DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-545/S-007

King Pharmaceuticals, Inc.
Attention: Mr. Mark Pilato
501 Fifth Street
Bristol, Tennessee 37620

Dear Mr. Pilato:

Please refer to your September 28, 2001 supplemental new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Procanbid (procainamide hydrochloride) 500 and 1000 mg extended-release tablets.

We acknowledge receipt of your submissions dated May 22 and June 26, 2002 that constituted a complete response to our February 1, 2002 approvable letter.

This supplemental new drug application provides for: (1) the use of DSM Pharmaceuticals' (formerly named Catalytica Pharmaceuticals) facilities in Greenville, North Carolina as a new manufacturing and testing (release and stability) facility for Procanbid (500 mg and 1000 mg) Tablets, (2) the change in (b)(4)----------(b)(4)---- (procainamide hydrochloride) from(b)(4)----------., (3) the ad----------ng laboratory, (b)(4)----------, (4) revised raw material testing instructions for the excipient, magnesium----------ling revised to incorporate these changes.

We note that the package insert has been revised as follows:

1) Under **WARNINGS**, in the boxed warning regarding **BLOOD DYSCRASIAS**, the hyphen has been deleted from the word "hydro-chloride" in the second sentence.

2) Throughout the package insert, the font style of the section or subsection words in the parenthetical references have been made consistent with that of the actual section or subsection headers, e.g., the word "WARNINGS" in the phrase "(See WARNINGS)" has been changed to bold font style.

3) Under **DOSAGE AND ADMINISTRATION**, the lines forming the table entitled "To provide up to 50 mg/kg of body weight per day*" have been removed.

4) Under **HOW SUPPLIED**, the statement "Manufactured by: Catalytica Pharmaceuticals, Inc., Greenville, NC 27834" has been changed to "Manufactured by: DSM Pharmaceuticals, Inc., Greenville, NC 27834."

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert and immediate container labels included in your May 22, 2002 submission). Accordingly, the supplemental application is approved effective on the date of this letter.

At the time of your next printing, please make the following minor editorial corrections to the package insert and include them in your annual report:

1) Under **DESCRIPTION**, in the first two paragraphs, please separate "(diethyl-" on one line and "amino)" on the next line instead of "(diethy-" on one line and "lamino)" on the next line.

2) Under **CLINICAL PHARMACOLOGY/Pharmacokinetics and Drug Metabolism/Absorption/Bioavailability**, in the third paragraph, please separate "N-acetyl-" on one line and "procainamide" on the next line instead of "N-acetylp-" on one line and "rocainamide" on the next line.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact:

Quynh Nguyen, Pharm.D.
Regulatory Health Project Manager
(301) 594-5311

Sincerely,

{See appended electronic signature page}

Douglas C.Throckmorton, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Doug Throckmorton

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