



NDA 018569/S-071

## **SUPPLEMENT APPROVAL**

Epic Pharma, LLC  
c/o MLV Pharma, LLC  
Attention: Harinath Gangasani  
U.S. Agent  
2760 Dolores Home Ave  
Valrico, FL 33594

Dear Mr. Gangasani:

Please refer to your Supplemental New Drug Application (sNDA) dated and received December 4, 2025, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Furosemide Tablets, USP.

This “Changes Being Effected” supplemental new drug application provides for:

- Changes to the drug product description in “How Supplied” section of prescribing information to be aligned with the approved drug product specifications.
- Changes to the NDC number and packaging configurations (tablet count/bottle) in “How Supplied” section of prescribing information and primary container labels to be aligned with the approved drug product packaging configurations and container sizes.

### **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.

We note that your May 22, 2026, submission includes final printed labeling (FPL) for your prescribing information. You are responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

### **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 patient package insert) 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**

We acknowledge your May 18, 2026, submission containing final printed carton and container labeling.

### **PROPRIETARY NAME**

If you intend to have a proprietary name for this product, the name and its use in the labels must conform to the specifications under 21 CFR 201.10 and 201.15. We recommend that you submit a request for a proposed proprietary name review. (See the guidance for industry *Contents of a Complete Submission for the Evaluation of Proprietary Names*, available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm075068.pdf> and “PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2008 through 2012”.)

### **REQUIRED PEDIATRIC ASSESSMENTS**

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, 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(s) 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.

### **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, contact Mikee Aguirre, Regulatory Business Process Manager, at [mikee.aguirre@fda.hhs.gov](mailto:mikee.aguirre@fda.hhs.gov).

Sincerely,

*{See appended electronic signature page}*

Vilayat Sayeed, Ph.D.  
Director, Division of Product Quality Assessment II  
Office of Product Quality Assessment I  
Office of Pharmaceutical Quality  
Center for Drug Evaluation and Research

Enclosures:

Content of Labeling  
Carton and Container Labeling



Vilayat  
Sayeed

Digitally signed by Vilayat Sayeed

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