DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 50-638/S-011

Baxter Healthcare Corporation
Attention: Margarita Aguilera, MS
Director, Regulatory Affairs
Route 120 and Wilson Road
Round Lake, Illinois 60073-0490

Dear Ms. Aguilera:

Please refer to your supplemental new drug application dated July 19, 2004, received July 22, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Penicillin G 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.

This supplement provides for the addition of the statement, "and pain at the injection site has been reported" to the Local Reactions subsection of the Adverse Reactions section of the package insert.

We have completed our review of this application and it is approved, effective on the date of this letter.

If you issue a letter communicating important information about these drug products (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, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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 Susmita Samanta, M.D., Regulatory Project Manager, at (301) 827-2125.

Sincerely,

{See appended electronic signature page}

Janice M. Soreth, M.D.
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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