



NDA 20-849/S-007

Baxter Healthcare Corporation
Route 120 & Wilson Road; RLT-10
Round Lake, IL 60073

Attention: Marcia Marconi
Vice President, Regulatory Affairs

Dear Ms. Marconi:

Please refer to your supplemental new drug application dated May 17, 2002, received May 20, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for 20% Pro-Sol-sulfite-free (amino acid) Injection, USP in Viaflex plastic container.

Reference is also made to the April 9, 2003 telephone conversation between Ms. Kristen Wheeler of your company and Ms. Parinda Jani of this Division.

This supplemental new drug application provides for a revised **PRECAUTIONS** section. A **Geriatric Use** subsection is added in accordance with 21CFR 201.57(f)(10).

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

The final printed labeling (FPL) must be identical and include the minor editorial revision indicated, to the draft package insert submitted May 17, 2002. These revisions are terms of the approval of this application.

As agreed to by Ms Kristen Wheeler of your company the following revisions will be made.

1. Revise the third sentence of the second paragraph of the **DESCRIPTION** from “Solutions in contact with the plastic container may leach out certain chemical components from the plastic in very small amounts; however, biological testing was supportive of the safety of the plastic container materials.” to “Solutions in contact with the plastic container can leach out certain of its chemical components in very small amounts within the expiration period, e.g., di-2-ethylhexyl phthlate (DEHP), up to 5 parts per million. However, the safety of the plastic has been confirmed in tests in animals according to USP biological tests for plastic containers as well as by tissue culture toxicity studies.”
2. Revise the **Nursing Mothers** subsection of the **PRECAUTIONS** section from “Caution should be exercised when 20% ProSol sulfite-free (amino acid) Injection is administered to a nursing woman” to “It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, and because of the potential for adverse reactions, e.g.,

hyperammonemia in nursing infants, caution should be exercised when 20% ProSol sulfite-free (amino acid) Injection is administered to a nursing mother.”

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 20-849/007." Approval of this submission by FDA is not required before the labeling is used.

In addition, all previous revisions as reflected in the most recently approved labeling must be included. To facilitate review of your submission, please provide a highlighted or marked-up copy that shows the changes that are being made.

If additional information relating to the safety or effectiveness of this drug becomes available, revision of the labeling may be required.

If a letter communicating important information about these drug products (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 appropriate 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 Ms. Lisa Malandro, Regulatory Health Project Manager, at (301) 827-7410.

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
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/s/

Bob Rappaport

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