DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 16677/S-148
NDA 18016/S-062
NDA 19022/S-026

SUPPLEMENT APPROVAL

Baxter Healthcare Corporation
Attention: Linda Coleman
Director, Regulatory Affairs
32650 N. Wilson Rd.
Mail Stop WG2-3S
Round Lake, IL 60073

Dear Ms. Coleman:

Please refer to the following Supplemental New Drug Applications (sNDAs) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA):

NDA	Supplement	Drug	Received
16677	148	0.9% Sodium Chloride Injection, USP in Plastic Container	11/1/13
18016	062	0.45% Sodium Chloride Injection, USP in Plastic Container	11/1/13
19022	026	3% and 5% Sodium Chloride Injection, USP in Plastic Container	11/1/13

These "Prior Approval" supplemental new drug applications provide for the following changes to the package inserts:

- Warnings – elevate hypersensitivity reactions from Precautions; reorganize information; add the following information:
  - risk for fluid and/or solute overloading resulting and dilution of serum electrolyte concentrations
  - caution to patients at risk for hypernatremia, hypercholermia, hypervolemia or conditions causing sodium retention, fluid overload and edema
- Precautions
  - add information regarding air embolism and rapid correction of hypo- and hypernatremia
  - remove subsections containing no data
  - Drug Interactions – update language with information regarding corticosteroids and lithium
- Adverse Reactions – update with postmarketing adverse reactions
- Add Overdosage section
- Dosage and Administration – clarify information regarding plastic containers, and dosage; add recommendation to use final filter and inspect solution
- Directions for Use – add instruction to visually inspect container

- Preparation for Administration – remove unnecessary cautions regarding the container

APPROVAL & LABELING

We have completed our review of these supplemental applications. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling, with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes labeling changes for these NDAs, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the address above or by fax to 301-847-8444.

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}

Joyce Korvick, M.D., M.P.H.
Deputy Director for Safety
Division of Gastroenterology and Inborn Errors Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

ENCLOSURES: Content of Labeling

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

/s/

JOYCE A KORVICK
12/22/2014