ANDA 214557

ANDA APPROVAL

Ascend Laboratories, LLC
U.S. Agent for Alkem Laboratories Limited
339 Jefferson Road
Parsippany, NJ 07054
Attention: Hindy Schiff

Dear Hindy Schiff:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on March 23, 2020, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Varenicline Tablets, 0.5 mg and 1 mg.[1]

Reference is also made to the complete response letter issued by this office on April 5, 2023, and to any amendments thereafter.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug meets the requirements for approval under the FD&C Act. Accordingly the ANDA is **approved**, effective on the date of this letter. We have determined your Varenicline Tablets, 0.5 mg and 1 mg to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Chantix Tablets, 0.5 mg and 1 mg, of PF Prism C.V. (PF Prism).

Please note that if FDA requires a Risk Evaluation and Mitigation Strategy (REMS) for a listed drug, an ANDA referencing that listed drug also will be required to have a REMS. See section 505-1(i) of the FD&C Act.

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.

Sincerely yours,

{See appended electronic signature page}

For Edward M. Sherwood
Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

[1] We note that the reference listed drug (RLD) upon which you have based this ANDA, PF Prism's Chantix Tablets, 0.5 mg and 1 mg, is no longer being marketed in the United States and is currently listed in the discontinued section of FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"). The Agency has determined that PF Prism's Chantix Tablets, 0.5 mg and 1 mg, were not withdrawn from sale for reasons of safety or effectiveness. FDA published this determination in the Federal Register (88 FR 12384; February 27, 2023). This determination allows the Agency to approve ANDAs for the discontinued drug product.

Julie Kuriakose

Digitally signed by Julie Kuriakose
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