DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022325/S-009

SUPPLEMENT APPROVAL

Baxter Healthcare Corporation
Attention: Ms. Andrea Doyle
Associate Director, Global Regulatory Affairs
32650 N. Wilson Road
Mail Stop WG2-3S
Round Lake, Illinois 60073

Dear Ms. Doyle:

Please refer to your Supplemental New Drug Application (sNDA) dated and received May 19, 2014, submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Nexterone (amiodarone) 1.5 mg/mL and 1.8 mg/mL Premixed Injection.

This supplemental new drug application provides for labeling revised as follows (additions are marked as underlined text and deletions are marked as ~~strikethrough text~~):

1. In **HIGHLIGHTS/RECENT MAJOR CHANGES**, the following text was added:

RECENT MAJOR CHANGES	
Dosage and Administration (2)	March 2015
Warnings and Precautions (5)	March 2015

2. Under **HIGHLIGHTS/DOSAGE AND ADMINISTRATION**, the following text was added/deleted:

- The recommended starting dose is about 1000 mg over the first 24 hours of therapy, delivered by the following infusion regimen (2):
  - Initial Load: 150 mg ~~per~~ in 100 mL ~~(in D5W or Normal Saline)~~ infused over 10 minutes
  - Followed by: 1 mg/min for 6 hours
  - Followed by: 0.5 mg/min thereafter
- ~~In the event of~~ For breakthrough episodes of VF or hemodynamically unstable VT (2); repeat the Initial Load ~~described above as needed (infused over 10 minutes)~~
- ~~Increase the rate of the maintenance infusion to achieve effective arrhythmia suppression.~~ (2)

3. In **HIGHLIGHTS/DOSAGE FORMS AND STRENGTHS**, the following text was added/deleted:

21 Page(s) of Draft Labeling have been Withheld in Full as B4 (CCI/TS) immediately following this page

~~St~~ore at 20° - 25°C (68° - 77°F); excursions permitted to 15° - 30°C (59° - 86°F).
See USP Controlled Room Temperature.
Protect from light and excessive heat. Protect from freezing.
Use carton ~~or blister pack~~ to protect contents from light until used.
Sto~~ppers and tip caps do not contain natural rubber latex~~

19. The manufacturing information was revised as follows:

Baxter Galaxy and Nexterone are trademarks of Baxter International Inc. ~~Vials manufactured by: HollisterStier Laboratories, LLC Spokane, WA 99207~~

~~Pre-filled Syringes manufactured by: Baxter Pharmaceutical Solutions, LLC Bloomington, IN 47403~~

~~For: *Baxter*~~
Baxter Healthcare Corporation
Deerfield, IL 60015

20. The revision date was 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), 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 from 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 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).

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at http://www.fda.gov/opacom/morechoices/fdaforms/cder.html; instructions are provided on page 2 of the form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the address above or by fax to 301-847-8444.

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 call:

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

Sincerely,

{See appended electronic signature page}

Mary Ross Southworth, PharmD.
Deputy Director for Safety
Division of Cardiovascular and Renal Products
Office of Drug Evaluation 1
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
03/13/2015