DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-849/S-008

Baxter Healthcare Corporation
Route 120 & Wilson Road
Round Lake, Illinois 60073-0490

Attn: Marcia Marconi
Vice President, Regulatory Affairs

Dear Ms. Marconi:

Please refer to your supplemental new drug application dated November 5, 2002, received November 6, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act 20% Pro-Sol-sulfite-free (amino acid) Injection, USP in Viaflex plastic container.

The "Changes Being Effected" supplemental new drug application provides for a revised package insert per the requirements of 21 CFR 201.323 and revised release and stability specifications, which include a test for aluminum determination with the acceptance criterion of "NMT 25 mcg/L of aluminum."

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

The final printed labeling (FPL) must include the editorial revisions to the **Nursing Mothers** subsection of the **PRECAUTIONS** section as indicated in the approval letter dated April 24, 2003 (S-007). All other sections of the FPL must be identical to the labeling submitted November 5, 2002.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case 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 20-849/S-008." Approval of this submission by FDA is not required before the labeling is used.

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, 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 Lisa Malandro, Regulatory Project Manager, at (301) 827-7407.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, M.D.
Acting Director
Division of Anesthetic, Critical Care,
and Addiction Drug Products
Office of Drug Evaluation II
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/

Celia Winchell
5/2/03 11:44:12 AM
for Bob A. Rappaport, M.D., Acting Division Director