ANDA 212569/S-004

CHANGES BEING EFFECTED IN 30 DAYS
APPROVAL

Amneal Pharmaceuticals of New York, LLC
U.S. Agent for Amneal EU, Limited
50 Horseblock Road
Brookhaven, NY 11719
Attention: Pavan Kumar Gangavarapu
Vice President

Dear Pavan Kumar Gangavarapu:

This letter is in reference to your supplemental abbreviated new drug application (sANDA) received for review on October 30, 2023, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Pirfenidone Capsules, 267 mg.

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

> Addition of Alternate Testing Site for In-Process Tests in Drug Product (Amneal Pharmaceuticals of New York, LLC; FEI: 3005263655)

We have completed the review of this sANDA 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 further questions regarding this supplement, you may contact Karen Ireland, Regulatory Business Process Manager, at (240) 402 - 9213.

Sincerely yours,

{See appended electronic signature page}

For:
Paul Schwartz, Ph.D.
Director, Division of Post Marketing Activities II
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Niles Ron

Digitally signed by Niles Ron
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