DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022325/S-014

SUPPLEMENT APPROVAL

Baxter Healthcare Corporation
Attention: Kristin Henney
Associate Director, Regulatory Affairs
32650 Wilson Road
WG1-3
Round Lake, Illinois 60073

Dear Ms. Henney:

Please refer to your Supplemental New Drug Application (sNDA) dated and received November 29, 2017, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Nexterone (amiodarone hydrochloride) 360 mg/200mL Premixed Injection.

We also refer to our Prior Approval Supplement Request letter dated September 29, 2016 requesting a revision to your carton and container labels to mitigate the risk of medication errors.

This "Prior Approval" supplemental new drug application provides for the following revision:

- The carton label was revised by adding an additional color (black) to the currently approved carton label.

APPROVAL & LABELING

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.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and immediate container labels that are identical to the: enclosed carton and immediate container labels as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008).* Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 022325/S-014**." Approval of this submission by FDA is not required before the labeling is used.

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

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, RAC
Regulatory Project Manager for Safety
(301) 796-3975

Sincerely,

{See appended electronic signature page}

Mary Ross Southworth, PharmD.
Deputy Director for Safety
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE(S):
Carton and Container 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
03/22/2017