

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
NDA 22-090

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

21 DECEMBER 2007

NDA: 22-090

Drug Product Name

Proprietary: PRIMOVIST

Non-proprietary: Gadoxetate Disodium

Drug Product Priority Classification: S

Review Number: 1

Dates of Submission(s) Covered by this Review

Letter	Stamp	Review Request	Assigned to Reviewer
6/29/2007	7/2/2007	7/25/2007	7/26/2007
10/11/2007	10/12/2007	N/A	N/A

Submission History (for amendments only): N/A

Applicant/Sponsor

Name: Bayer Healthcare Pharmaceuticals Inc.

Address: PO Box 1000, 340 Changebridge Road, Montville, NJ 07045

Representative: Dr. Sibylle Jennings

Telephone: 973-487-2027

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

Conclusion: Recommended for Approval

Product Quality Microbiology Data Sheet

- A.
1. **TYPE OF SUBMISSION:** Original New Drug Application
 2. **SUBMISSION PROVIDES FOR:** A sterile parenteral drug product
 3. **MANUFACTURING SITE:** Bayer Schering Pharma AG
Mullerstrasse 170-178
D-13353 Berlin
Federal Republic of Germany
 4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** Sterile solution for injection, in _____ a glass vial
 5. **METHOD(S) OF STERILIZATION:** _____
 6. **PHARMACOLOGICAL CATEGORY:** Imaging Agent
- B. **SUPPORTING/RELATED DOCUMENTS:** N/A
- C. **REMARKS:** This was an eCTD submission. An initial quality assessment (IQA) was performed by ONDQA (IQA dated 21 August 2007). No specific product quality microbiology issues were identified in the IQA. The filing review of the original submission by this reviewer disclosed several deficiencies related to product quality microbiology. An information request was sent to the applicant in the filing letter dated 14 September 2007. The applicant amended the application with the requested information.

filename: N022090R1.doc

APPEARS THIS WAY
ON ORIGINAL

Executive Summary

I. Recommendations

- A. **Recommendation on Approvability** – This submission is recommended for approval on the basis of product quality microbiology.
- 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 _____
- 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.
- B. **Endorsement Block** _____
James L. McVey
Microbiology Team Leader
- C. **CC Block**
N/A

6 Page(s) Withheld

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/s/

Bryan Riley
1/4/2008 07:35:56 AM
MICROBIOLOGIST

James McVey
1/4/2008 08:35:30 AM
MICROBIOLOGIST