



NDA 19022/S-031

SUPPLEMENT APPROVAL

Baxter Healthcare Corporation
Attention: Kelly Jones
Specialist, Regulatory Affairs
32650 N. Wilson Road
Mail Stop WG1-3
Round Lake, IL 60073

Dear Ms. Jones,

Please refer to your Supplemental New Drug Application (sNDA) dated and received on, May 23, 2018, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Sodium Chloride Injection, USP, 3% and 5%.

This “Changes Being Effected” supplemental new drug application proposes to revise the prescribing information to as follows: 1) add Hyperchloremia to the ADVERSE REACTIONS section, and 2) remove Pregnancy Category to align with FDA’s Pregnancy, Lactation, and Reproductive Potential: Labeling for Human Prescription Drug and Biological Product (PLLR) guidance.

We have completed our review of this supplemental application, as amended. It is 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 include labeling changes for this NDA, 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).

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 Thao Vu, Regulatory Project Manager, at (240) 402-2690.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURE(S):
Prescribing information

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

JOYCE A KORVICK
09/14/2018