NDA 019708/S-040

SUPPLEMENT APPROVAL

B Braun Medical Inc.
Attention: Cindy Lombardy, MS
Sr. Director, Regulatory Affairs
824 12th Ave
Bethlehem, PA 18018

Dear Cindy Lombardy:

Please refer to your Supplemental New Drug Application (sNDA) dated and received July 22, 2025, and your amendments, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Potassium Chloride in Sodium Chloride Injections USP in EXCEL Plastic Container.

This "Changes Being Effected" supplemental new drug application provides for optimizing the container labeling to improve printing efficiency and to improve end-user readability, including revision of strength from 0.15% to 20 mEq to align with clinically recognized Potassium Chloride naming convention.

APPROVAL & LABELING

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.

CARTON AND CONTAINER LABELS

Submit final printed carton and container labels that are identical to enclosed carton and container labels, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels 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 "**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 019708/S-040.**" Approval of this submission by FDA is not required before the labeling is used.

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 Emma Gimose, Regulatory Business Process Manager, at Emma.Gimose@fda.hhs.gov or (240) 402 - 1681.

Sincerely,

{See appended electronic signature page}

David Claffey, Ph.D.
Supervisor
Division of Product Quality Assessment III
Office of Product Quality Assessment I
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosures:
Carton and Container Labeling

David Claffey

Digitally signed by David Claffey
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