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RESEARCH**

APPLICATION NUMBER:

202192Orig1s000

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

23 August 2011

NDA: 202192/N-000

Drug Product Name

Proprietary:

N/A.

Non-proprietary:

ruxolitinib phosphate.

Review Number:

1.

Dates of Submission(s) Covered by this Review

Submit	Received	Review Request	Assigned to Reviewer
03 JUN 2011	03 JUN 2011	29 JUN 2011	30 JUN 2011

Applicant/Sponsor

Name:

Incyte Corporation.

Address:

Route 141 & Henry Clay Road.

Building 336

Wilmington, DE 19880

Representative:

Ronald C. Falcone, Ph.D.

Telephone:

302-498-6846

Name of Reviewer:

John W. Metcalfe, Ph.D.

Conclusion:

Recommended for approval.

Product Quality Microbiology Data Sheet

- A.**
- 1. TYPE OF SUBMISSION:** A 505(b)(1) NDA.
 - 2. SUBMISSION PROVIDES FOR:** Marketing authorization.
 - 3. MANUFACTURING SITE:**
DSM Pharmaceuticals, Inc.
5900 Martin Luther King Jr. Highway
Greenville, NC 27834
 - 4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:**
 - Tablet.
 - Oral.
 - 5, 10, 15, 20 and 25 mg.
 - 5. METHOD(S) OF STERILIZATION:** Not applicable, the product is not sterile.
 - 6. PHARMACOLOGICAL CATEGORY:** The subject drug product is indicated for the treatment of myelofibrosis.
- B. SUPPORTING/RELATED DOCUMENTS:** None.
- C. REMARKS:**
The subject NDA is submitted electronically in the CTD format.

File Name: N202192R1.doc

Executive Summary

I. Recommendations

- A. **Recommendation on Approvability** – NDA 202192/N-000 is recommended for approval on the basis 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** -  (b) (4)
- B. **Brief Description of Microbiology Deficiencies** - There are no microbiology deficiencies identified.
- C. **Assessment of Risk Due to Microbiology Deficiencies** – Not applicable.

III. Administrative

- A. **Reviewer's Signature** _____
John W. Metcalfe, Ph.D.
- B. **Endorsement Block** _____
Bryan S. Riley, Ph.D.
- C. **CC Block**
N/A

3 Page(s) has been Withheld in Full as b4 (CCI/TS) immediately following this page

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

JOHN W METCALFE
08/23/2011

BRYAN S RILEY
08/23/2011
I concur.