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*APPLICATION NUMBER:*

**202408Orig1s000**

**SUMMARY REVIEW**

## Deputy Division Director and Cross-Discipline Team Leader Review NDA 202408

<b>Date</b>	March 28, 2019
<b>From</b>	Wiley Chambers, M.D.; William M. Boyd, M.D.
<b>Subject</b>	Deputy Division Director and Cross Discipline Team Leader Review
<b>NDA #</b>	202408
<b>Applicant</b>	Fera Pharmaceuticals, Inc.
<b>Application Type</b>	505(b)(2)
<b>Name</b>	Avaclyr (acyclovir ophthalmic ointment) 3%
<b>Dosage forms / Strength</b>	Topical ophthalmic ointment
<b>Proposed Indication(s)</b>	treatment of acute herpetic keratitis (dendritic ulcers)
<b>Regulatory Action:</b>	Approval

NDA 202408, Avaclyr (acyclovir ophthalmic ointment) 3%, will be approved for the treatment of acute herpetic keratitis (dendritic ulcers).

Reference is made to the Office of New Drugs, Director Memorandum in DARRTS dated 3/28/2019, which supports proceeding with the approval of NDA 202408, Avaclyr (acyclovir ophthalmic ointment 3%) and addresses the Deputy Division Director's appeal of the Agency's previous actions on this NDA.

This is a 505(b)(2) application referencing two data sources for approval: an FDA-approved listed drug (i.e., Zovirax topical ointment (5%) under NDA 18604 for nonclinical studies) and the literature reports of adequate and well controlled clinical studies evaluating the use of acyclovir 3% ophthalmic ointment in the treatment of acute herpetic keratitis. The Office of New Drugs, Director memorandum has addressed the deficiencies cited in the 3/31/2014 and 6/24/2016 Complete Response letters to the applicant.

A safety update to the NDA was submitted by Fera Pharmaceuticals, LLC on 11/27/2018, stating that Fera is not aware of any new safety or efficacy information regarding acyclovir ophthalmic ointment. They have no new safety or efficacy information to provide to the Agency at this time. The trademark, Avaclyr, has been re-reviewed and found to be acceptable.

Upon re-review, the Division of Medication Error Prevention and Analysis (DMEPA) found the proposed proprietary name, Avaclyr, acceptable from both a promotional and safety perspective. The Office of Prescription Drug Promotion (OPDP) completed a review of the substantially complete labeling on 2/25/14 in a previous review cycle.

NDA 202408, Avaclyr (acyclovir ophthalmic ointment) 3%, will be approved for the treatment of acute herpetic keratitis (dendritic ulcers) as previously recommended in the Deputy Division Director's Reviews dated March 15, 2014, and June 21, 2016, with the attached labeling in this review.

5 Pages of Draft Labeling have been Withheld in Full as B4 (CCI/TS) immediately following this page

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/s/

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WILLIAM M BOYD  
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WILEY A CHAMBERS  
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