ANDA 215328

ANDA APPROVAL

Padagis US LLC
U.S. Agent for Padagis Israel Pharmaceuticals Ltd.
3940 Quebec Avenue North
Minneapolis, MN 55427
Attention: Nancy Christiansen
Senior Project Manager

Dear Nancy Christiansen:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on February 14, 2022, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Budesonide Rectal Foam, 2 mg/dose.

Your product is a combination product as defined by 21 CFR 3.2(e) and is comprised of drug and device constituent parts.

Reference is also made to the complete response letter issued by this office on December 12, 2022, 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 Budesonide Rectal Foam, 2 mg/dose to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Uceris Rectal Foam, 2 mg/dose, of Salix Pharmaceuticals, Inc.

Reference is also made to FDA's Competitive Generic Therapy Designation – Grant letter dated October 30, 2020.

We note that Padagis Israel Pharmaceuticals Ltd. (Padagis) was granted a Competitive Generic Therapy (CGT) designation for Budesonide Rectal Foam, 2 mg/dose. Padagis is the "first approved applicant" for Budesonide Rectal Foam, 2 mg/dose, as defined in section 505(j)(5)(B)(v)(III) of the FD&C Act. Therefore, with this approval, Padagis is eligible for 180 days of CGT exclusivity for Budesonide Rectal Foam, 2 mg/dose, under section 505(j)(5)(B)(v) of the FD&C Act. This exclusivity begins to run from the date of the first commercial marketing of the CGT (including the commercial marketing of the listed drug) by Padagis, as specified in section 505(j)(5)(B)(v) of the FD&C Act. Furthermore, in accordance with section 505(j)(5)(B)(v)(I) of the FD&C Act, this 180-day CGT exclusivity will not block approval of other applications until Padagis has

commenced commercial marketing. Please submit a correspondence to this ANDA informing the Agency of the date you begin commercial marketing. Please also submit notice of first commercial marketing via e-mail to the Patent and Exclusivity Team at CDER-OGDPET@fda.hhs.gov. This e-mail should be sent the same day you commence commercial marketing. Reference is also made to the Special Forfeiture Rule for Competitive Generic Therapy in section 505(j)(5)(D)(iv) of the FD&C Act. Please be aware that, pursuant to this forfeiture rule, you will forfeit your eligibility for the 180-day CGT exclusivity period for Budesonide Rectal Foam, 2 mg/dose, if you fail to market this CGT within 75 days after the date on which the approval of this application is made effective.

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.

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

Catherine Poole

Digitally signed by Catherine Poole
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