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

/s/

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Norman Stockbridge
2/4/2008 08:30:20 AM