DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-863/S-042

Baxter Healthcare Corporation
Attention: Marcia Marconi
Vice President, Regulatory Affairs
Route 120 and Wilson Road
RLT-10
Round Lake, IL 60073-0490

Dear Ms. Marconi:

Please refer to your supplemental new drug application dated November 28, 2000, and received on November 29, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for 3% Sorbitol Urologic Irrigation Solution.

We also acknowledge your submission dated February 13, 2004. This supplemental new drug application proposes the addition of a Geriatric Use subsection in accordance with ruling [21 CFR 201.57 (f)(10)(ii)(A)], and modifications to the Description section.

We completed our review of this application, as amended, and it is approved, effective on the date of this letter. The final printed labeling (FPL) that was submitted for supplements 040 and 045 on February 13, 2004 is acceptable to the Division to also serve as the FPL for this supplement 042.

As required by 21 CFR 314.550, submit three copies of all promotional materials including promotional labeling and advertisements that you intend to use within 120 days following approval of this product. Submit all proposed materials in draft or mock up form, not final print. Send one copy to the Division of Reproductive and Urologic Drug Products, HFD-580 and two copies of both the promotional materials and the proposed package insert directly to:

Division of Drug Marketing, Advertising
And Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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 reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Jean Makie, R.D., Regulatory Project Manager, at (301) 827-4260.

Sincerely,

{See appended electronic signature page}

Daniel Shames, M.D.
Director
Division of Reproductive and Urologic
Drug Products (HFD-580)
Office of Drug Evaluation III
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/

Daniel A. Shames

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