

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

75-176

APPROVAL LETTER

FEB 9 2000

King Pharmaceuticals, Inc.
Attention: Greg Carrier
501 Fifth Street
Bristol, TN 37620

Dear Sir:

This is in reference to your abbreviated new drug application dated July 30, 1997, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Haloperidol Decanoate Injection 50 mg (base)/mL and 100 mg (base)/mL, packaged in 1 mL ampules and 5 mL multiple-dose vials.

Reference is also made to your amendments dated July 8, July 27, August 26, August 27, October 1, October 22, November 18, December 22, and December 28, 1999; and January 7 and January 28, 2000.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your Haloperidol Decanoate Injection 50 mg (base)/mL and 100 mg (base)/mL, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Haldol Decanoate-50 Injection and Haldol Decanoate-100 Injection, respectively, of RW Johnson Pharmaceutical Research Institute).

Under Section 506(A) of the Act, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

We request that you submit, in duplicate, any proposed advertising or promotional copy that you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the proposed or final printed labeling to the Division of Drug Marketing, Advertising,

and Communications (HFD-40). Please do not use Form FD-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-40) with a completed Form FD-2253 at the time of their initial use.

Sincerely yours,



Douglas L. Sporn
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

