DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 18-461/S-050

Baxter Healthcare Corporation
Attention: Ms. Marcia Marconi
Route 120 and Wilson Road
Round Lake, IL 60073

Dear Ms. Marconi:

Please refer to your December 10, 1999 supplemental new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Lidocaine Hydrochloride in 5% Dextrose Injection in Viaflex® Plastic Container.

We acknowledge receipt of your submission dated April 25, 2001 that constitutes a complete response to our May 30, 2000 approvable letter.

This supplemental new drug application provides for final printed labeling revised as follows:

1. Under the **Description** section, the last two sentences have been changed from:

   > Solutions in contact with the plastic container can leach out certain of its chemical components in very small amounts within the expiration period, e.g., di-2-ethylhexyl phthalate (DEHP), up to 5 parts per million. However, the safety of the plastic has been confirmed in tests in animals according to USP biological standards for plastic containers as well as by tissue culture toxicity studies.
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   > to:
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   > Solutions in contact with the plastic container may leach out certain chemical components from the plastic in very small amounts; however, biological testing was supportive of the safety of the plastic container materials.

2. Under the **Precautions/Drug Interactions** subsection, "Amiodarone" has been added to the first sentence of the third paragraph.

3. After the **Pediatric Use** section, the following section has been added:

   > **Geriatric Use**
   > Clinical studies of Lidocaine Hydrochloride did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert included in your April 25, 2001 submission). Accordingly, the supplemental application is approved effective on the date of this letter.

At the time of your next printing, please make the following minor editorial corrections and include them in your annual report:

1) Under the **Precautions/Drug Interactions** subsection, in the first sentence of the third paragraph, the capital letter "A" in "Amiodarone" should be changed to lowercase letter "a."

2) Under 21 CFR 201.57(f), the information on pediatric and geriatric use should be provided in subsections under the **Precautions** section, rather than in sections. Therefore, the font size of the **Pediatric Use and Geriatric Use** section headers should be changed to that of the subsection headers.

3) Under **Geriatric Use**, there should be a comma after the word "range" in the last sentence.

4) The statement "Do not administer unless solution is clear and seal is intact" should be moved from the end of the **Geriatric Use** section to the end of the **Precautions/General** subsection.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact:

Quynh Nguyen, Pharm.D.
Regulatory Health Project Manager
(301) 594-5311

Sincerely,

{See appended electronic signature page}

Raymond J. Lipicky, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

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

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/s/

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Raymond Lipicky
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