

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**212480Orig1s000**

**MULTI-DISCIPLINE REVIEW**

**Summary Review**

**Office Director**

**Cross Discipline Team Leader Review**

**Clinical Review**

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

<b>Date</b>	August 27, 2019
<b>From</b>	Samer El-Kamary, MD, MPH, Medical Officer Kimberly Struble, PharmD, Cross Discipline Team Leader Debra Birnkrant, MD, Division Director
<b>Subject</b>	Combined Clinical Review, Cross-Discipline Team Leader Review and Division Director Summary Memo
<b>NDA# and Supplement#</b>	204671/Supplement 14 NDA 212480
<b>Applicant</b>	Gilead Sciences, Incorporated.
<b>Date of Submission</b>	February 28, 2019
<b>PDUFA Goal Date</b>	August 28, 2019
<b>Proprietary Name</b>	Sovaldi
<b>Established or Proper Name</b>	sofosbuvir (SOF)
<b>Dosage Form(s)</b>	Oral tablets: 200 mg Oral pellets: 150 mg and 200 mg
<b>Applicant Proposed Indication(s)/Population(s)</b>	Pediatric Patients 3 to < 12 years of age: For treatment of genotype 2 or genotype 3 HCV infection
<b>Applicant Proposed Dosing Regimen(s)</b>	Weight based dosing (see <a href="#">Table 3</a> in Labeling)
<b>Recommendation on Regulatory Action</b>	Approval

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