



NDA 17-863/S-040

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

Dear Ms. Marconi:

Please refer to your supplemental new drug application dated April 2, 1997, received April 3, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for 3% Sorbitol Irrigation Solution in Plastic Container, PL 146.

We acknowledge receipt of your submissions dated October 3 and November 19, 2001 and June 25, 2002.

This supplemental new drug application provides for a revision to the package insert in response to the Final Rule titled, "Specific Requirements on Content and Format of Labeling for Human Prescription Drugs; Revision of "Pediatric use" Subsection in the Labeling." The revised package insert proposed the addition of a Pediatric Use subsection, which reads, "Safety and effectiveness in pediatric patients have not been established."

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 agreed upon labeling text for the package insert. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the labeling text for the package insert submitted on October 3, 2001.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format-NDA (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 17-863/S-040." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, 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 the requirements for an approved NDA set forth under 21 CFR

314.80 and 314.81.

If you have any questions, call Kassandra Sherrod, R.Ph., 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

Office of Drug Evaluation III

Center for Drug Evaluation and Research

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/s/

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Daniel A. Shames  
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