CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

75-176

CHEMISTRY REVIEW(S)

OFFICE OF GENERIC DRUGS

ABBREVIATED NEW DRUG APPLICATION
CHEMISTRY, MANUFACTURING AND CONTROLS REVIEW

1. **CHEMIST'S REVIEW NO.# 4**

2. **ANDA #** 75-176

3. **NAME AND ADDRESS OF APPLICANT:**
King Pharmaceuticals, Inc.
Attention: Greg Carrier
501 Fifth Street
Bristol, TN 37620

4. **LEGAL BASIS OF SUBMISSION:**
Reference Listed Drugs: **Haldol® Decanoate 50 and**
Haldol® Decanoate 100 (Injections)
Manufacturer: McNeil Pharmaceutical (an R.W. Johnson company)
NDA # 18-701
(Application # N18701 001; Jan 14, 1986; EQ 50 mg base/ml and
N18701 002; Oct 31, 1989; EQ 100 mg base/ml)

King's proposed drug product contains the same active and inactive ingredients and has the same strength, dosage form, route of administration, indications and usage as that of the listed drug product (page 6-7 and 10-11).

The applicant has certified in their application that in its opinion and to the best of its knowledge, and based upon the published information on the list, the reference listed drug products are not entitled to any patent and exclusivity provisions (v1.1, page 8-9).

5. **SUPPLEMENT(s):** N/A

6. **PROPRIETARY NAME:** N/A

7. **NONPROPRIETARY NAME: Haloperidol Decanoate Injection**

8. **SUPPLEMENT(s) PROVIDE(s) FOR:** N/A

9. **AMENDMENTS AND OTHER DATES:**
Applicant:

01-28-2000	Response to telephone amendment dated 1/28/00
01-07-2000	Response to telephone amendment dated 1/3/00
12-22&28-1999	Response to telephone amendment dated 12/13/99
08-27-1999	Response to the deficiency letter dated 7/22/99

05-19-1999	Response to the deficiency letter dated 5/3/99
11-23-1998	Response to the deficiency letter of 12/22/97.
07-30-1997	Original submission date
FDA:	
01-28-2000	Telecon - Additional information request
01-03-2000	Telecon - Additional information request
12-13-1999	Telecon - Information request
07-22-1999	Deficiency letter - FACSIMILE
05-03-1999	Deficiency letter - FACSIMILE
12-22-1997	Deficiency letter - Major Amendment
09-03-1997	ANDA Acceptance letter
07-31-1997	Acknowledge

Debarment Certification: Included section XIX(v1.3, page 1012)

10. **PHARMACOLOGICAL CATEGORY**: Antipsychotic

11. **Rx or OTC**: Rx

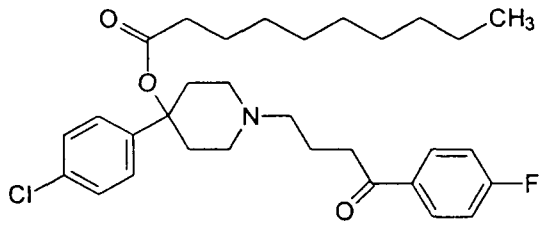
12. **RELATED IND/NDA/DMF(s)**:
Approved NDA 18-701 for innovator

13. **DOSAGE FORM**: Injectable (Intramuscular Injection)

14. **STRENGTH**: 50 mg/mL and 100 mg/mL (1 mL ampules and 5 mL MDVs)

15. **CHEMICAL NAME, STRUCTURE AND PHYSICAL PROPERTIES**:
Haloperidol decanoate is the decanoate ester of the butyrophenone, haloperidol. It is available in sesame oil in sterile form for intramuscular (IM) injection. Haloperidol decanoate is almost insoluble in water, but is soluble in most organic solvents.

Haloperidol Decanoate. Decanoic acid, 4-(4-chlorophenyl)-1-[4-(4-fluorophenyl)-4-oxobutyl]-4-piperidinyl ester. $C_{31}H_{41}ClFNO_3$. 530.12. 74050-97-8. Antipsychotic. USAN 1993, page 309.



16. **COMMENTS**: N/A

17. **CONCLUSIONS AND RECOMMENDATIONS**: The application is Approvable.

18. **RECORDS AND REPORTS**: N/A

19. **REVIEWER**: Neeru B. Takiar
Endorsed by D. Gill

DATE COMPLETED: 1/18/00
Revised: 2/2/00

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Contain Trade Secret, Commercial/Confidential Information and are not releasable.

Chen Rev 4

1/18/00