



NDA 050717/S-010

SUPPLEMENT APPROVAL

Zambon S.p.A.
Attention: Nadia C. Success
Senior Manager, Regulatory Affairs
5 Giralda Farms
Madison, NJ 07940

Dear Ms. Success:

Please refer to your Supplemental New Drug Application (sNDA) dated September 11, 2018, received September 11, 2018, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Monurol (fosfomycin tromethamine) Granules for Oral Solution.

This “Changes Being Effected” supplemental new drug application has been submitted in response to the Agency supplement request letter dated September 5, 2018, requesting revision to the carton and container labels to reflect a change in the established name from Monurol (fosfomycin tromethamine) Sachet to Monurol (fosfomycin tromethamine) Granules for Oral Solution.

APPROVAL & LABELING

We have completed our review of this supplemental application. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and immediate container labels that are identical to the carton and immediate-container labels, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (May 2015, Revision 3)*. For administrative purposes, designate this submission “**Final Printed Carton and Container Labels for approved NDA 050717/S-010.**” Approval of this submission by FDA is not required before the labeling is used.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Jane A. Dean, RN, MSN, Regulatory Health Project Manager, at 301-796-1202.

Sincerely,

{See appended electronic signature page}

Dmitri Iarikov, MD, PhD
Deputy Director
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURES:

Carton and Container Labeling

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

DMITRI IARIKOV
11/12/2018