NDA 019018/S-036

**APPROVAL LETTER**

B. Braun Medical Inc.
Attention: Cindy Katsempris
Director, Regulatory Affairs
901 Marcon Blvd.
Allentown, PA 18109-9341

Dear Ms. Katsempris:

Please refer to your Supplemental New Drug Application (sNDA) dated and received May 17, 2019, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Trophamine (10% Amino Acid Injections).

We acknowledge receipt of your amendment dated July 20, 2020, which constituted a complete response to our June 4, 2020, action letter.

- This Prior Approval supplemental new drug applications provides for a change in formulation for the drug product, a change to the TrophAmine container type (glass bottle to plastic bag), and the addition of the B. Braun facility in Melsungen, Germany to manufacture the re-formulated TrophAmine product. The differences between the proposed product and the currently marketed NDA 019018 product are as follows:
  - The proposed product doesn't contain the antioxidant sodium metabisulfite.
  - The nominal value for the concentration of [redacted] (b) (4) is higher for the proposed product [redacted] (b) (4) compared to the currently marketed product [redacted] (b) (4) Clinical nutrition (plastic) bags are used as containers of the proposed product, whereas the currently marketed product was filled in glass bottles.
  - The proposed product will be manufactured in Melsungen (Germany) instead of Irvine (California, USA)
- Addition of an Elemental Impurities Risk Assessment to demonstrate that the reformulated NDA 019018 drug product (TrophAmine 10%) continues to meet the ICH Q3D and USP <232> requirements for elemental impurities and qualifies for non-testing of elemental impurities in the TrophAmine 10% drug product.
- Update of the port design [redacted] (b) (4) (b) (4)
- Updates to the container label and labeling for the TrophAmine 10% drug product.

## 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.

## 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 (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 titled *SPL Standard for Content of Labeling Technical Qs and As* at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

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/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via 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).

## 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**

**019018/S-036.**" Approval of this submission by FDA is not required before the labeling is used.

We remind you that you must comply with reporting requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Grecia C. Edwards, Regulatory Business Process Manager, at (240) 402 - 1773.

Sincerely,

*{See appended electronic signature page}*

David Lewis, PhD.
Branch Chief, BII
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosures:
Content of Labeling
Carton and Container Labeling

David Lewis

Digitally signed by David Lewis
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