
Amendment Request for Proprietary Name Review	(b) (4)	30-May-2012
Amendment Response to 08-May-2012 Quality Information Request	Seq. 0012	19-Jun-2012
Amendment Response to 27-Jun-2012 Quality Information Request	Seq. 0015	02-Jul-2012
Amendment Response to 27-Jun-2012 Quality Information Request (2, 6 & 7)	Seq. 0018	23-Jul-2012
Amendment Request for Proprietary Name Review	(b) (4) Seq. 0021	08-Aug-2012
Amendment Response to 19-Jul-2012 Quality Information Request	Seq. 0023	31-Aug-2012
Amendment Response to 06-Sep-2012 Quality Information Request	Seq. 0028	28-Sep-2012

6. SUBMISSION(S) BEING REVIEWED:

Submission(s) Reviewed

Document Date

Original Amendment Request for Proprietary Name Review (Juxtapid™) Seq. 0032

27-Nov-2012

7. NAME & ADDRESS OF APPLICANT:

Name: Aegerion Pharmaceuticals
 Address: 101 Main St., Suite 1850
 Cambridge, MA 02142
 Representative: Martha J. Carter
 Chief Regulatory Officer and Senior Vice President
 Telephone: 617-500-7795

8. DRUG PRODUCT NAME/CODE/TYPE:

a) Proprietary Name:

(b) (4) (proposed tradenames)
 (b) (4) not acceptable (29-May-2012)
 (b) (4) (03-Aug-2012)
 (b) (4) (not acceptable)
 Juxtapid™ (under review)
 Lomitapide Mesylate

b) Non-Proprietary Name (USAN):

c) Chem. Type/Submission Priority (ONDC only):

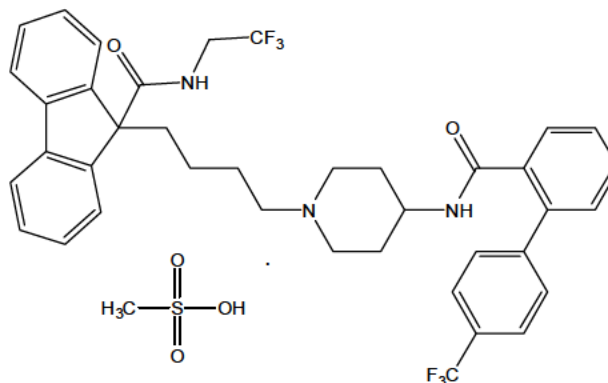
- Chem. Type: Type 1-New Molecular Entity
- Submission Priority: Standard

Chemistry Review Data Sheet

9. LEGAL BASIS FOR SUBMISSION: 505(b)(1)
Orphan Drug (Designation request 07-2459, granted for treatment of homozygous familial hypercholesterolemia on 23-Oct-2007)
10. PHARMACOL. CATEGORY: Microsomal triglyceride transfer protein (MTP) inhibitor.
Lipid altering agent.
[Indication: Treat homozygous familial hypercholesterolemia (HoFH) as an adjunct to diet and other lipid-lowering treatments.]
11. DOSAGE FORM: [Hard Gelatin] Capsules
12. STRENGTH/POTENCY: 5, 10, and 20 mg
13. ROUTE OF ADMINISTRATION: Oral
14. Rx/OTC DISPENSED: Rx
15. SPOTS (SPECIAL PRODUCTS ON-LINE TRACKING SYSTEM): Not a SPOTS product
16. CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOLECULAR WEIGHT:

Lomitapide Mesylate

Chemical Structure:



Molecular Formula: $C_{39}H_{37}F_6N_3O_2 \cdot CH_4O_3S$

Molecular Weight: 789.8 amu (693.7 + 96.1)

Chemical Name:

N-(2,2,2-trifluoroethyl)-9-[4-[4-[[4'-(trifluoromethyl)[1,1'-biphenyl]-2-yl]carbonyl]amino]-1-piperidinyl]butyl]-9*H*-fluorene-9-carboxamide, methanesulfonate salt

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