March 8, 2024

Division of Dockets Management
U.S. Food and Drug Administration
Department of Health and Human Services Room1061, HFA-305
5630 Fishers Lane
Rockville, MD 20852

Docket Number: FDA-2024-P-0422

ANDA Suitability Petition for Folic Acid Oral Solution, 0.1 mg/mL and 1 mg/mL.

Dear Sir/Madam,

Reference is made to the submission dated January 11, 2024, seeking permission to file an ANDA for Folic Acid Oral Solution, 0.1 mg/mL and 1 mg/mL.

Reference is also made to the e-mail from Kim-Yen Nguyen dated March 4, 2024, requesting to submit the information as an amendment to the ANDA Suitability Petition to the Division of Dockets Management, for the Agency to complete the review of the petition:

1. ***We note that your claim in the petition requests a change in dosage form only. The RLD identified as the basis of submission (ANDA 080680) does not cover the 0.1 mg/mL strength. Revise the proposed type of change to also include a strength change in addition to the dosage form change.***

Petitioner Response:

The petitioner is submitting the amendment to Suitability Petition for Folic Acid Oral Solution, 0.1 mg/mL and 1 mg/mL.

Sincerely,
For Method Pharmaceuticals LLC.

Scott Tucker
Chief Executive Officer

Reference: FDA-2024-P-0422 **March 8, 2024**

Division of Dockets Management
U.S. Food and Drug Administration
Department of Health and Human Services
Room 1061, l-IFA-305
5630 Fishers Lane
Rockville, MD 20852

ANDA Suitability Petition Amendment for Folic Acid, Oral Solution

Method Pharmaceuticals LLC would like to amend the ANDA suitability Petition for Folic Acid, Oral Solution, 0.1 mg/mL, and 1 mg/mL (Docket ID FDA-2024-P-0422) so that the proposed change presented under "Action Requested" and "Statement of Grounds" read as follows.

A. Action Requested:

The Suitability Petition requests that the FDA determine that the proposed Folic Acid Oral Solution, 0.1 mg/mL and 1 mg/mL is suitable for submission in an ANDA. This Suitability Petition pursuant to Section 505(j)(2)(C) of the FDC Act and 21C.F.R. §314.93, is the appropriate mechanism for securing FDA authorization to submit an ANDA for a drug product that differs in dosage form and strength from the Reference Listed Drug (RLD).

The Reference Listed Drug (RLD) upon which this petition is based is Folic Acid Tablets, 1 mg which FDA approved prior to January 1, 1982, under ANDA A080680 as identified in the Orange Book.

The drug, the route of administration and the recommendations for use are the same as the reference listed drug product. The proposed drug product would differ only in dosage form and strength from the marketed tablet products.

B. Statement of Grounds:

The FDC Act permits, at Section 505(j)(2)(A)(iii) and 21C.F.R. §314.93, the submission of an ANDA for a drug product that differs in dosage form and strength from the RLD after FDA has approved a petition seeking permission to file such an application.

The drug, the route of administration and the recommendations for use are the same as the reference listed drug product. The proposed drug product would differ only in dosage form and strength from the marketed tablet products.

Sincerely,
For Method Pharmaceuticals LLC.

Scott Tucker
Chief Executive Officer