CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-065

MICROBIOLOGY REVIEW

Product Quality Microbiology Review

Review for Division of Oncology Drug Products

21 September 2007

NDA: 22-065

Drug Product Name
Proprietary: IXEMPRA considered
Non-proprietary: Ixabepilone
Drug Product Priority Classification: S1

Review Number: 1

Dates of Submission(s) Covered by this Review

Letter	Stamp	Consult Sent	Assigned to Reviewer
April 16, 2007	April 16, 2007	June 6, 2007	June 13, 2007

Submission History (for amendments only) NA

Applicant/Sponsor
Name: Bristol-Meyers Squibb Company
Address: 5 Research Parkway, Wallingford, CT 06492
Representative: A. Heather Knight-Trent, Director Global Regulatory Science
Telephone: 203-677-3858

Name of Reviewer: Vinayak B. Pawar, Ph.D.

Conclusion: The application is recommended for approval from microbiology product quality standpoint.

Product Quality Microbiology Data Sheet

A. 1. **TYPE OF SUBMISSION:** Original NDA

2. **SUBMISSION PROVIDES FOR:** New drug Ixabepilone.

3. **MANUFACTURING SITE:** Baxter Oncology facility at Halle, Germany.

4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** Lyophilized powder in 15 mg/vial and 45 mg/vial plus vehicle for constitution for intravenous injection.

5. **METHOD(S) OF STERILIZATION:** ———

6. **PHARMACOLOGICAL CATEGORY:** Metastatic or locally advanced breast cancer.

B. **SUPPORTING/RELATED DOCUMENTS:** None

C. **REMARKS:** The consult requests review of an Original NDA 22-065 for the drug product Ixabepilone to be manufactured at Baxter Halle, Germany facility. The application was submitted in electronic format following the electronic CTD structure. Initial IQA was filed in DFS on April 16, 2007.

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Executive Summary

I. Recommendations

A. Recommendation on Approvability -
The application is recommended for approval based on microbiology product quality safety issues.

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 – The product is filled in a 15mg/vial and 45mg/vial presentation with a compatible vehicle for constitution vial with each format. Both the product and the vehicle are [redacted] in separate vials and packaged together as a single unit. The filling equipment, containers and closures used in filling both the product and the [redacted]

B. Brief Description of Microbiology Deficiencies - NA

C. Assessment of Risk Due to Microbiology Deficiencies - NA

III. Administrative

A. Reviewer's Signature _____
Vinayak B. Pawar, Ph.D.

B. Endorsement Block _____
Bryan Riley, Ph.D.

C. CC Block
N/A

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15 Page(s) Withheld

9 Trade Secret / Confidential

_____ Draft Labeling

_____ Deliberative Process

Withheld Track Number: Microbiology-_____

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

/s/

Vinayak Pawar
9/28/2007 12:19:42 PM
MICROBIOLOGIST

Recommended for Approval from microbiology product quality standpoint

Bryan Riley
9/28/2007 12:31:02 PM
MICROBIOLOGIST