ANDA 217252

ANDA APPROVAL

Slayback Pharma LLC
301 Carnegie Center, Suite 303
Princeton, NJ 08540
Attention: Praveen Subbappa
Senior Director

Dear Praveen Subbappa:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on May 20, 2022, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Baclofen Oral Suspension, 25 mg/5 mL (5 mg/mL).

Reference is also made to the complete response letter issued by this office on March 13, 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 Baclofen Oral Suspension, 25 mg/5 mL (5 mg/mL) to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Fleqsuvy Oral Suspension, 25 mg/5 mL (5 mg/mL), of Azurity Pharmaceuticals, Inc. (Azurity).

Reference is also made to FDA's Competitive Generic Therapy Designation – Grant letter dated April 12, 2022.

The RLD upon which you have based your ANDA, Azurity's Fleqsuvy Oral Suspension, 25 mg/5 mL (5 mg/mL), 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
11,324,696 (the '696 patent)	September 29, 2037
11,446,246 (the '246 patent)	September 8, 2037

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 Baclofen Oral Suspension, 25 mg/5 mL (5 mg/mL), under this ANDA. You have notified the Agency that Slayback Pharma LLC (Slayback) complied with the requirements of section 505(j)(2)(B) of the FD&C Act and that no action for infringement was brought against Slayback within the statutory 45-day period.

With respect to 180-day generic drug exclusivity, we note that Slayback was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification for Baclofen Oral Suspension, 25 mg/5 mL (5 mg/mL). Therefore, with this approval, Slayback is eligible for 180 days of generic drug exclusivity for Baclofen Oral Suspension, 25 mg/5 mL (5 mg/mL). 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 Slayback was granted a Competitive Generic Therapy (CGT) designation for Baclofen Oral Suspension, 25 mg/5 mL (5 mg/mL). However, Slayback 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 '246 patents were submitted to the Agency after submission of your ANDA. Litigation, if any, with respect to these patents would not create a statutory stay of approval.

Catherine Poole

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