CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

75-176

MICROBIOLOGY REVIEW

OFFICE OF GENERIC DRUGS, HFD-620

Microbiologist's Review #4

November 12, 1999

A. 1. **ANDA 75-176**

APPLICANT King Pharmaceuticals, Inc.
501 fifth Street
Bristol TN 37620

2. PRODUCT NAMES: Haloperidol Decanoate Injection

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: 50 mg/mL in a 5 mL Multiple Dose Vial, 50 mg/mL in a 1 mL Ampule, 100 mg/mL in a 5 mL Multiple Dose Vial and 100 mg/mL in a 1 mL Ampule, Intramuscular

4. METHOD(S) OF STERILIZATION:

5. PHARMACOLOGICAL CATEGORY: Antipsychotic

B. 1. DATE OF INITIAL SUBMISSION: July 31, 1997
(Received, July 31, 1997)

2. DATE OF TELEPHONE AMENDMENT: October 22, 1999
Subject of this Review (Received, October 25, 1999) November 18, 1999 (Received, November 19, 1999)
12/8/99

3. RELATED DOCUMENTS: None

4. ASSIGNED FOR REVIEW: 11/10/99

C. REMARKS: The subject amendment(s) provide for the response to the microbiology deficiencies in the fax dated October 21, 1999. It did not appear that the applicant calculated the endotoxin limit for the current labeled dose in the 10/22/99 amendment therefore, a T.con was initiated on 11/18/99 (See attached).

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

Andrea S. High 11/19/99
Andrea S. High, Ph. D.

cc:

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micro Rev. 4

11/12/99

OFFICE OF GENERIC DRUGS, HFD-620

Microbiologist's Review #3

October 19, 1999

A. 1. **ANDA 75-176**

APPLICANT King Pharmaceuticals, Inc.
501 fifth Street
Bristol TN 37620

2. PRODUCT NAMES: Haloperidol Decanoate Injection

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: 50 mg/mL in a 5 mL Multiple Dose Vial, 50 mg/mL in a 1 mL Ampule, 100 mg/mL in a 5 mL Multiple Dose Vial and 100 mg/mL in a 1 mL Ampule, Intramuscular

4. METHOD(S) OF STERILIZATION: - --

5. PHARMACOLOGICAL CATEGORY: Antipsychotic

B. 1. DATE OF INITIAL SUBMISSION: July 31, 1997
(Received, July 31, 1997)

2. DATE OF AMENDMENT: August 27, 1999
Subject of this Review (Received, August 30, 1999)
DATE OF TELEPHONE AMENDMENT: October 1, 1999
Subject of this Review (Received Hard Copy, October 4, 1999)

3. RELATED DOCUMENTS: None

4. ASSIGNED FOR REVIEW: 10/19/99

C. REMARKS: The subject amendments provide for the response to the microbiology deficiencies in the correspondence dated July 22, 1999.
Note to investigator: The water testing methods, frequency, etc. may be a GMP issue.

D. CONCLUSIONS: ***It does not appear that the applicant has taken measures to assure a sterile product,*** therefore, 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".

10/19/99
Andrea S. High, Ph. D.
10/20/99

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micro Rev 3
10/19/99

OFFICE OF GENERIC DRUGS, HFD-620
Microbiologist's Review #2
June 9, 1999

A. 1. **ANDA 75-176**

APPLICANT King Pharmaceuticals, Inc.
501 fifth Street
Bristol TN 37620

2. PRODUCT NAMES: Haloperidol Decanoate Injection

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: 50 mg/mL in a 5 mL Multiple Dose Vial, 50 mg/mL in a 1 mL Ampule, 100 mg/mL in a 5 mL Multiple Dose Vial and 100 mg/mL in a 1 mL Ampule, Intramuscular

4. METHOD(S) OF STERILIZATION:

5. PHARMACOLOGICAL CATEGORY: Antipsychotic

B. 1. DATE OF INITIAL SUBMISSION: July 31, 1997
(Received, July 31, 1997)

2. DATE OF AMENDMENT: November 23, 1998
Subject of this Review (Received, November 24, 1998)

3. RELATED DOCUMENTS: NDA 17-530

4. ASSIGNED FOR REVIEW: 6/8/99

C. REMARKS: The subject amendment provides for the response to the microbiology deficiencies in the letter dated June 15, 1998. The amendment also provides validation summaries for the new double-door The glassware es for the were approved for NDA 17-530 [pertains to and will not be reviewed.

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".

Andrea S. High 6/9/99
Andrea S. High, Ph. D.

cc:

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Micro Review 2

6/9/99

OFFICE OF GENERIC DRUGS, HFD-620

Microbiologist's Review #1

June 4, 1998

A. 1. **ANDA** 75-176

APPLICANT King Pharmaceuticals, Inc.
501 fifth Street
Bristol TN 37620

2. PRODUCT NAMES: Haloperidol Decanoate Injection

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: 50 mg/mL in a 5 mL Multiple Dose Vial, 50 mg/mL in a 1 mL Ampule, 100 mg/mL in a 5 mL Multiple Dose Vial and 100 mg/mL in a 1 mL Ampule, Intramuscular

4. METHOD(S) OF STERILIZATION:

5. PHARMACOLOGICAL CATEGORY: Antipsychotic

B. 1. DATE OF INITIAL SUBMISSION: July 31, 1997
Subject of this Review (Received, July 31, 1997)

2. DATE OF AMENDMENT: None

3. RELATED DOCUMENTS: None

4. ASSIGNED FOR REVIEW: 5/28/98

C. REMARKS: The subject drug product will be filled in Room 3 for ampuls and Room vials at the Bristol Tennessee pharmaceutical facility. The Antimicrobial Preservative Effectiveness Test will be performed by

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".

6/5/98
Andrea S. High, Ph. D.

cc: Original **ANDA**

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Micro Rev 8

1/4/98