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RESEARCH**

*APPLICATION NUMBER:*

**214187Orig1s000**

**SUMMARY REVIEW**

## Clinical Review, Cross-Discipline Team Leader Review and Division Director Summary Review

<b>Date</b>	May 28, 2021
<b>From</b>	Samer El-Kamary, MD, MPH Yodit Belew, MD, Cross-Discipline Team Leader Poonam Mishra, MD, MPH, Deputy Division Director (Safety)
<b>Subject</b>	Combined Clinical Review, Cross-Discipline Team Leader Review and Division Director Summary Review
<b>NDA# and Supplement#</b>	208341/Supplement 17; 214187 (Original)
<b>Applicant</b>	Gilead Sciences, Incorporated.
<b>Date of Submission</b>	December 15, 2020
<b>PDUFA Goal Date</b>	June 14, 2021
<b>Proprietary Name</b>	Epclusa®
<b>Established or Proper Name</b>	Sofosbuvir/Velpatasvir (SOF/VEL)
<b>Dosage Form(s)</b>	Oral tablets: <ul style="list-style-type: none"> <li>▪ 400 mg of sofosbuvir and 100 mg of velpatasvir</li> <li>▪ 200 mg sofosbuvir and 50 mg of velpatasvir</li> </ul> Oral pellets: <ul style="list-style-type: none"> <li>▪ 200 mg sofosbuvir and 50 mg of velpatasvir</li> <li>▪ 150 mg sofosbuvir and 37.5 mg of velpatasvir</li> </ul>
<b>Applicant Proposed Indication(s)/Population(s)</b>	Pediatric Patients 3 to < 6 years of age: For treatment of genotype 1, 2, 3, 4, 5 or 6 chronic HCV infection
<b>Applicant Proposed Dosing Regimen(s)</b>	Weight based dosing (see Table 2)
<b>Recommendation on Regulatory Action</b>	Approval

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