ANDA 090055/S-034

CHANGES BEING EFFECTED IN 30 DAYS
APPROVAL

Strides Pharma, Inc.
U.S. Agent for Strides Pharma Global Pte Limited
1 Ram Ridge Road
Chestnut Ridge, NY 10977-6714
Attention: Chandran Tiruvattar
Sr. Vice President - RA

Dear Chandran Tiruvattar:

This letter is in reference to your supplemental abbreviated new drug application (sANDA) received for review on October 30, 2024, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Mycophenolate Mofetil Capsules USP, 250 mg.

Reference is also made to any amendments submitted prior to the issuance of this letter.

The sANDA, submitted as “Changes Being Effected in 30 Days," provides for:

> Addition of drug product manufacturing, testing (excipients, in-process and stability) and packaging site – Strides Pharma, Inc. (FEI: 2434223).

We have completed the review of this sANDA, as amended, and it is **approved**.

COMPENDIAL STANDARDS

A drug with a name recognized in the official United States Pharmacopeia or official National Formulary (USP-NF) generally must comply with the compendial standard for strength, quality, and purity, unless the difference in strength, quality, or purity is plainly stated on its label (see FD&C Act § 501(b), 21 USC 351(b)). FDA typically cannot share application-specific information contained in submitted regulatory filings with third parties, which includes USP-NF. To help ensure that a drug continues to comply with compendial standards, application holders may work directly with USP-NF to revise official USP monographs. More information on the USP-NF is available on USP’s website as https://www.uspnf.com/.

REQUIREMENTS AND RECOMMENDATIONS POST APPROVAL

Under applicable statutes, regulations, and guidances, your ANDA may be subject to certain requirements and recommendations post approval, including requirements regarding changes to approved ANDAs, postmarketing reporting, promotional materials, and annual facility fees, among others. For information on post-approval requirements and recommendations for ANDAs and a list of resources for ANDA holders, we refer you to https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/requirements-and-resources-approved-andas.

If you have any questions, contact Zeyneb Aydilek, Regulatory Business Process Manager, at (301) 796 - 3368 or zeyneb.aydilek@fda.hhs.gov.

Sincerely yours,

{See appended electronic signature page}

For:
Ee-Sunn (Joanne) Chia, Ph.D.
Director
Division of Product Quality Assessment X
Office of Product Quality Assessment II
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Niles Ron

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