Our STN: BN 125695/0

NDA APPROVAL
September 5, 2019

Fresenius Kabi AG
Attention: Cheryl Roscher, PhD
Fenwal, Inc.
Three Corporate Drive, 2nd Floor
Lake Zurich, IL 60047

Dear Dr. Roscher:

Please refer to your new drug application (NDA) dated September 28, 2018, received October 1, 2018, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for 0.9% Sodium Chloride Injection USP.

This new drug application provides for the use of 0.9% Sodium Chloride Injection USP as a pre-attached subassembly component of the Fresenius Kabi apheresis kit for apheresis kit priming and/or for use as a replenishment fluid to maintain isovolemia in subjects undergoing an apheresis procedure.

APPROVAL & LABELING

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the labeling submitted on October 5, 2018.

CONTAINER LABELING

Submit final printed carton and container labeling that are identical to the container label submitted on October 5, 2018, as soon as it is available, but no more than 30 days after they are printed. Please submit these labeling electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission "**Final Printed Container Labeling for approved NDA BN 125695**." Approval of this submission by FDA is not required before the labeling is used.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

POSTMARKETING COMMITMENTS NOT SUBJECT TO THE REPORTING REQUIREMENTS UNDER SECTION 506B

We acknowledge your written commitments as described in your letter of September 3, 2019, as outlined below:

1. Fresenius Kabi AG commits to submitting a summary report for studies originally performed to support the validation of the (b) (4) test method, including the study design and how the positive controls were made and verified. This (b) (4) test is used to verify container closure integrity testing (CCIT) of the new 0.9% Sodium Chloride Injection USP container closure system. The summary report will be submitted to the Agency no later than January 31, 2020.

   Final Report Submission: January 31, 2020

2. Fresenius Kabi AG commits to demonstrating that the (b) (4) CCIT method remains suitable for the testing of the new 0.9% Sodium Chlride Injection USP container closure system. The additional supportive information will be submitted to the Agency no later than January 31, 2020.

   Final Report Submission: January 31, 2020

We request that you submit information concerning nonclinical and chemistry, manufacturing, and control postmarketing commitments and final reports to your NDA BN 125695/0. Please refer to the sequential number for each commitment.

Please use the following designators to prominently label all submissions, including supplements, relating to these postmarketing study commitments as appropriate:

- **Postmarketing Commitment – Status Update**
- **Postmarketing Commitment – Final Study Report**
- **Supplement contains Postmarketing Commitment – Final Study Report**

For each postmarketing commitment not subject to the reporting requirements of 21 CFR 601.70, you may report the status to FDA as a **Postmarketing Commitment – Status Update**. The status report for each commitment should include:

- the sequential number for each study as shown in this letter;
- the submission number associated with this letter;
- describe what has been accomplished to fulfill the non-section 506B PMC; and,
- summarize any data collected or issues with fulfilling the non-section 506B PMC.

When you have fulfilled your commitment, submit your final report as **Postmarketing Commitment – Final Study Report** or **Supplement contains Postmarketing Commitment – Final Study Report**.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

Sincerely,

Nicole Verdun, MD
Director
Office of Blood Research and Review
Center for Biologics Evaluation and Research