Suitability Petition
Completeness Assessment Correspondence

Fast Track Drugs and Biologics, LLC on behalf of Amivas, Inc.
20010 Fisher Avenue, Suite G
Poolesville, MD 20837
Attn: Janet Ransom

Sent via email to: Jransom@fasttrackresearch.com

Docket No. FDA-2024-P-1913

Dear Janet Ransom:

This is in reference to your petition received on April 17, 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: Methylene Blue Injection USP, 50 mg/5 mL (10 mg/mL) vials. 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 30, 2024.

If you have any questions, contact 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

U.S. Food & Drug Administration
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Bijal Patel

Digitally signed by Bijal Patel
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