CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-161

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

10 JANUARY 2008

NDA: 22-161

Drug Product Name
Proprietary: LEXISCAN
Non-proprietary: regadenoson
Drug Product Priority Classification: S

Review Number: 1

Dates of Submission(s) Covered by this Review

Letter	Stamp	Review Request	Assigned to Reviewer
5/14/2007	5/14/2007	6/27/2007	7/2/2007
1/7/2008	1/8/2008	N/A	N/A

Submission History (for amendments only): N/A

Applicant/Sponsor
Name: CV Therapeutics, Inc
Address: 3172 Porter Drive
Representative: Carol Karp
Telephone: 650-384-8875

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 parenteral drug product

3. **MANUFACTURING SITES:**
5 mL vials:
Baxter Pharmaceutical Solutions LLC
927 S Curry Pike
Bloomington, IN

5 mL pre-filled syringes:
Hospira
Highway 301 North
Rocky Mount, NC

4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** The drug product is a single-use, sterile, non-preserved aqueous solution for intravenous administration. 0.08 mg/mL, in a 5 mL glass vial or a 5 mL pre-filled glass syringe

5. **METHOD(S) OF STERILIZATION:** [redacted]

6. **PHARMACOLOGICAL CATEGORY:** The drug product is intended as a pharmacologic stress agent for radionuclide myocardial perfusion imaging.

B. **SUPPORTING/RELATED DOCUMENTS:** DMF [redacted]

C. **REMARKS:** This was an eCTD submission. An initial quality assessment was performed on this NDA (IQA dated 20 August 2007). No specific product quality microbiology concerns were noted in the IQA. The drug product is manufactured at two different contract manufacturers. The descriptions of the manufacturing processes and [redacted] validations for the pre-filled syringe are provided in DMF [redacted] The submission referred to DMF [redacted] for the validation of the [redacted] of the drug product vials. This reviewer was unable to find the validation data in the DMF and contacted the DMF holder to request the data. The representative of BPS stated that product specific information is not placed in the DMF but will be provided to the applicant. The applicant called this reviewer (4 January 2008) to confirm the information request. Subsequently, the applicant amended the NDA with the requested validation data summary.

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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 [redacted]

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

5 Page(s) Withheld

✓ Trade Secret / Confidential

_____ Draft Labeling

_____ Deliberative Process

Withheld Track Number: Microbiology- 8

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
1/16/2008 08:13:01 AM
MICROBIOLOGIST

James McVey
1/16/2008 09:34:41 AM
MICROBIOLOGIST