ANDA 214445

**ANDA APPROVAL**

Advagen Pharma Limited
U.S. Agent for Rubicon Research Private Limited
50 Millstone Road
Building 200, Suite 180
East Windsor, NJ 08520
Attention: Daliya Bharati
Director – Regulatory & IP

Dear Daliya Bharati:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on July 26, 2021, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Baclofen Oral Solution, 5 mg/5 mL.[1]

Reference is also made to the approval letter issued on December 6, 2024. This corrected letter is being issued to include reference to your Competitive Generic Therapy (CGT) Designation as well as 180-day CGT exclusivity language. This letter supersedes our December 6, 2024 approval letter. The action date for the approval letter remains unchanged as December 6, 2024.

Reference is also made to the tentative approval letter issued by this office on March 13, 2023, the complete response letter issued by this office on December 22, 2023, and to any amendments thereafter.

Reference is also made to FDA's Competitive Generic Therapy (CGT) Designation – Grant letter dated February 18, 2020.

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 remains **approved**. We have determined your Baclofen Oral Solution, 5 mg/5 mL to be bioequivalet and therapeutically equivalent to the reference listed drug (RLD), Ozobax Oral Solution, 5 mg/5 mL, of Metacel Pharmaceuticals, LLC (Metacel) NDA - 208193.

The RLD upon which you have based your ANDA, Metacel's Ozobax Oral Solution, 5 mg/5 mL, is subject to a period of patent protection. The following patent and expiration date is currently listed in the Agency's publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"):

| U.S. Patent Number | Expiration Date |
|---|---|
| 10,610,502 (the '502 patent) | August 30, 2039 |

Your ANDA contains a paragraph IV certification to the '502 patent under section 505(j)(2)(A)(vii)(IV) of the FD&C Act stating that the patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Baclofen Oral Solution, 5 mg/5 mL, under this ANDA. You have notified the Agency that Rubicon Research Private Limited (Rubicon) 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 Rubicon for infringement of the '502 patent in the United States District Court for the District of New Jersey [Metacel Pharmaceuticals LLC v. Rubicon Research Private Limited, Civil Action No. 21-19463]. You have also notified the Agency that on August 31, 2023 the court entered a Final Judgment that the "Defendant's ANDA Product that is the subject of ANDA No. 214445 (the "Rubicon ANDA") does not infringe any claim of the '502 patent".[2]

With respect to 180-day generic drug exclusivity, we note that Rubicon was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification for Baclofen Oral Solution, 5 mg/5 mL. Therefore, with this approval, Rubicon is eligible for 180 days of generic drug exclusivity for Baclofen Oral Solution, 5 mg/5 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 Rubicon was granted a Competitive Generic Therapy (CGT) designation for Baclofen Oral Solution, 5 mg/5 mL. However, Rubicon 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

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[1] We note that the reference listed drug (RLD) upon which you have based this ANDA, Metacel's Ozobax Oral Solution, 5 mg/5 mL, 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 Metacel's Ozobax Oral Solution, 5 mg/5 mL, was not withdrawn from sale for reasons of safety or effectiveness. FDA will publish this determination in the *Federal Register* as soon as is practicable. This determination allows the Agency to approve ANDAs for the discontinued drug product.

[2] Final Judgment, Metacel Pharmaceuticals LLC. v. Rubicon Research Private Limited., Civil Action No. 21-19463 (August 31, 2023).

John Ibrahim

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