CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

75184

MICROBIOLOGY REVIEW

DF

OFFICE OF GENERIC DRUGS, HFD-620

Microbiology Review #1

August 12, 1998

A. 1. **ANDA 75-184**

APPLICANT Immunex
51 University Street
Seattle Washington 98101-2936

2. PRODUCT NAME: Paclitaxel Injection

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: 30 mg (6 mg/mL), 5 mL Single-Dose Vial, Intravenous

4. METHOD(S) OF STERILIZATION:

5. PHARMACOLOGICAL CATEGORY: Anti-Neoplastic Chemotherapeutic Agent

B. 1. DATE OF INITIAL SUBMISSION: July 22, 1997
Subject of this Review (Received, August 8, 1997)
2. DATE OF AMENDMENT: None
3. RELATED DOCUMENTS: None
4. ASSIGNED FOR REVIEW: 8/5/98

C. REMARKS: The subject drug product is manufactured for Immunex by [redacted]. The subject drug product is in Room 166.

Note to Labeling:
The microbiology review is for the original submission which provides for a **single dose vial only.**

Note to Chemist:
The batch record title indicates that the subject drug product is **"For Injection".**

D. CONCLUSIONS: **The submission is not recommended for approval on the basis of sterility assurance. Specific comments are provided in "E. Review Notes" and "Microbiology Comments to be Provided to the Applicant".**

/S/ 8/13/98
Andrea S. High, Ph. D.

cc: Original **ANDA**
Duplicate ANDA
Division Copy
Field Copy
Drafted by A. High, HFD 620 x:wp\microrev\75-184
Initialed by M. Fanning, R. Patel, F. Fang/F. Holcombe, Jr.

Rpatel
8/14/98

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micro #1

OFFICE OF GENERIC DRUGS, HFD-640
Microbiology Review #1
June 9, 2000

A. 1. ANDA 75-184

APPLICANT Baker Norton Pharmaceuticals
(formerly Immunex)

2. PRODUCT NAME: Paclitaxel Injection

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: 30mg/5mL (6mg/mL) for Intravenous Injection; Additional sizes 150mg/25mL and 300mg/50mL

4. METHOD(S) OF STERILIZATION:

5. PHARMACOLOGICAL CATEGORY: Anti Neoplastic

B. 1. DATE OF INITIAL SUBMISSION: July 22, 1997
(Received August 8, 1997)

2. DATE OF AMENDMENT: Gratuitous Amendment June 15, 1999
Subject of this Review (Received June 16, 1999)

3. RELATED DOCUMENTS: None

4. ASSIGNED FOR REVIEW: June 8, 2000

C. REMARKS: The subject gratuitous amendment provides for two additional fill sizes (25mL and 50mL) of the subject drug product in addition to the 5mL fill size contained in the amendment dated April 2, 1999 which was last reviewed for sterility assurance. The subject drug product will be manufactured at the Faulding facilities in Mulgrave North, Australia.

D. CONCLUSIONS: The submission is **not recommended** for approval on the basis of sterility assurance. Specific comments are provided in "E. Review Notes" and "Microbiology Comments to be Provided to the Applicant" found at the end of this review. The deficiencies represent a **minor** amendment.

/S/
Nrapendra Nath, Ph. D.
6/14/00

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Micro

OFFICE OF GENERIC DRUGS, HFD-640
Microbiology Review #2
May 19, 2000

A. 1. ANDA 75-184

APPLICANT Baker Norton Pharmaceuticals (formerly Immunex)

2. PRODUCT NAME: Paclitaxel Injection

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: 30mg/5mL (6mg/mL) for Intravenous injection

4. METHOD(S) OF STERILIZATION:

5. PHARMACOLOGICAL CATEGORY: Anti Neoplastic

B. 1. DATE OF INITIAL SUBMISSION: July 22, 1997 (Received August 8, 1997)

2. DATE OF AMENDMENT: April 2, 1999 **Subject of this Review (Received April 5, 1999)**

3. RELATED DOCUMENTS: None

4. ASSIGNED FOR REVIEW: May 12, 2000

C. REMARKS: The subject amendment provides for the response to microbiology deficiencies in the letter dated March 6, 1999. The subject drug product will be manufactured at the Faulding facilities in Mulgrave, Australia in Rooms #8 and #13.

D. CONCLUSIONS: The submission is **not recommended** for approval on the basis of sterility assurance. Specific comments are provided in "E. Review Notes" and "Microbiology Comments to be Provided to the Applicant" found at the end of this review. The deficiencies represent a minor amendment.

/S/
Nrapendra Nath, Ph. D.

ABH 6/2/00

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Micro#2

OW

OFFICE OF GENERIC DRUGS, HFD-640
Microbiology Review #3
July 6, 2000

A. 1. **ANDA 75-184**

APPLICANT Baker Norton Pharmaceuticals (formerly Immunex)

2. PRODUCT NAME: Paclitaxel Injection

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: 30mg/5mL (6mg/mL), 150mg/25mL and 300mg/50mL for Intravenous injection.

4. METHOD(S) OF STERILIZATION:

5. PHARMACOLOGICAL CATEGORY: Anti Neoplastic

B. 1. DATE OF INITIAL SUBMISSION: July 22, 1997 (Received August 8, 1997)

2. DATE OF AMENDMENT: Amendment June 23, 2000
Subject of this Review (Received June 26, 2000)

3. RELATED DOCUMENTS: None

4. ASSIGNED FOR REVIEW: July 6, 2000

C. REMARKS: The subject drug product will be manufactured at the Faulding facilities in Mulgrave North, Australia. The subject amendment provides for the response to microbiology deficiencies in the facsimile letter, dated June 16, 2000.

D. CONCLUSIONS: The submission is **recommended** for approval on the basis of sterility assurance. Specific comments are provided in "E. Review Notes".

/S/ 7/6/2000
Nrapendra Nath, Ph. D.
CDR 7/11/00

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Micro #3