DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 18461/S-056

SUPPLEMENT APPROVAL

Baxter Healthcare Corporation
Attention: Linda Coleman
Director, Global Regulatory Affairs
1620 Waukegan Road, MPGR-AL
McGaw Park, IL 60085

Dear Ms. Coleman:

Please refer to your Supplemental New Drug Application (sNDA) dated January 11, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Lidocaine in 5% Dextrose Injection, USP in plastic container.

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

1. Under WARNINGS, the following information has been added after the second paragraph:

   Anaphylactic reactions may occur following administration of lidocaine hydrochloride. (See ADVERSE REACTIONS).

   In the case of severe reaction, discontinue the use of the drug.

2. Under ADVERSE REACTIONS/Central Nervous System and ADVERSE REACTIONS/ Cardiovascular System, the order of the listed adverse reactions has been revised to decreasing severity.

3. Under ADVERSE REACTIONS, the following new heading has been added:

   Hematologic Effects: methemoglobinemia

4. Under ADVERSE REACTIONS, the first sentence of the fifth paragraph has been changed from:

   Allergic reactions may occur but are infrequent.

   To:

   Allergic reactions, including anaphylactic reactions, may occur but are infrequent.

5. Under ADVERSE REACTIONS, the Management of Adverse Reactions section has been deleted.

6. The OVERDOSAGE section has been changed from:

   Reported adverse reactions are due to overdosage (see Adverse Reactions).

To:

Overdosage may result in severe systemic toxicity (see Warnings and Precautions and Adverse Reactions).

7. Under HOW SUPPLIED, the 500 ml size of the 0.8% Lidocaine product has been removed as that product has been discontinued.

8. The document control number and revision date have been updated.

We have completed our review of this supplemental application. It is approved, effective on the date of this letter, for use as 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, Medication Guide), 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
Office of Prescription Drug Promotion (OPDP)
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 Office of Prescription Drug Promotion (OPDP), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

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 Russell Fortney, Regulatory Project Manager, at (301) 796-1068.

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

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
03/05/2012