DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

NDA 017385/S-064, NDA 017484/S-074, NDA 018629/S-048

SUPPLEMENT APPROVAL

Baxter Healthcare Corporation
Attention: Rosario Thacker
Senior Associate, Regulatory Affairs
32650 N. Wilson Road, Mail Stop WG1-3
Round Lake, IL 60073

Dear Ms. Thacker:

Please refer to your Supplemental New Drug Applications (sNDAs) dated and received November 20, 2017, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

NDA	Supplement No.	Product Name
017385	064	PLASMA-LYTE 56 in 5% Dextrose Injection in Plastic Container Injection
017484	074	5% Dextrose and Electrolyte No. 48 Injection
018629	048	5% Dextrose, 0.33% Sodium Chloride and Potassium Chloride Injections in Plastic Container, USP

We also refer to our approval letter dated May 17, 2018, in which we erroneously stated NDA 018269/S-048, which should state NDA 018629/S-048 a part of this bundled supplement. This replacement letter incorporates the correction of this error. The effective date will remain May 17, 2018, the date of the original approval letter.

These "Changes Being Effected in 30 days" supplemental new drug applications provide for addition of Baxter S.A. Boulevard Rene Branquart 80, 7860, Lessines, Belgium [FEI# 300468265] as an alternate manufacturing facility for the empty 1-liter (b) (4) plastic VIAFLEX® container closure system.

APPROVAL

We have completed our review of this supplemental new drug application. These supplements are approved.

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 Grecia C. Edwards, Regulatory Business Process Manager, at (240) 402 - 1773.

Sincerely,

{See appended electronic signature page}

David Lewis, PhD.
Branch Chief, BII
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

David Lewis

Digitally signed by David Lewis
Date: 7/11/2018 09:22:29AM
GUID: 508da72000029f287fa31e664741b577