NDA 016677/S-185
NDA 016682/S-124
NDA 018016/S-071

SUPPLEMENT APPROVAL

Baxter Healthcare Corporation
Attention: Melissa Klesch
Senior Manager, Regulatory Affairs
25212 W. Illinois Route 120
Round Lake, IL 60073

Dear Melissa Klesch:

Please refer to your supplemental new drug applications (sNDAs) dated and received on February 9, 2024, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for for the following:

NDA/Supplement #	**Product Name**
016677/S-185	0.9% Sodium Chloride Injection, USP in Plastic Container
016682/S-124	Lactated Ringer's Injection, USP in Plastic Container
018016/S-071	0.45% Sodium Chloride Injection, USP

These Prior Approval sNDAs provide for updates to the the DOSAGE AND ADMINISTRATION section, Important Preparation and Administration Instructions subsection of the Prescribing Information to clarify a statement regarding pressurization of the container during use.

APPROVAL & LABELING

We have completed our review of these applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling with minor editorial revisions listed below and reflected in the enclosed labeling.

1. In NDA 016677/S-185, in the following sentence, a comma was added after the word "required", "*However, if pressure infusion is required, ensure that any air within the bag is fully evacuated prior to initiation of infusion*."

2. In all three sNDAs: NDA 016677/S-185, NDA 016682/S-124, NDA 018016/S-071, a comma was added after the first clause of the following sentence, "*The solution should be clear, and there should be no precipitates*."

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 FDA.gov.[1] Content of labeling must be identical to the enclosed labeling text for the Prescribing Information, 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 *SPL Standard for Content of Labeling Technical Qs and As*.[2]

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 Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), 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).

PATENT LISTING REQUIREMENTS

Pursuant to 21 CFR 314.53(d)(2) and 314.70(f), certain changes to an approved NDA submitted in a supplement require you to submit patent information for listing in the Orange Book upon approval of the supplement. You must submit the patent information required by 21 CFR 314.53(d)(2)(i)(A) through (C) and 314.53(d)(2)(ii)(A) and (C), as applicable, to FDA on Form FDA 3542 within 30 days after the date of approval of the supplement for the patent information to be timely filed (see 21 CFR 314.53(c)(2)(ii)). You also must ensure that any changes to your approved NDA that require the submission of a request to remove patent information from the Orange Book are submitted to FDA at the time of approval of the supplement pursuant to 21 CFR 314.53(d)(2)(ii)(B) and 314.53(f)(2)(iv).

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[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

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, contact me at 240-402-3448 or chinedu.ebonine@fda.hhs.gov .

Sincerely,

{See appended electronic signature page}

Judith A. Racoosin, M.D., M.P.H.
Deputy Director for Safety
Division of Hepatology and Nutrition
Office of Immunology and Inflammation
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURE:

- Content of Labeling
  - 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/

JUDITH A RACOOSIN
07/24/2024 11:12:10 AM