DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-638/S-010

Baxter Healthcare Corporation
Attention: Marcia Marconi
Vice President, Regulatory Affairs
Route 120 & Wilson Road
Round Lake, IL 60073-0490

Dear Ms. Marconi:

Please refer to your supplemental new drug application dated December 23, 2003, received December 29, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Penicillin G Potassium Injection, USP in Plastic Container, PL 2040.

We note that this application is subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

We also acknowledge receipt of your submission dated January 2, 2004, containing final printed labeling for this supplement.

This supplemental new drug application provide for revisions to the label to comply with the Final Rule entitled "Labeling Requirements for Systemic Antimicrobial Drug Products Intended for Human Use" (68FR 6062, February 6, 2003).

We have completed our review of this application and it is approved effective on the date of this letter for use as recommended in the final printed labeling submitted on January 2, 2004.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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, call Judit Milstein, Regulatory Project Manager, at (301) 827-2207.

Sincerely,

{See appended electronic signature page}

Janice M. Soreth, MD
Director
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
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/

Janice Soreth

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