

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-660

CHEMISTRY REVIEW(S)

NDA 21-660

**Abraxane (Paclitaxel Protein Bound
Particles for Injectable Suspension) for
Injectable Suspension, 100 mg**

**American Bioscience, Inc.
Division of American Pharmaceutical Partners,
Inc.**

Yung-Ao Hsieh, Ph.D.

Division of Oncology Drug Products

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Chemistry Review Data Sheet

1. NDA 21-660
2. REVIEW No.: 1
3. REVIEW DATE: 30-Nov-04
4. REVIEWER: Yung-Ao Hsieh, Ph.D.
5. PREVIOUS DOCUMENTS: None

6. SUBMISSIONS BEING REVIEWED:

<u>Submissions Reviewed</u>	<u>Document date</u>
NDA 21-660	4-Mar-04
NDA 21-660 BC	18-Mar-04
NDA 21-660 BC	2-Apr-04
NDA 21-660 BC	8-Apr-04
NDA 21-660 BC	26-Jul-04
NDA 21-660 BC	28-Jul-04
NDA 21-660 BC	25-Aug-04
NDA 21-660 BC	12-Oct-04
NDA 21-660 BC	27-Oct-04
NDA 21-660 BC	

7. NAME & ADDRESS OF APPLICANT:

Name: American BioScience, Inc.

Address: 2730 Wilshire Boulevard, Santa Monica, CA 90403

Representative: Robert A. Miranda, Director, Drug Regulatory Affairs

Telephone: 310-883-1300

8. DRUG PRODUCT NAME/CODE/TYPE:

- a) Proprietary Name: Abraxane
- b) Non- Proprietary Name: (nab paclitaxel) for Injectable Suspension
- c) Code name: ABI-007
- d) Chem. Type/Submission Priority:
 - Chem. Type: a taxane derivative
 - Submission Priority: 1S

9. LEGAL BASIS FOR SUBMISSION: N/A

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