DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022325/S-002

SUPPLEMENT APPROVAL

Baxter Healthcare Corporation
Attention: Amy Giertych
Senior Director, Global Regulatory Affairs
1620 Waukegan Road
McGaw Park, IL 60085

Dear Ms. Giertych:

Please refer to your Supplemental New Drug Application (sNDA) dated December 5, 2011, received December 5, 2011, submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Nexterone (amiodarone hydrochloride) 1.5 mg/mL, 1.8 mg/mL and 50 mg/mL Premixed for Injection.

This "Prior Approval" supplemental new drug application provides for labeling revised as follows:

1. Under **HIGHLIGHTS/DRUG INTERACTIONS**, following language was added:

    - If simvastatin is co-administered with amiodarone, do not exceed doses greater than 20 mg daily of simvastatin
    - If lovastatin is co-administered with amodarone, do not exceed greater than 40 mg daily of lovastatin

2. Under **DRUG INTERACTIONS**, HMG-CoA Reductase Inhibitors, the following language was replaced:

    HMG-CoA Reductase Inhibitors:
    Simvastatin (CYP3A substrate) in combination with amiodarone has been associated with reports of myopathy/rhabdomyolysis.

    With:

    HMG-CoA reductase inhibitors:
    The use of HMG-CoA reductase inhibitors that are CYP3A4 substrates in combination with amiodarone has been associated with reports of myopathy/rhabdomyolysis.

Limit the dose of simvastatin in patients on amiodarone to 20 mg daily. Limit the daily dose of lovastatin to 40 mg. Lower starting and maintenance doses of other CYP3A4 substrates (e.g., atorvastatin) may be required as amiodarone may increase the plasma concentration of these drugs.

3. Annual Reportable revisions were made such as use of registered trademark symbol "®" throughout document and revised contact information to reflect transfer of ownership from Prism Pharmaceuticals to Baxter Healthcare.

4. The version number and revision date were updated.

There are no other changes from the last approved package insert.

We have completed our review of this supplemental application, and it is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to, the enclosed labeling (text for the package insert, text for the patient package insert) with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes with the revisions listed approved in this supplemental application, as well as annual reportable changes, and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REPORTING REQUIREMENTS

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 contact:

Lori Anne Wachter, RN, BSN
Regulatory Project Manager for Safety
(301) 796-3975

Sincerely,

{See appended electronic signature page}

Mary Ross Southworth, Pharm.D.
Deputy Director for Safety
Division of Cardiovascular and Renal Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

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

/s/

MARY R SOUTHWORTH
12/12/2011