CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-660

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review
Review for HFD 150

7-May-2004

NDA:	21-660/RR1-004
Drug Product Name:	—
Non-proprietary	Nanoparticle Paclitaxel for Injectable Suspension
Drug Product Classification:	
Review Number:	2
Subject of this Review	
Submission Date:	February 27, 2004
Receipt Date:	March 1, 2004
Consult Date:	March 3, 2004
Date Assigned for Review:	March 24, 2004
Submission History (for amendments only)	
Date(s) of Previous Submission(s):	June 30, 2003
Date(s) of Previous Micro Review(s):	February 19, 2004
Applicant/Sponsor	
Name:	American Bioscience, Inc
Address:	2730 Wilshire Blvd, Suite 10 Santa Monica, CA 90403
Representative:	Mitchall Clark
Telephone:	(310) 883-3141
Name of Reviewer:	Stephen E. Langille, Ph.D.
Conclusion:	Recommended for approval

Product Quality Microbiology Data Sheet

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

2. **SUPPLEMENT PROVIDES FOR:** Not applicable

3. **MANUFACTURING SITE:** American Pharmaceutical Partners, Inc.
2020 Ruby St.
Melrose Park, IL 60160

4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:**

- Sterile lyophilized powder
- Intravenous infusion
- 100 mg/vial

5. **METHOD(S) OF STERILIZATION:** —

6. **PHARMACOLOGICAL CATEGORY:** Cancer therapy

B. **SUPPORTING/RELATED DOCUMENTS:** DMF — and 21-660 form 483 for pre-approval inspection issues

C. **REMARKS:** NDA 21-660 was filed electronically.

filename: c:\reviews\21-660r2.doc

Executive Summary

I. Recommendations

A. Recommendation on Approvability -

NDA 21-660 is recommended for approval from the standpoint of product quality microbiology.

B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable -

Not applicable

II. Summary of Microbiology Assessments

A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology -

An — lyophilized powder will be manufactured at American Pharmaceutical Partners, Inc., Melrose Park, IL.

B. Brief Description of Microbiology Deficiencies -

No microbiology deficiencies were found based upon the information provided.

C. Assessment of Risk Due to Microbiology Deficiencies -

Not applicable

III. Administrative

A. Reviewer's Signature _____

B. Endorsement Block

Stephen E. Langille, Ph.D.
Peter Cooney, Ph.D.

C. CC Block

In DFS

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/s/

Stephen Langille
5/24/04 02:36:08 PM
MICROBIOLOGIST

Peter Cooney
5/24/04 02:49:03 PM
MICROBIOLOGIST

Product Quality Microbiology Review
Review for HFD 150

12-February-2004

NDA:	21-660
Drug Product Name:	— ®
Non-proprietary	Nanoparticle Paclitaxel for Injectable Suspension
Drug Product Classification:	
Review Number:	1
Subject of this Review	
Submission Date:	June 30, 2003
Receipt Date:	June 30, 2003
Consult Date:	September 16, 2003
Date Assigned for Review:	October 24, 2003
Submission History (for amendments only)	
Date(s) of Previous Submission(s):	
Date(s) of Previous Micro Review(s):	
Applicant/Sponsor	
Name:	American Bioscience, Inc
Address:	2730 Wilshire Blvd, Suite 10 Santa Monica, CA 90403
Representative:	Mitchall Clark
Telephone:	(310) 883-3141
Name of Reviewer:	Stephen E. Langille, Ph.D.
Conclusion:	Approvable pending revision

Product Quality Microbiology Data Sheet

A. 1. TYPE OF SUPPLEMENT: Original Application

2. SUPPLEMENT PROVIDES FOR: Not applicable

3. MANUFACTURING SITE: American Pharmaceutical Partners, Inc.
2020 Ruby St.
Melrose Park, IL 60160

4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:

- Sterile lyophilized powder
- Intravenous infusion
- 100 mg/vial

5. METHOD(S) OF STERILIZATION: —

6. PHARMACOLOGICAL CATEGORY: Cancer therapy

B. SUPPORTING/RELATED DOCUMENTS: DMF —

C. REMARKS: NDA 21-660 was filed electronically.

filename: c:\reviews\21-660r1.doc

Executive Summary

I. Recommendations

A. Recommendation on Approvability -

NDA 21-660 is approvable pending the revision of microbiological deficiencies.

B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable -

Not applicable

II. Summary of Microbiology Assessments

A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology -

An [redacted] lyophilized powder will be manufactured at American Pharmaceutical Partners, Inc., Melrose Park, IL.

B. Brief Description of Microbiology Deficiencies -

The Applicant failed to provide:

- adequate documentation for [redacted] sterilization validation.
- A detailed description of the storage conditions for the [redacted]

C. Assessment of Risk Due to Microbiology Deficiencies -

Failure to address the microbiology deficiencies may result in contamination of the drug product [redacted]

III. Administrative

A. Reviewer's Signature _____

B. Endorsement Block

Stephen E. Langille, Ph.D.
Peter Cooney, Ph.D.

C. CC Block

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/s/

Stephen Langille
2/20/04 09:28:56 AM
MICROBIOLOGIST

Peter Cooney
2/20/04 01:21:25 PM
MICROBIOLOGIST