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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

7 Page(s) Withheld

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

§ 552(b)(5) Deliberative Process

§ 552(b)(5) Draft Labeling

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