DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020255/S-016

SUPPLEMENT APPROVAL

Baxter Healthcare Corporation
Attention: Ms. Linda Coleman, RAC
32650 N. Wilson Road
Round Lake, IL 60073

Dear Ms. Coleman:

Please refer to your Supplemental New Drug Application (sNDA) dated September 28, 2012, received October 1, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Dobutamine HCl in 5% Dextrose Injection, USP in plastic container.

We acknowledge receipt of your amendment dated April 9, 2013.

This "Changes Being Effected" supplemental new drug provides for a revision to the content of labeling to correct an error that was identified in the infusion rate table for one of the four different formulations of Dobutamine. The error in the infusion rate table was identified during an internal review of the labeling by Baxter. In addition, some infusion rate values were changed for consistency of rounding practice.

The changes are as follows:

1. In Table 2, the infusion rate (b) (4) for 4000 mcg/mL for a 60 kg patient was replaced by the infusion rate of 0.9 mL/h.
2. In Table 2, some infusion rate values were changed for consistency of rounding practice.
3. The label number and revision dates have been updated.

We have completed our review of this supplemental application, as amended. 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 that includes labeling changes 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).

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:

Quynh Nguyen, Pharm.D., RAC
Regulatory Health Project Manager
(301) 796-0510

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

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/

NORMAN L STOCKBRIDGE
04/17/2013