



NDA 18-063/S-060

King Pharmaceuticals, Inc.  
Attention: Karen Baker  
501 Fifth Street  
Bristol, TN 37620

### SUPPLEMENT APPROVAL

Dear Ms. Baker:

Please refer to your supplemental new drug application (NDA) dated January 9, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Corgard (nadolol) 20, 40, and 80 mg Tablets.

This supplemental new drug application provides for the following revisions to the package insert:

Addition of the following statement to the **PRECAUTIONS/Drug Interactions** section of the package insert

“Both digitalis glycosides and beta-blockers slow atrioventricular conduction and decrease heart rate. Concomitant use can increase the risk of bradycardia.”

We have completed our review of this application, and it is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon electronic labeling text. We will transmit the SPL version of the labeling submitted on January 9, 2008 to the National Library of Medicine for public dissemination.

If you issue a letter communicating important information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH  
Food and Drug Administration  
5515 Security Lane  
HFD-001, Suite 5100  
Rockville, MD 20852

Marketing the product with labeling that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

NDA 18-063/S-060

Page 2

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please call Dan Brum, Pharm.D., Regulatory Project Manager, at (301)796-0578.

Sincerely,

*{See appended electronic signature page}*

Norman Stockbridge, M.D., Ph.D.  
Director  
Division of Cardiovascular and Renal Products  
Office of Drug Evaluation I  
Center for Drug Evaluation and Research

cc: Enclosed Labeling Text

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Norman Stockbridge  
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