CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

202324Orig1s000

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

06 January 2012

NDA: 202-324/N000

Drug Product Name
Proprietary: INLYTA
Non-proprietary: Axitinib

Review Number: 2

Dates of Submission(s) Covered by this Review

Submit	Received	Review Request	Assigned to Reviewer
21 December 2011 (SD 24)	22 December 2011	NA	NA

Submission History (for amendments only) –

Submit Date(s)	Microbiology Review #	Review Date(s)
14 April 2011	1	12 December 2011

Applicant/Sponsor
Name: Pfizer, Inc.
Address: 10646 Science enter Drive
San Diego CA 92121
Representative: Alison Russell, Worldwide Regulatory Strategy
Telephone: (858) 622-3234

Name of Reviewer: Denise A. Miller

Conclusion: Approve

Product Quality Microbiology Data Sheet

A. 1. TYPE OF SUBMISSION: Original New Drug Application

2. SUBMISSION PROVIDES FOR: The manufacture of a tablet drug product.

3. MANUFACTURING SITE:

Pfizer Manufacturing Deutcshland GmbH
Betriebsstatte Freiburg
Mooswaldallee 1
79090 Freiburg Germany

4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:

- Tablet
- Oral, Immediate Release
- 1 and 5 mg /tablet

5. METHOD(S) OF STERILIZATION: not sterile

6. PHARMACOLOGICAL CATEGORY: tyrosine kinase inhibitor used for the treatment for advanced renal cell carcinoma

B. SUPPORTING/RELATED DOCUMENTS: NA

C. REMARKS:
1) Application is in e-CTD format.

filename: N202324N000R2.doc

Executive Summary

I. Recommendations

A. Recommendation on Approvability – The recommendation is to approve this submission from a quality microbiology standpoint.

B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable - NA

II. Summary of Microbiology Assessments

A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology – Formulated powders are (b) (4) film coated and packaged. This is a non-sterile drug product.

B. Brief Description of Microbiology Deficiencies – None

C. Assessment of Risk Due to Microbiology Deficiencies – NA

III. Administrative

A. Reviewer's Signature _____

Denise A. Miller
Microbiologist, NDMS

B. Endorsement Block _____

Stephen E. Langille
Senior Microbiologist, NDMS

C. CC Block

N/A

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/s/

DENISE A MILLER
01/09/2012

STEPHEN E LANGILLE
01/09/2012

Product Quality Microbiology Review

12 December 2011

NDA: 202-324/N000

Drug Product Name
Proprietary: INLYTA
Non-proprietary: Axitinib

Review Number: 1

Dates of Submission(s) Covered by this Review

Submit	Received	Review Request	Assigned to Reviewer
14 April 2011	14 April 2011	17 May 2011	17 May 2011
28 October 2011	28 October 2011	NA	NA

Submission History (for amendments only) – NA

Applicant/Sponsor
Name: Pfizer, Inc.
Address: 10646 Science enter Drive
San Diego CA 92121
Representative: Alison Russell, Worldwide Regulatory Strategy
Telephone: (858) 622-3234

Name of Reviewer: Denise A. Miller

Conclusion: Approvable pending resolution of quality microbiological deficiencies listed on page 9.

Product Quality Microbiology Data Sheet

A. 1. TYPE OF SUBMISSION: Original New Drug Application

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- Tablet
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- 1 and 5 mg /tablet

5. METHOD(S) OF STERILIZATION: not sterile

6. PHARMACOLOGICAL CATEGORY: tyrosine kinase inhibitor used for the treatment for advanced renal cell carcinoma

B. SUPPORTING/RELATED DOCUMENTS: NA

C. REMARKS:

1) Application is in e-CTD format.
2) Consult requested evaluation of Pfizer's request exclude microbial limit testing as a release test. The testing was also excluded in the stability program.
3) Information request #1 was sent on 26 September 2011. A response was received on 28 October 2011.

filename: N202324N000R1.doc

Executive Summary

I. Recommendations

A. Recommendation on Approvability - This submission is approvable pending resolution of microbiological deficiencies.

B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable - NA

II. Summary of Microbiology Assessments

A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology – Formulated powders are (b) (4) film coated and packaged. This is a non-sterile drug product.

B. Brief Description of Microbiology Deficiencies – Lack of microbial testing on the final product for either release or stability was not sufficiently justified.

C. Assessment of Risk Due to Microbiology Deficiencies – There is a small risk to the patient to ingest contaminated product as a result of the deficiencies.

III. Administrative

A. Reviewer's Signature _____

Denise A. Miller
Microbiologist, NDMS

B. Endorsement Block _____

Bryan S. Riley,
Senior Microbiologist, NDMS

C. CC Block

N/A

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/s/

DENISE A MILLER
12/12/2011

BRYAN S RILEY
12/13/2011
I concur.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

CMC MICROBIOLOGY AND STERILITY ASSURANCE REVIEW REQUEST

TO *(Division/Office)*: **New Drug Microbiology Staff**

Email to: **CDER OPS IO MICRO**

Mail to: **WO Bldg 51, Room 4193**

FROM: Don Henry

PROJECT MANAGER *(if other than sender):*

REQUEST DATE	IND NO.	NDA NO.	TYPE OF DOCUMENT	DATE OF DOCUMENT
5/17/2011		202324	Original NDA submission	4/14/2011

NAMES OF DRUG	PRIORITY CONSIDERATION	PDUFA DATE	DESIRED COMPLETION DATE
axitinib	standard	February 14, 2012	September 14, 2011

NAME OF APPLICANT OR SPONSOR: Pfizer

GENERAL PROVISIONS IN APPLICATION

- ☐ 30-DAY SAFETY REVIEW NEEDED
- ☐ NDA FILING REVIEW NEEDED BY: _____
- ☐ BUNDLED
- ■ DOCUMENT IN EDR
- ☐ CBE-0 SUPPLEMENT
- ☐ CBE-30 SUPPLEMENT
- ☐ CHANGE IN DOSAGE, STRENGTH / POTENCY

COMMENTS / SPECIAL INSTRUCTIONS:

This is a NME. For this solid oral tablet, the sponsor has provided justification for not including the microbial limits testing as part of the specification.

SIGNATURE OF REQUESTER

Don L. Henry

REVIEW REQUEST DELIVERED BY (Check one):

☐ DARRTS ☐ EDR ■ E-MAIL ☐ MAIL ☐ HAND

DOCUMENTS FOR REVIEW DELIVERED BY (Check one):

☐ EDR ■ E-MAIL ☐ MAIL ☐ HAND

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/s/

DON L HENRY
05/17/2011