DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 50-671/S-022

SUPPLEMENT APPROVAL

Baxter Healthcare Corporation
Attention: Melissa I. Klesch
Manager, Global Regulatory Affairs
32650 North Wilson Road
Mail Stop WG2-3S
Round Lake, IL 60073

Dear Ms. Klesch:

Please refer to your Supplemental New Drug Application (sNDA) dated July 28, 2015, received, July 28, 2015, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Vancomycin Injection, USP, Intravenous 500 mg/100 mL, 750 mg/100 mL and 1 g/200 mL.

We also acknowledge receipt of your amendments dated October 7, November 11, and December 15, 2015.

This "Prior Approval" supplemental new drug application provides for three (3) new drug product configurations of Vancomycin Injection, USP. In addition, revisions have been made to the **DESCRIPTION** section, the **CLINICAL PHARMACOLOGY, Microbiology** subsection, **PRECAUTIONS, General** subsection, **DOSAGE AND ADMINISTRATION, Directions for Use** subsection, **HOW SUPPLIED/STORAGE AND HANDLING** and the **REFERENCES** sections of the package insert.

APPROVAL & LABELING

We have completed our review of this supplemental application, as amended 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, 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).

CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge your July 28, 2015, submission containing final printed carton and container labels.

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, call J. Christopher Davi, MS, Senior Regulatory Project Manager, at (301) 796-0702.

Sincerely,

{See appended electronic signature page}

Sumathi Nambiar, MD, MPH
Director
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURES: Content of Labeling
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/

JOSEPH G TOERNER
12/18/2015