ANDA 219165

ANDA APPROVAL

PAI Holdings, LLC
Attention: Billie J. Wiltison
Vice President, Regulatory Affairs

Dear Billie J. Wiltison:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on March 21, 2024, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Propranolol Hydrochloride Oral Solution, 20 mg/5 mL.[1]

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

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 that your Propranolol Hydrochloride Oral Solution, 20 mg/5 mL, can be expected to have the same therapeutic effect as that of the listed drug product upon which the Agency relied as the basis of safety and effectiveness.

Reference is also made to FDA's Competitive Generic Therapy (CGT) Designation – Grant letter dated December 18, 2023.

We note that PAI Holdings, LLC (PAI) was granted a CGT designation for Propranolol Hydrochloride Oral Solution, 20 mg/5 mL. PAI is the "first approved applicant" for Propranolol Hydrochloride Oral Solution, 20 mg/5 mL, as defined in section 505(j)(5)(B)(v)(III) of the FD&C Act. Therefore, with this approval, PAI is eligible for 180 days of CGT exclusivity for Propranolol Hydrochloride Oral Solution, 20 mg/5 mL, 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 PAI, 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 PAI 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 CGT 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 Propranolol Hydrochloride Oral Solution, 20 mg/5 mL, 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.

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 at: 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 Kendra S. Stewart, R.Ph., Pharm.D.
Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

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[1] We note that the reference listed drug (RLD) upon which you have based this ANDA, Wyeth Pharmaceuticals LLC's (Wyeth's) Inderal Tablets, 20 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 Wyeth's Inderal Tablets, 20 mg, was not withdrawn from sale for reasons of safety or effectiveness. FDA published this determination in the *Federal Register* (73 FR 01619; January 9, 2008). This determination allows the Agency to approve ANDAs for the discontinued drug product.

Paul Levine

Digitally signed by Paul Levine
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