DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-678; S-013
NDA 20-734; S-012

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

Attn: Marcia Marconi
Vice President, Regulatory Affairs

Dear Ms. Marconi:

Please refer to your supplemental new drug applications dated November 21, 2002, received November 22, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Clinimix E®-sulfite-free (Amino Acid with Electrolytes in Dextrose with Calcium) Injections in Clarity® Dual Chamber Container (1L) and Clinimix®-sulfite-free (Amino Acid in) Injections in Clarity® Dual Chamber Container (1L).

These "Changes Being Effected" supplemental new drug applications provide 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 these supplemental new drug applications and they are approved effective on the date of this letter. However, we have the following comment.

> The data used to support these supplemental NDAs were obtained by an older analytical method that was not provided to the Agency for review. Aluminum determinations should be performed using the validated analytical method which was provided in these supplemental NDAs. The resulting data (aluminum determination) should be submitted to the Agency in the next annual report.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert submitted November 21, 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, these submissions should be designated "FPL for approved supplement NDA 20-678/S-013, NDA 20-734/S-012." Approval of these submissions 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 these NDAs 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}

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/

Bob Rappaport

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