NDA 19632/S-050
NDA 19634/S-050
NDA 20002/S-032

SUPPLEMENT APPROVAL

B. Braun Medical Inc.
Attention: Cindy Katsempris
Director, Regulatory Affairs
901 Marcon Blvd.
Allentown, PA 18109

Dear Ms. Katsempris,

Please refer to your supplemental new drug application (sNDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

Application	Supplement	Product Name	Date of Submission	Date of Receipt
NDA 19632	S-050	Lactated Ringer's Injection USP in EXCEL® Plastic Container	12/08/2020	12/08/2020
NDA 19634	S-050	5% Dextrose in Lactated Ringer's Injection in EXCEL® Container Injection	12/11/2020	12/11/2020
NDA 20002	S-032	Ringer's Injection USP in EXCEL® Plastic Container	2/24/2021	2/24/2021

These "Changes Being Effected" sNDAs provide for the following:

- The update of the Contraindications, Warnings, Drug Interactions, Precautions/ Pediatric Use, and Dosage and Administration sections of the prescribing information (PI) to include the incompatibility between ceftriaxone and calcium-containing crystalloid fluid products.

- For NDA 19632/S-050 only: Removal of the (b) (4) per guidance for industry, *Pregnancy, Lactation, and Reproductive Potential: Labeling for Human Prescription Drug and Biological Products — Content and Format.*[1]

[1] https://www.fda.gov/media/90160/download

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 enclosed agreed-upon labeling.

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.[2] 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*.[3]

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).

REPORTING REQUIREMENTS

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

[2] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
[3] 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.

If you have any questions, call Thao Vu, Regulatory Project Manager, at (240) 402-2690.

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

ENCLOSURES:

- 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
11/03/2021 02:45:01 PM