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APPROVAL PACKAGE FOR:

APPLICATION NUMBER

NDA 21-768

Microbiology Review(s)

Product Quality Microbiology Review

Review for HFD-160

25 MAY 2004

NDA: 21-768

Drug Product Name

Proprietary: N/A

Non-proprietary: [F-18]FDG

Drug Product Priority Classification: S

Review Number: 1

Subject of this Review

Submission Date: 10 March 2004

Receipt Date: 24 March 2004

Consult Date: 9 April 2004

Date Assigned for Review: 14 April 2004

Submission History (for amendments only)

Date(s) of Previous Submission(s): N/A

Date(s) of Previous Micro Review(s): N/A

Applicant/Sponsor

Name: Weill Medical College of Cornell University

Address: 516 East 72nd Street, New York, NY 10021

Representative: Shankar Vallabhajosula, Ph.D.

Telephone: 212-746-5694

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

Conclusion: Recommend Approval

Product Quality Microbiology Data Sheet

- A.
1. **TYPE OF SUPPLEMENT:** N/A
 2. **SUPPLEMENT PROVIDES FOR:** N/A
 3. **MANUFACTURING SITE:** Weill Medical College of Cornell University
Citigroup Biomedical Imaging Ctr
516 E 72nd Street
New York, NY 10021
 4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** Sterile solution for intravenous administration, 4-90 mCi/mL.
 5. **METHOD(S) OF STERILIZATION:** C J
 6. **PHARMACOLOGICAL CATEGORY:** PET
- B. **SUPPORTING/RELATED DOCUMENTS:** N/A
- C. **REMARKS:** The drug product is a PET imaging agent manufactured as a single unit batch.

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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 **C**
J
- B. **Brief Description of Microbiology Deficiencies** – N/A
- C. **Assessment of Risk Due to Microbiology Deficiencies** – N/A

III. Administrative

- A. **Reviewer's Signature** _____
- B. **Endorsement Block**
Bryan S. Riley, Ph.D. (Microbiology Reviewer)
Microbiology Supervisor
- C. **CC Block**
N/A

3 Page(s) Withheld

§ 552(b)(4) Trade Secret / Confidential

§ 552(b)(5) Deliberative Process

§ 552(b)(4) Draft Labeling

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/s/

Bryan Riley
6/30/04 10:34:25 AM
MICROBIOLOGIST

Peter Cooney
6/30/04 11:14:17 AM
MICROBIOLOGIST