



## SUPPLEMENT APPROVAL

NDA 18-647/S-020

King Pharmaceuticals  
Attention: Karen C. Baker  
501 Fifth Street  
Bristol, TN 37620  
Dear Ms. Baker:

Please refer to your supplemental new drug application (NDA) dated February 21, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Corzide (nadolol and bendroflumethiazide) 40/5 mg and, 80/5 mg Tablets.

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

To add "Both digitalis glycosides and beta-blockers slow atrioventricular conduction and decrease heart rate. Concomitant use can increase the risk of bradycardia." to the **DRUG INTERACTIONS** section under the heading **PRECAUTIONS**.

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 February 21, 2008, with minor editorial changes, 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.

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

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If you have any questions, please call:

Dan Brum Pharm.D.  
Regulatory Project Manager  
(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  
this page is the manifestation of the electronic signature.**  
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/s/

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Norman Stockbridge  
8/12/2008 09:34:27 AM