CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-277

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

25 SEPTEMBER 2008

NDA: 22-277

Drug Product Name
Proprietary: Temodar
Non-proprietary: Temozolomide for injection
Drug Product Priority Classification: S

Review Number: 1

Dates of Submission(s) Covered by this Review

Letter	Stamp	Review Request	Assigned to Reviewer
1/23/2008	1/24/2008	3/19/2008	3/21/2008
9/24/2008	9/24/2008	N/A	N/A

Submission History (for amendments only): N/A

Applicant/Sponsor
Name: Schering Corporation
Address: 2000 Galloping Hill Road, Kenilworth, NJ 07033
Representative: Lucine Karjian
Telephone: 908-740-5224

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

Conclusion: Recommend 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 SITES: (b) (4)

4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY: Sterile powder in a glass vial for intravenous infusion, 100 mg/vial

5. METHOD(S) OF STERILIZATION: (b) (4)

6. PHARMACOLOGICAL CATEGORY: Oncology agent

B. SUPPORTING/RELATED DOCUMENTS: N/A

C. REMARKS: This was an electronic submission in the eCTD format. A product quality microbiology information request was sent to the applicant on 10 July 2008 (see page 3 of this review for the text of the IR). The applicant responded to the IR letter with an amendment (dated 24 September 2008). The review of the information in the amendment has been integrated into the overall review of the NDA.

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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) (4) lyophilized.

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

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

/s/

Bryan Riley
9/25/2008 02:48:43 PM
MICROBIOLOGIST

James McVey
9/25/2008 02:55:29 PM
MICROBIOLOGIST