CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-290

MICROBIOLOGY REVIEW(S)

PRODUCT QUALITY MICROBIOLOGY FILING CHECKLIST

NDA Number: 22-290 **Applicant: GE Healthcare** **Letter Date: 20 MAR 2008**

Drug Name: AdreView **NDA Type: TBD** **Stamp Date: 21 MAR 2008**

The following are necessary to initiate a review of the NDA application:

	Content Parameter	Yes	No	Comments
1	Is the product quality microbiology information described in the NDA and organized in a manner to allow substantive review to begin? Is it legible, indexed, and/or paginated adequately?	X		Submitted in electronic CTD format. Accessible for review via [redacted] b(4)
2	Has the applicant submitted an overall description of the manufacturing processes and microbiological controls used in the manufacture of the drug product?	X		Section 3.2.P.3.3
3	Has the applicant submitted protocols and results of validation studies concerning microbiological control processes used in the manufacture of the drug product?		X	See Additional Comments below.
4	Are any study reports or published articles in a foreign language? If yes, has the translated version been included in the submission for review?		X	
5	Has the applicant submitted preservative effectiveness studies (if applicable) and container-closure integrity (CCI) studies?		X	No CCI studies. Product is not preserved. See Additional Comments below.
6	Has the applicant submitted microbiological specifications for the drug product and a description of the test methods?	X		
7	Has the applicant submitted the results of analytical method verification studies?		X	No sterility or BET validation studies. See Additional Comments below.
8	Has the applicant submitted all special/critical studies/data requested during pre-submission meetings and/or discussions?	n/a	n/a	
9	Is this NDA fileable? If not, then describe why.	X		Fileable but additional information is requested

Additional Comments: The product contains 1% (v/v) benzyl alcohol but the applicant states in the labeling text that the drug product is not preserved. The benzyl alcohol is listed as [redacted] b(4)

The applicant should be requested to provide the following for microbiology review of the NDA:

1. Current copies of the sterility test method and the bacterial endotoxin test (BET) method in order for the reviewer to adequately assess the sterility and BET specifications.
2. Drug product specific assay validation reports for the sterility test.
3. Drug product specific assay validation reports for the bacterial endotoxin test.
4. The protocol and summary report for the [redacted] validation for the drug product. b(4)
5. Summary reports of the validation of container closure integrity for the maintenance of sterility of the drug product following [redacted]

Robert J. Mello, Ph.D. / Reviewing Microbiologist Date

James McVey / Team Leader Date

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

/s/

Robert Mello
5/6/2008 07:31:02 AM
MICROBIOLOGIST

Submission is fileable from Microbiology perspective

James McVey
5/8/2008 02:44:56 PM
MICROBIOLOGIST

Product Quality Microbiology Review

03 September 2008

NDA: 22-290/N-000

Drug Product Name
Proprietary: AdreView™
Non-proprietary: Iobenguane I^{123} Injection
Drug Product Priority Classification: P

Review Number: 1

Dates of Submission(s) Covered by this Review

Letter	Stamp	Review Request	Assigned to Reviewer
20 MAR 2008	21 MAR 2008	21 MAR 2008	27 MAR 2008
07 JULY 2008	08 JULY 2008	n/a	n/a
16 JULY 2008	18 JULY 2008	n/a	n/a
19 AUG 2008	20 AUG 2008	n/a	n/a

Submission History (for amendments only): N/A

Applicant/Sponsor
Name: GE Healthcare
Address: 101 Carnegie Center
Princeton, NJ 08545
Representative: Fred E. Longenecker
Telephone: 609-514-6573

Name of Reviewer: Robert J. Mello, Ph.D.

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

Product Quality Microbiology Data Sheet

A. 1. **TYPE OF SUBMISSION:** New Drug Application

2. **SUBMISSION PROVIDES FOR:** Marketing Approval

3. **MANUFACTURING SITE:** GE Healthcare
3350 North Ridge Avenue
Arlington Heights, IL 60004

4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** Sterile Solution, Intravenous injection, 2mCi/ml at calibration. (5ml fill in a 10ml ——— b(4)

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

6. **PHARMACOLOGICAL CATEGORY:** Diagnostic Radiopharmaceutical

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

C. **REMARKS:**

- The ONDQA PAL Initial Quality Assessment was completed on May 1, 2008. The PAL noted that the details of the ——— appeared 'sketchy' and that microbiology consult would be needed. There is a USP monograph for Iobenguane I^{123} Injection.
- The submission is in electronic CTD (eCTD) format.
- It was noted that 1% benzyl alcohol is included in the formula ——— The label does NOT indicate that the product is preserved. b(4)

Filename: N022290N000R1.doc

Appears This Way
On Original

Executive Summary

I. Recommendations

A. Recommendation on Approvability – Recommend Approval

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 radiolabeled drug product is

b(4)

B. Brief Description of Microbiology Deficiencies - None

C. Assessment of Risk Due to Microbiology Deficiencies – N/A

III. Administrative

A. Reviewer's Signature _____
Robert Mello, Ph.D.

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

C. CC Block
NDA 22-290 file

7 Page(s) Withheld

✓ Trade Secret / Confidential (b4)

_____ Draft Labeling (b4)

_____ Draft Labeling (b5)

_____ Deliberative Process (b5)

Withheld Track Number: Microbiology- 1

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

/s/

Robert Mello
9/3/2008 01:53:19 PM
MICROBIOLOGIST

Recommend Approval

Bryan Riley
9/3/2008 01:56:40 PM
MICROBIOLOGIST
I concur.