DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 17-865/S-038

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 1.5% Glycine Irrigation, USP in Plastic Container, PL 146®.

We acknowledge receipt of your submissions dated October 3, 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 17-865/S-038." 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

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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