ANDA 215266

ANDA 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 abbreviated new drug application (ANDA) received for review on January 28, 2021, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Halobetasol Propionate Topical Foam, 0.05%.

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 tentative approval letter issued by this office on October 17, 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 Halobetasol Propionate Topical Foam, 0.05% to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Lexette Topical Foam, 0.05%, of Mayne Pharma LLC (Mayne).

Reference is also made to FDA's Competitive Generic Therapy Designation – Grant letter dated December 8, 2020.

The RLD upon which you have based your ANDA, Mayne's Lexette Topical Foam, 0.05%, is subject to periods of patent protection. The following patents and expiration dates are currently listed in the Agency's publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"):

U.S. Patent Number	Expiration Date
10,857,159 (the '159 patent)	May 30, 2037*
11,020,407 (the '407 patent)	November 30, 2036

* with pediatric exclusivity added

Your ANDA contains paragraph IV certifications to each of the patents[1], under section 505(j)(2)(A)(vii)(IV) of the FD&C Act stating that the patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Halobetasol Propionate Topical Foam, 0.05%, under this ANDA. You have notified the Agency that Padagis Israel Pharmaceuticals Ltd. (Padagis) complied with the requirements of section 505(j)(2)(B) of the FD&C Act. Litigation was initiated within the statutory 45-day period against Padagis for infringement of the '159 patent in the United States District Court for the District of Delaware [Mayne Pharma LLC, v. Padagis Israel Pharmaceuticals LTD and Padagis US LLC, Civil Action No. 21-00612]. You have also notified the Agency that this case was dismissed.

In addition, you have provided a copy of a letter from Mayne that waives the unexpired NPP exclusivity period with respect to ANDA 215266.

With respect to 180-day generic drug exclusivity, we note that Padagis was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification for Halobetasol Propionate Topical Foam, 0.05%. Therefore, with this approval, Padagis is eligible for 180 days of generic drug exclusivity for Halobetasol Propionate Topical Foam, 0.05%. FDA notes that after issuance of this approval letter, eligibility for 180-day exclusivity is subject to future events that may result in forfeiture of exclusivity under section 505(j)(5)(D) of the FD&C Act. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the FD&C Act, begins to run from the date of the commercial marketing identified in section 505(j)(5)(B)(iv). Please submit correspondence to this ANDA notifying the Agency within 30 days of the date of the first commercial marketing of this drug product or the RLD. If you do not notify the Agency within 30 days, the date of first commercial marketing will be deemed to be the date of the drug product's approval. See 21 CFR 314.107(c)(2).

We note that Padagis was granted a Competitive Generic Therapy (CGT) designation for Halobetasol Propionate Topical Foam, 0.05%. However, Padagis is not a "first approved applicant" for such competitive generic therapy, as defined in section 505(j)(5)(B)(v)(III) of the FD&C Act, because this drug product is eligible for 180-day patent challenge exclusivity under section 505(j)(5)(B)(iv) of the FD&C Act. See section 505(j)(5)(B)(v)(III)(bb)(BB) of the FD&C Act. Therefore, this drug product is not eligible for CGT exclusivity under section 505(j)(5)(B)(v) of the FD&C Act.

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] The Agency notes that the '407 patent was submitted to the Agency after submission of your ANDA. Litigation, if any, with respect to this patent would not create a statutory stay of approval.

Paul
Levine

Digitally signed by Paul Levine
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