DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20-678/S-021 **APPROVAL LETTER**

Baxter Healthcare Corporation
Attention: Carey Anderson
Senior Director, Regulatory Affairs
1620 Waukegan Road
McGaw Park, IL 60085

Dear Mr. Anderson:

Please refer to your supplemental new drug application dated October 28, 2008, received October 30, 2008, 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) Injection in Clarity Dual Chamber Container.

We acknowledge receipt of your submission dated July 13, 2009.

This supplemental new drug application provides for revisions to the "Directions for Use of Plastic Container" and "Dosage and Administration" sections of the Package Insert (PI) and container labels.

We completed our review of this application as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in SPL format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 20-678."

CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge your October 28, 2008, submissions containing final printed carton and container labels.

Marketing the products with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

PROMOTIONAL MATERIALS

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

LETTERS TO HEALTH CARE PROFESSIONALS

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 an electronic copy of the letter to both this NDA and to the following address:

MEDWATCH
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

REPORTING REQUIREMENTS

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 Heather Buck, Regulatory Project Manager, at (301) 796-1413.

Sincerely,

{See appended electronic signature page}

Donna Griebel, M.D.
Director
Division of Gastroenterology Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure: Package Insert

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-20678	SUPPL-21	BAXTER HEALTHCARE CORP	CLINIMIX E 2.75/10 SULFITE-FREE W/ ELECT
NDA-20734	SUPPL-19	BAXTER HEALTHCARE CORP	CLINIMIX 2.75/10 SULFITE FREE IN DEXTROS

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

DONNA J GRIEBEL
11/02/2009