

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

204677Orig1s000

MICROBIOLOGY / VIROLOGY REVIEW(S)

Product Quality Microbiology Review

Positron Emission Tomography (PET) Products

12 August 2013

NDA: 204677

Drug Product Name

Proprietary: Neuraceq

Non-proprietary: Florbetaben

Review Number: 1

Dates of Submission(s) Covered by this Review

Submit	Received	Review Request	Assigned to Reviewer
21 DEC 2012	21 DEC 2012	3 JAN 2012	3 JAN 2013
01 MAR 2013	01 MAR 2013	N/A	N/A
26 APR 2013	26 APR 2013	N/A	N/A
02 JUL 2013	02 JUL 2013	N/A	N/A

Applicant/Sponsor

Name: Piramal Imaging SA

Address: Route de l'Ecole 13, c/o Pascale Nguyen, 1753 Matran,
Switzerland

Representative: Jenne M. Novak, Ph.D, Authorized US Agent

Telephone: 720-746-1190

Name of Reviewer: Erika Pfeiler, Ph.D.

Conclusion: Recommended for Approval

Product Quality Microbiology Data Sheet

- A.
1. **TYPE OF SUBMISSION:** 505(b)(1)
 2. **SUBMISSION PROVIDES FOR:** Initial marketing of a sterile PET drug
 3. **MANUFACTURING SITE:**
Iba Molecular North America, (b) (4)
[REDACTED]
[REDACTED]
[REDACTED]
 4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:**
Sterile, clear radiopharmaceutical (30 mL)
Intravenous injection
300 MBq in (b) (4) -10 mL at the time of administration.
30 mL glass vial with rubber stopper
 5. **METHOD(S) OF STERILIZATION:** Sterile filtration at the aseptic dispensing (filling) station.
 6. **PHARMACOLOGICAL CATEGORY:** PET Diagnostic
- B. **SUPPORTING/RELATED DOCUMENTS:**
Microbiology Review 1 of BBMF (b) (4) (LoA Date 26 June 2013) – BBMF review is archived in BIRAMS (CBER), submit date 12 August 2013
- C. **REMARKS:** This application was submitted in the eCTD format.

filename: N204677R1.doc

Executive Summary

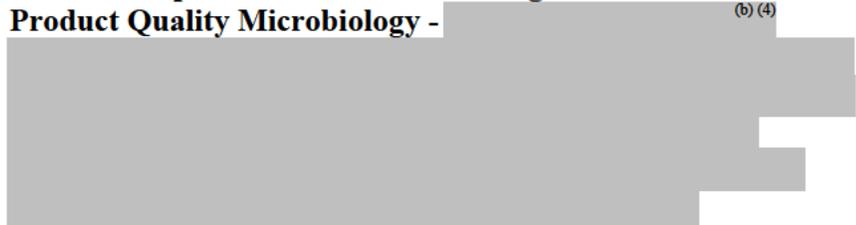
I. Recommendations

A. Recommendation on Approvability - Recommended for 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 - ^{(b) (4)}



B. Brief Description of Microbiology Deficiencies – N/A

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

D. Contains Potential Precedent Decision(s)- Yes No

III. Administrative

A. Reviewer's Signature _____
Erika Pfeiler, Ph.D.
Microbiologist

B. Endorsement Block _____
David Hussong, Ph.D.
Associate Director for New Drug Microbiology

C. CC Block
N/A

8 Page(s) has been Withheld in Full as b4 (CCI/TS) immediately following this page

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

/s/

ERIKA A PFEILER
08/12/2013

DAVID HUSSONG
08/13/2013

The applicant has provided the necessary CMC microbiology information or addressed the reviewer's information requests. The review describes adequate procedures and process controls for approval of the product.

PRODUCT QUALITY MICROBIOLOGY FILING CHECKLIST

NDA Number: 204677 **Applicant:** Piramal Imaging SA **Letter Date:** 21 DEC 2012

Drug Name: Florbetaben **NDA Type:** 505(b)(1) **Stamp Date:** 21 DEC 2012

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		
2	Has the applicant submitted an overall description of the manufacturing processes and microbiological controls used in the manufacture of the drug product?	X		
3	Has the applicant submitted protocols and results of validation studies concerning microbiological control processes used in the manufacture of the drug product?	X		
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	The submission is in English.
5	Has the applicant submitted preservative effectiveness studies (if applicable) and container-closure integrity studies?	X		
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		
8	Has the applicant submitted all special/critical studies/data requested during pre-submission meetings and/or discussions?			N/A
9	If sterile, are extended post-constitution and/or post-dilution hold times in the draft labeling supported by microbiological data?			N/A
10	Is this NDA fileable? If not, then describe why.	X		

Additional Comments: This drug product is indicated for the detection of beta-amyloid in the brain, and to assist in the diagnosis of Alzheimer's disease.

Erika Pfeiler, Ph.D. Date

Bryan Riley, Ph.D. Date
Microbiology Team Leader

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

/s/

ERIKA A PFEILER
01/30/2013

BRYAN S RILEY
01/30/2013
I concur.