ANDA 211951/S-003

PRIOR APPROVAL SUPPLEMENT
APPROVAL

Padagis US LLC
U.S. Agent for Padagis Israel Pharmaceuticals Ltd.
3940 Quebec Avenue North
Minneapolis, MN 55427
Attention: Anna Voght
RA Manager

Dear Anna Voght:

This letter is in reference to your supplemental abbreviated new drug application (sANDA) received for review on April 20, 2023, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Naloxone Hydrochloride Nasal Spray, 4 mg/spray (OTC).

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

The sANDA, submitted as “Prior Approval Supplement," provides for a change from prescription marketing status to over-the-counter (OTC) marketing status

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.

Sincerely yours,

{See appended electronic signature page}

For Rachel Goehe, Ph.D.
Director
Division of Labeling Review
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

Burhan Nour

Digitally signed by Burhan Nour
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