ANDA 090377/S-012

PRIOR APPROVAL SUPPLEMENT
APPROVAL

Impax Laboratories, LLC
50 Horseblock Road
Brookhaven, NY 11719
Attention: Pavan Kumar Gangavarapu
Vice President, Global Regulatory Affairs

Dear Pavan Kumar Gangavarapu:

This letter is in reference to your supplemental abbreviated new drug application (sANDA) received for review on February 6, 2025, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Tamsulosin Hydrochloride Capsules USP, 0.4 mg.

The sANDA, submitted as “Prior Approval Supplement," provides for:

1. Addition of Alternate API Manufacturer (DMF#021041). Quimica Sintetica S.A., Calle Dulcinea, S/N, Alcala De Henares, Madrid, 28805, Spain (ESP); FEI #3002807965; DUNS #460054141.
2. Addition of Drug Product Manufacturing, Packaging and Testing Site. Amneal Pharmaceuticals of New York, LLC, 50 Horseblock Rd, Brookhaven, New York (NY) 11719-9509, USA; FEI# 3005263655; DUNS#123797875.
3. Addition of Alternate Testing Site for Drug Substance and Drug Product. Amneal Pharmaceuticals Pvt. Ltd. Oral Solid Dosage Unit, Plot No 16 & 17, PHARMEZ Special Economic Zone Sarkhej-Bavla N.H. No. 8A, Vil.: Matoda, Tal.: Sanand, Ahmedabad, GJ 382213, India; FEI: 3010661577; DUNS: 650762060.
4. Changes in the Finished Product Specification as follows:
    - Addition of N-Nitroso-Tamsulosin Impurity (NDSRI) control in Drug Product Release and Stability Specifications
    - Revision of Drug product specification and methods to comply with current USP monograph of Tamsulosin Hydrochloride Capsule.
5. Addition of alternate Container closure source. Alternate source of 150cc HDPE Bottle and Alternate source of CR Cap.
6. Addition of alternate Source of excipients.

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 any questions, contact DeWayne Johnson, Regulatory Business Process Manager, at (301) 796 - 2343 or dewayne.johnson@fda.hhs.gov.

Sincerely yours,

{See appended electronic signature page}

For:
Vilayat Sayeed, PhD.
Director
Division of Product Quality Assessment II
Office of Product Quality Assessment I
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Matthew Vera

Digitally signed by Matthew Vera
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