

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**206545Orig1s000**

**MICROBIOLOGY / VIROLOGY REVIEW(S)**

**PRODUCT QUALITY MICROBIOLOGY NON-STERILE  
DRUG PRODUCT FILING CHECKLIST**

**NDA Number:** 206-545      **Applicant:** Gilead Sciences      **Letter Date:** 06 December 2013  
**Drug Name:** Idelalisib      **NDA Type:** NME NDA      **Stamp Date:** 06 December 2013  
**Dosage Form:** Oral tablet      **Reviewer:** Jessica Cole, PhD

This NDA refers to NDA 205-858 for all CMC information and is fileable.

Jessica Cole, PhD      31 January 2014  
\_\_\_\_\_  
Reviewing Microbiologist      Date

Bryan Riley, PhD  
\_\_\_\_\_  
Microbiology Team Leader      Date

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/s/  
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JESSICA COLE  
01/31/2014

BRYAN S RILEY  
01/31/2014  
I concur.

MEMORANDUM



DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION  
CENTER FOR DRUG EVALUATION AND RESEARCH

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**DATE:** 02 January 2014

**TO:** NDA 205858  
NDA 206545 (references NDA 205858 for all CMC information)

**FROM:** Jessica G. Cole, PhD  
Review Microbiologist  
CDER/OPS/New Drug Microbiology Staff

**THROUGH:** Bryan Riley, PhD  
Microbiology Team Leader  
CDER/OPS/New Drug Microbiology Staff

**cc:** Mara Bauman Miller  
Regulatory Health Project Manager  
CDER/OND/OHOP/DHP

**SUBJECT:** Product Quality Microbiology assessment of Microbial Limits for  
Idelalisib [Submission Date: 11 September 2013]

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**The Microbial Limits specification for Idelalisib is acceptable from a Product Quality Microbiology perspective. Therefore, this submission is recommended for approval from the standpoint of product quality microbiology.**

Idelalisib is a coated tablet for oral administration. The tablets are provided in a 100 mg and 150 mg strength and are intended for treatment of refractory non-Hodgkin lymphoma.

The manufacturing process consists of [REDACTED] (b) (4)

[REDACTED]

The applicant conducted microbial limits testing on all drug product lots during development. On-going stability studies include microbial limits testing at 6, 12, and 24 months. All stability and release results demonstrated [REDACTED] (b) (4)

[REDACTED] (b) (4)

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/s/  
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JESSICA COLE  
01/02/2014

BRYAN S RILEY  
01/02/2014  
I concur.