# CENTER FOR DRUG EVALUATION AND RESEARCH

***APPLICATION NUMBER:***

# 214187Orig1s000

# SUMMARY REVIEW

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

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|---|---|
| **Date** | May 28, 2021 |
| **From** | Samer El-Kamary, MD, MPH<br>Yodit Belew, MD, Cross-Discipline Team Leader<br>Poonam Mishra, MD, MPH, Deputy Division Director (Safety) |
| **Subject** | Combined Clinical Review, Cross-Discipline Team Leader Review and Division Director Summary Review |
| **NDA# and Supplement#** | 208341/Supplement 17; 214187 (Original) |
| **Applicant** | Gilead Sciences, Incorporated. |
| **Date of Submission** | December 15, 2020 |
| **PDUFA Goal Date** | June 14, 2021 |
| **Proprietary Name** | Epclusa® |
| **Established or Proper Name** | Sofosbuvir/Velpatasvir (SOF/VEL) |
| **Dosage Form(s)** | Oral tablets:<br>▪ 400 mg of sofosbuvir and 100 mg of velpatasvir<br>▪ 200 mg sofosbuvir and 50 mg of velpatasvir<br>Oral pellets:<br>▪ 200 mg sofosbuvir and 50 mg of velpatasvir<br>▪ 150 mg sofosbuvir and 37.5 mg of velpatasvir |
| **Applicant Proposed Indication(s)/Population(s)** | Pediatric Patients 3 to < 6 years of age: For treatment of genotype 1, 2, 3, 4, 5 or 6 chronic HCV infection |
| **Applicant Proposed Dosing Regimen(s)** | Weight based dosing (see Table 2) |
| **Recommendation on Regulatory Action** | Approval |

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