Suitability Petition
Completeness Assessment Correspondence

Method Pharmaceuticals, LLC
419 Bank Street, Suite 100
Southlake, TX 76092
Attn: Scott Tucker

Sent via email to: hari@mlvpharma.com

Docket No. FDA-2024-P-0422

Dear Scott Tucker:

This is in reference to your petition received on January 12, 2024, by the U.S. Food and Drug Administration (FDA or Agency) and your amendments dated February 23, 2024 and March 8, 2024, 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: Folic Acid Oral Solution, 0.1 mg/mL and 1 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 September 12, 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}

Elizabeth Kim, MSN, APRN, FNP-BC
Regulatory Officer
Division of Filing Review
Office of Regulatory Operations
Office of Generic Drugs

Center for Drug Evaluation and Research

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Elizabeth Kim

Digitally signed by Elizabeth Kim
Date: 3/12/2024 02:11:58PM
GUID: 5589699300c03b18e9f30807f0193d16