

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

22-119

MICROBIOLOGY REVIEW

Product Quality Microbiology Review

23 MAR 2007

NDA: 22-119
22-119 BI

Drug Product Name

Proprietary: Ammonia N-13 injection

Non-proprietary: Ammonia N-13 injection

Drug Product Priority Classification: N/A

Review Number: 1

Dates of Submission(s) Covered by this Review

Letter	Stamp	Consult Sent	Assigned to Reviewer
16-OCT-2006	25-OCT-2006	06-NOV-2006	08-NOV-2006
06-MAR-2007	08-MAR-2007	N/A	12-MAR-2007

Submission History (for amendments only) – N/A

Applicant/Sponsor

Name: The Feinstein Institute for Medical Research

Address: 350 Community Drive
Manhasset, NY 11030

Representative: Thomas Chaly, Ph.D., FAIC
Associate Professor and Chief, Radiochemistry

Telephone: 516-562-1042

E-mail: tchaly@nshs.edu

Name of Reviewer: Anastasia G. Lolas

Conclusion: Recommended for approval

Product Quality Microbiology Data Sheet

- A.
1. **TYPE OF SUBMISSION:** New Drug Application
 2. **SUBMISSION PROVIDES FOR:** New drug product
 3. **MANUFACTURING SITE:**
The Feinstein Institute for Medical Research
Cyclotron/Radiochemistry
North Shore-LIJ Health System
350 Community Drive
Manhasset, NY 11030
 4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:**
 - Sterile solution in a 20 mL multiple-dose glass vial
 - Intravenous injection
 - 3.75-37.5 mCi/mL (30-300 mCi in 8 mL)
 5. **METHOD(S) OF STERILIZATION:** _____
 6. **PHARMACOLOGICAL CATEGORY:** Positron emission tomography products (PET)
- B. **SUPPORTING/RELATED DOCUMENTS:**
- Microbiology Review #1 of NDA 21-870 (dated 02-AUG-2005); another PET product application for the same applicant, FDG, was reviewed and recommended for approval.
- C. **REMARKS:** This is a non-CTD electronic submission. A desk copy was also provided. The PAL assessment in DFS does not indicate any major issues in this application that would pose risk to the safety and/or quality of the product.

A facsimile was sent to the applicant requesting the following:

_____ should simulate the manufacturing process as closely as possible including all production steps in the _____. In addition, SOP NH3V011 should address in more detail the actions taken following a _____. An investigation should be initiated to identify the cause of the _____ and appropriate actions taken _____.

A BI amendment was submitted on March 6, 2007. The applicant's response has been incorporated in the relevant section of the review.

file name: N022119R1.doc

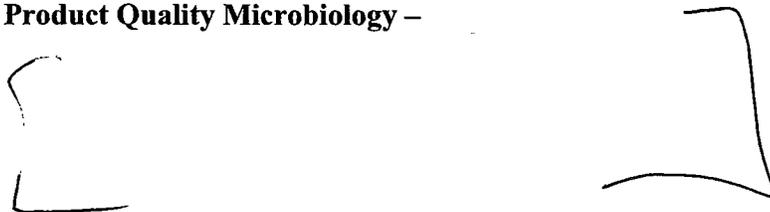
Executive Summary

I. Recommendations

- A. Recommendation on Approvability** – Recommended for approval based on 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** –



- B. Brief Description of Microbiology Deficiencies** – None
- C. Assessment of Risk Due to Microbiology Deficiencies** – N/A

III. Administrative

- A. Reviewer's Signature** _____
Anastasia G. Lolas
- B. Endorsement Block**
James L. McVey
- C. CC Block**
N/A

6 Page(s) Withheld

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

 § 552(b)(4) Draft Labeling

 § 552(b)(5) 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/

Anastasia Lolos
3/23/2007 07:41:02 AM
MICROBIOLOGIST

James McVey
3/23/2007 07:49:11 AM
MICROBIOLOGIST