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RESEARCH**

APPLICATION NUMBER:

202570Orig1s000

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

1 August 2011

NDA: 202-570

Drug Product Name

Proprietary: Crizotinib

Non-proprietary: PF -02341066

Review Number: 1

Dates of Submission(s) Covered by this Review

Submit	Received	Review Request	Assigned to Reviewer
30 March 2011	30 March 2011	5 May 2011	11 May 2011
27 July 2011	27 July 2011	N/A	N/A

Submission History (for amendments only): N/A

Applicant/Sponsor

Name: Pfizer Inc.

Address: 10646 Science Center Drive
San Diego, CA 92121

Representative: Ron Domingo

Telephone: 858-622-3234

Name of Reviewer: Stephen E. Langille, Ph.D.

Conclusion: Recommended for approval

Product Quality Microbiology Data Sheet

- A.**
- 1. TYPE OF SUBMISSION:** Original NDA
 - 2. SUBMISSION PROVIDES FOR:** The manufacture of a solid oral drug product.
 - 3. MANUFACTURING SITE:**
Pfizer Manufacturing
Deutschland GmbH
Betriebsstätte Freiburg,
Mooswaldallee 1
79090 Freiburg, Germany
 - 4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:**
 - Oral
 - Capsule
 - 200 mg and 250 mg
 - 5. METHOD(S) OF STERILIZATION:** Not applicable
 - 6. PHARMACOLOGICAL CATEGORY:** Cancer treatment
- B. SUPPORTING/RELATED DOCUMENTS:** Not applicable
- C. REMARKS:** The submission was provided in eCTD format. A product quality microbiology information request was sent to the applicant in June of 2011.

filename: N202570R1.doc

Executive Summary

I. Recommendations

- A. Recommendation on Approvability -**
NDA 202- (b) (4) is recommended for approval from the standpoint of product quality microbiology.
- B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable -**
Not applicable

II. Summary of Microbiology Assessments

- A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology -**
The drug product will be (b) (4) dispensed into gelatin capsules.
- B. Brief Description of Microbiology Deficiencies -**
No product quality microbiology deficiencies were identified based upon the information provided.
- C. Assessment of Risk Due to Microbiology Deficiencies -**
Not applicable

III. Administrative

- A. Reviewer's Signature** _____
Stephen E. Langille
- B. Endorsement Block**
James McVey – Team Leader
- C. CC Block**
N/A

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/s/

STEPHEN E LANGILLE
08/01/2011

JAMES L MCVEY
08/01/2011
I concur.