



ANDA 217608

**ANDA APPROVAL**

Aurobindo Pharma USA, Inc.  
U.S. Agent for Aurobindo Pharma Limited  
Attention: Blessy Johns  
Vice President

Dear Blessy Johns:

This letter is in reference to your abbreviated new drug application (ANDA) received for review on July 29, 2022, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Fosfomycin Tromethamine Granules for Oral Solution, 3 grams (Single-Dose Sachet).<sup>1</sup>

Reference is also made to the complete response letter issued by this office on November 7, 2024, 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 Fosfomycin Tromethamine Granules for Oral Solution, 3 grams (Single-Dose Sachet) to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Monurol Granules for Oral Solution, 3 grams, of Zambon S.p.A. (Zambon) NDA - 050717.

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 Kendra S. Stewart, R.Ph., Pharm.D.  
CAPT, United States Public Health Service  
Director  
Office of Regulatory Operations  
Office of Generic Drugs  
Center for Drug Evaluation and Research

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<sup>1</sup> We note that the RLD upon which you have based this ANDA, Zambon's Monurolo Granules for Oral Solution, 3 grams, 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 Zambon's Monurolo Granules for Oral Solution, 3 grams, 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.



Catherine  
Poole

Digitally signed by Catherine Poole

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