DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-678/S-010, S-011
NDA 20-734/S-010, S-011

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

Attention: Marcia Marconi
Vice President, Regulatory Affairs

Dear Ms. Marconi:

Please refer to your supplemental new drug applications dated March 22, 2002 (S-010), and April, 25, 2002 (S-011), received March 25, and April 26, 2002, respectively, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Clinimix - sulfite free Injections and Clinimix E - sulfite free Injections.

We acknowledge receipt of your submissions dated July 19, 2002 (S-010).

Supplements S-010 provide for an additional container presentation with a fill volume of one liter.

Supplements S-011 provide for the addition of the statements regarding Aluminum in Large and Small Volume Parenterals Used in Total Parenteral Nutriton, as required by 21 CFR 201.323.

We have completed the review of these supplemental applications, as amended, and they are approved effective on the date of this letter.

Please submit the copies of final printed labeling (FPL) electronically to each application 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, these submissions should be designated "FPL for approved supplement NDA 20-678/S-010, S-011; and 20-734/S-010, S-011.

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

Sincerely,

{See appended electronic signature page}

Cynthia McCormick, M.D.
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/

Bob Rappaport
7/25/02 04:13:03 PM
for C.G. McCormick, MD