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RESEARCH**

*APPLICATION NUMBER:*

**202806Orig1s000**

**MICROBIOLOGY REVIEW(S)**

# Product Quality Microbiology Review

12 FEBRUARY 2013

**NDA:** 202806

**Drug Product Name**

**Proprietary:** (b) (4)

**Non-proprietary:** dabrafenib

**Review Number:** 1

**Dates of Submission(s) Covered by this Review**

<b>Submit</b>	<b>Received</b>	<b>Review Request</b>	<b>Assigned to Reviewer</b>
29 July 2012	30 July 2012	7 August 2012	9 August 2012
4 February 2013	4 February 2013	N/A	N/A

**Submission History (for amendments only):** N/A

**Applicant/Sponsor**

**Name:** GlaxoSmithKline, LLC

**Address:** One Franklin Plaza, 200 North 16th Street, Philadelphia, PA 19102

**Representative:** Ellen Cutler, Senior Director, Regulatory Affairs, Oncology

**Telephone:** 610-917-6823

**Name of Reviewer:** Bryan S. Riley, Ph.D.

**Conclusion:** Recommended for Approval

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## Product Quality Microbiology Data Sheet

- A.
1. **TYPE OF SUBMISSION:** Original NDA 505(b)(1)
  2. **SUBMISSION PROVIDES FOR:** A new drug product
  3. **MANUFACTURING SITES:**  
GlaxoSmithKline Inc.  
 (b) (4)  
 (b) (4)
  4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** Capsule for oral administration, 50 and 75 mg.
  5. **METHOD(S) OF STERILIZATION:** N/A
  6. **PHARMACOLOGICAL CATEGORY:** Oncology
- B. **SUPPORTING/RELATED DOCUMENTS:** N/A
- C. **REMARKS:** This was an eCTD submission. A Microbiology Information Request was sent to the applicant on 29 January 2013. The applicant responded in an amendment dated 4 February. The text of the IR and the review of the response are included in the Product Quality Microbiology Assessment section.

**filename:** N202806R1.doc

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## **Executive Summary**

### **I. Recommendations**

- A. Recommendation on Approvability** - Recommended for Approval.
- B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable** – N/A

### **II. Summary of Microbiology Assessments**

- A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology** – The drug product is a non-sterile capsule for oral administration.
- B. Brief Description of Microbiology Deficiencies** – N/A
- C. Assessment of Risk Due to Microbiology Deficiencies** – N/A

### **III. Administrative**

- A. Reviewer's Signature** \_\_\_\_\_  
Bryan S. Riley, Ph.D.  
Senior Review Microbiologist, OPS/NDMS
- B. Endorsement Block** \_\_\_\_\_  
John W. Metcalfe, Ph.D.  
Senior Review Microbiologist, OPS/NDMS
- C. CC Block**  
N/A

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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BRYAN S RILEY  
02/13/2013

JOHN W METCALFE  
02/13/2013  
I concur.