CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-870

MICROBIOLOGY REVIEW

Product Quality Microbiology Review
Review for HFD- 160

2 AUG 2005

NDA: 21-870

Drug Product Name
Proprietary:
Non-proprietary: Fludeoxyglucose F 18 Injection
Drug Product Priority Classification: Standard

Review Number: 1

Dates of Submission(s) Covered by this Review

Letter	Stamp	Consult Sent	Assigned to Reviewer
11 NOV 2004		24 NOV 2004	01 DEC 2004
08 FEB 2005	09 FEB 2005	N.A.	10 FEB 2005
15 JUN 2005	15 JUN 2005	N.A.	05 JUL 2005
30 JUN 2005	01 JUL 2005	N.A.	11 JUL 2005
05 JUL 2005	06 JUL 2005	N.A.	11 JUL 2005
21 JUL 2005	22 JUL 2005	N.A.	25 JUL 2005

Submission History (for amendments only) **N.A.**

Applicant/Sponsor

Name:	North Shore / LIJ Research Institute Cyclotron/Radiochemistry Facility
Address:	350 Community Drive Manhasset, New York 11030
Representative:	Thomas Chaly, Ph.D.
Telephone:	(516) 562-1042

Name of Reviewer: James L. McVey

Conclusion: Recommend approval.

Product Quality Microbiology Data Sheet

A. 1. **TYPE OF SUBMISSION:** Original Application

2. **SUBMISSION PROVIDES FOR:** PET drug product application.

3. **MANUFACTURING SITE:** North Shore / LIJ Research Institute
Cyclotron/Radiochemistry Facility
350 Community Drive
Manhasset, New York 11030

4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** Sterile for intravenous injection during PET imaging diagnostic procedure. Contains 20.0 – 200.0 mCi/mL, half life = 109.7 minutes. 16.0 to 17.0 mL in a 20 mL vial. Estimated maximum dose is 7.5 mL.

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

6. **PHARMACOLOGICAL CATEGORY:** Positron Emission Tomography (PET) diagnostic.

B. **SUPPORTING/RELATED DOCUMENTS:** N.A.

C. **REMARKS:** An inspection of this facility was done on June 6th and 7th. Reports from that investigation have been provided. General inspectional observations were that the firm failed to maintain adequate specifications for the control of components etc. and that their specification sheets were not adequate; that the firm failed to provide adequate storage conditions and that the firm failed to adequately qualify the [redacted] personnel in that they only performed 1 requalification study per year. In addition the applicant was advised to provide a revised SOP for the simulation media fill using media instead of water; that the vendors be qualified for the microbiological media; that an SOP be provided for [redacted] information with an SOP; and that they should prepare or revise the SOP for monthly [redacted] monitoring to shorten the monitoring schedule. **The responses to the July 15th FAXed microbiology concerns and a subsequent phone call are summarized in section H.**

filename: N21870r1

Executive Summary

I. Recommendations

A. Recommendation on Approvability – Approve.

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 – [redacted]

[redacted]

B. Brief Description of Microbiology Deficiencies – None.

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

III. Administrative

A. Reviewer's Signature _____

B. Endorsement Block

Microbiologist : James L. McVey
Microbiology Supervisor: David Hussong

C. CC Block

cc: DFS

9 Page(s) Withheld

✓ Trade Secret / Confidential

_____ Draft Labeling

_____ Deliberative Process

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/

James McVey
8/2/05 01:58:26 PM
MICROBIOLOGIST

David Hussong
8/2/05 02:15:50 PM
MICROBIOLOGIST