# CENTER FOR DRUG EVALUATION AND RESEARCH

***APPLICATION NUMBER:***

# 209195Orig1s000

# CLINICAL REVIEW(S)

# CLINICAL REVIEW

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| **Application Type** | New Drug Application |
| **Application Number(s)** | 209195 |
| **Priority or Standard** | Priority |
| **Submit Date(s)** | December 8, 2016 |
| **Received Date(s)** | December 8, 2016 |
| **PDUFA Goal Date** | August 8, 2017 |
| **Division/Office** | Division of Antiviral Products/Office of Antimicrobial Products |
| **Reviewer Name(s)** | Kirk Chan-Tack, MD |
| **Review Completion Date** | May 5, 2017 |
| **Established Name** | sofosbuvir and velpatasvir and voxilaprevir |
| **(Proposed) Trade Name** | Vosevi® |
| **Applicant** | Gilead Sciences, Inc. |
| **Formulation(s)** | Fixed dose combination tablet containing 400 mg sofosbuvir and 100 mg velpatasvir and 100 mg voxilaprevir |
| **Dosing Regimen** | One tablet orally once daily |
| **Applicant Proposed Indication(s)/Population(s)** | Treatment of adult patients with chronic hepatitis C virus infection |
| **Recommendation on Regulatory Action** | Approval |
| **Recommended Indication(s)/Population(s)** (if applicable) | Treatment of adult patients with chronic hepatitis C virus infection |

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