



NDA 019386/S-055

**APPROVAL LETTER**

Baxter Healthcare Corp  
Attention: Aiste Kirkute-Entremont  
Senior Manager, Global Regulatory Affairs  
25212 W. Illinois  
Route 120  
Round Lake, IL 60073

Dear Aiste Kirkute-Entremont:

Please refer to your Supplemental New Drug Application (sNDA) dated and received February 14, 2025, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for BREVIBLOC (Esmolol Hydrochloride) injection.

This “Changes Being Effectuated in 30 days” supplemental new drug application provides for (b) (4) with (b) (4) on the container label. (b) (4) ink is currently used on Brevibloc (esmolol hydrochloride) Premixed Injection, 20 mg/mL bag container and (b) (4) overpouch labels. The proposed replacement of (b) (4) to already approved (b) (4) color is limited to the flexible bag container, where the (b) (4) ink remains on the overpouch label.

**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 carton and container labels submitted on July 23, 2025, 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 019386/S-055.**” 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.

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If you have any questions, contact Grafton Adams, Regulatory Business Process Manager, at [grafton.adams@fda.hhs.gov](mailto:grafton.adams@fda.hhs.gov) .

Sincerely,

*{See appended electronic signature page}*

Julia Pinto Ph.D.  
Supervisor  
Division of Product Quality Assessment VIII  
Office of Product Quality Assessment II  
Office of Pharmaceutical Quality  
Center for Drug Evaluation and Research

Enclosure(s):

Carton and Container Labeling



Julia  
Pinto

Digitally signed by Julia Pinto

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