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APPROVAL PACKAGE FOR:

APPLICATION NUMBER

NDA 20-545/S-007

Chemistry Review(s)

CHEMIST'S REVIEW	1. ORGANIZATION HFD-110	2. NDA Number 20-545
3. Name and Address of Applicant (City & State) King Pharmaceutical, Inc. 501 Fifth Street, Bristol, Tennessee 37620		4. Supplement(s) Number(s) Date(s) SCM-007 09/28/01
5. Drug Name Procanbid	6. Nonproprietary Name Procainamide Hydrochloride Extended Release tablets	8. Amendments & Other (reports, etc) - Dates SCM-007 (BZ) dated 01/14/02
7. Supplement Provides: 1) For the use of Catalytica Pharmaceuticals facilities in Greenville, NC as a new manufacturing and testing (release and stability) facility for Procanbid Tablets 2) Also the change in supplier of the active drug substance (procainamide HCl) from [redacted] to [redacted] a division Of Catalytica. **This is a "Prior Approval SUPPLEMENT" submission.**		
9. Pharmacological Category Antiarrhythmic agent	10. How Dispensed ☒Rx ☐OTC	11. Related IND(s)/ NDA(s)/DMF(s) [redacted] DMF [redacted]
12. Dosage Form(s) Tablets	13. Potency(ies) 500 mg, 1000 mg	
14. Chemical Name and Structure Benzamide, 4-amino-N-[(2-diethylamino)ethyl]-, monohydrochloride or p-Amino-N-[2-(diethylamino)ethyl]benzamide monohydrochloride **Molecular Formula** $C_{13}H_{21}N_3O$. HCl **Molecular Weight** 271.79 (anhydrous HCl)		15. Records/Reports Current ☒Yes ☐No Reviewed ☒Yes ☐No

16. Comments:

The currently approved manufacturer, [redacted] has discontinued to manufacture both the drug substance and drug product Therefore firm has contracted The Catalytica facility to manufacture Procanbid Tablets according to the currently approved process. All raw materials packaging components, labeling and specifications are consistent with those currently approved. All CMC information provided including the Bioequivalence study that is reviewed by Dr. E. Mishina is satisfactory. EER for Catalytica and [redacted] sites are acceptable. Overall OC acceptance recommendation is attached with this review.

The submission is Recommended for approval.

17. Conclusions and Recommendations:

The approval letter is issued.

18. REVIEWER

Name	Signature	Date Completed
JV Advani	[redacted]	01/05/02

Redacted 10

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