

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**206843Orig1s001, s003**

**CHEMISTRY REVIEW(S)**

**ONDP Division of New Drug Products-I  
Quality Assessment for Efficacy or Labeling Supplement**

**DAKLINZA (daclatasvir) tablets  
30 & 60 mg**

**BMS**

**NDA 206-843**

<b>S-001:</b>	<b>EDR-052</b>	<b>SD-68</b>	<b>August 5, 2015</b>
<b>S-002:</b>	<b>EDR-053</b>	<b>SD-69</b>	<b>August 5, 2015</b>
<b>S-003:</b>	<b>EDR-057</b>	<b>SD-84</b>	<b>Sept 1, 2015</b>

<b>Submission Date:</b>	<b>as above</b>
<b>GRMP Date:</b>	<b>Jan 12, 2016</b>
<b>PDUFA Date:</b>	<b>Feb 5, 2016</b>

**Summary:**

These efficacy supplements provide for these changes:

- S-001: expands the indication to include post liver transplant patients
- S-002: expands indication to include HIV-1 co-infected patients
- S-003: expands the indication to include decompensated cirrhotic patients

No CMC information is included in Module 2, and there is no Module 3.

There are no changes to the Description or How Supplied sections of the Prescribing Information, and no CMC-related edits to the Patient Information and Patient Counseling Information sections. No container labels are provided. This was verified on Sept 22 in the combined draft labeling on the DAVP Share Point.

This is all consistent with the use of the currently approved products, without any change to the dosage form, container/closure or CMC-related labeling.

In Section 1.12, the applicant requests a categorical exclusion from the requirements to prepare an Environmental Assessment. Although some increase in use of the drug may result from the change in labeling, the supplement meets the requirements of a categorical exclusion under:

- 21 CFR §25.31(b) because the estimated concentration of the active drug substance at the point of entry, referred to as the Expected Introduction Concentration (EIC), into the aquatic environment will be below 1 part per billion (ppb). The applicant states that no extraordinary circumstances exist, as referenced in 21 CFR 25.21(a).

**Conclusions:**

These supplements are recommended for filing and for approval from the Product Quality perspective. The only CMC issue is the categorical exclusion from the requirement to perform an environmental assessment. This should be granted, since the applicant has provided an appropriate claim per 21 CFR §25.31.

**Stephen  
Miller -S**

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Stephen P. Miller, Ph.D.

CMC-Lead

**Balajee  
Shanmugam -  
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Balajee Shanmugam, Ph.D.

Acting Branch Chief

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/s/  
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ROBYN S JORDON  
02/17/2016