



**Suitability Petition  
Completeness Assessment Correspondence**

Epic Pharma, LLC  
227-15 North Conduit Avenue  
Laurelton, NY 11413  
Attn: Pei Zhang

Sent via email to: RADept@epic-pharma.com

Docket No. FDA-2024-P-1441

Dear Pei Zhang:

This is in reference to your petition received on March 22, 2024, by the U.S. Food and Drug Administration (FDA or Agency), requesting permission, in accordance with 21 C.F.R. §314.93(b), to submit an Abbreviated New Drug Application (ANDA) for the following drug product: Leucovorin Calcium Injection, 200 mg (base)/20 ml (10 mg/ml) and 350 mg (base)/35 ml (10 mg/ml). The petition was examined for initial completeness (i.e. Completeness Assessment) under CFR 10.30 and the Agency has made a threshold determination that the petition is complete.

This petition is subject to the provisions of the Generic Drugs User Fee Amendments of 2022 (GDUFA III) whereby any suitability petitions submitted in FY 2024-2027 will receive a goal date of 6 months after the completeness assessment. The GDUFA goal date for review of this petition is October 5, 2024.

If you have any questions, contact [ANDAFiling@fda.hhs.gov](mailto:ANDAFiling@fda.hhs.gov).

A copy of this letter will be placed on public display in the Dockets Management Branch, Room 1061, Mail Stop HFA-305, 5630 Fishers Lane, Rockville, MD 20852.

Sincerely,

*{See appended electronic signature page}*

Bijal Patel, Pharm.D., BCPS  
Team Leader  
Division of Filing Review  
Office of Regulatory Operations  
Office of Generic Drugs  
Center for Drug Evaluation and Research



Bijal  
Patel

Digitally signed by Bijal Patel

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