



NDA 21618/S-006

SUPPLEMENT APPROVAL

Mission Pharmacal Company
Attention: Eric J. White
Senior Vice President, Regulatory Affairs
38505 IH 10 West
Boerne, TX 78006

Dear Mr. White:

Please refer to your supplemental new drug application (sNDA) dated June 28, 2018, received June 28, 2018, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Tindamax (tinidazole tablets), 250 mg and 500 mg.

This Prior Approval supplemental new drug application provides for revisions to update the TINDAMAX prescribing information (PI) to be in compliance with the requirements of the Pregnancy and Lactation Labeling Rule (PLLR). Specifically, revisions have been made to the **HIGHLIGHTS OF PRESCRIBING INFORMATION** to reflect revisions made throughout the PI, the risk mitigation language in the **BOXED WARNING** has been updated for clarity, the **INDICATIONS AND USAGE (1)**, Bacterial Vaginosis (1.4) subsection has been modified to include pregnant women, and the **WARNINGS AND PRECAUTIONS (5)**, Potential for Genotoxicity and Carcinogenicity (5.1) subsection has been updated to add more discussion of risks included in the **BOXED WARNING**. Revisions were also made to the **USE IN SPECIFIC POPULATIONS (8)** section, Pregnancy (8.1), Lactation (8.2), and Females and Males of Reproductive Potential Infertility (8.3) subsections, **DESCRIPTION (11)** section, **CLINICAL PHARMACOLOGY (12)** section, Pharmacodynamics (12.2), and Pharmacokinetics (12.3) subsections, **NONCLINICAL TOXICOLOGY (13)** section, and the **PATIENT COUNSELING INFORMATION (17)**. Minor editorial revisions have been made throughout the PI.

APPROVAL & LABELING

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

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at FDA.gov.¹ Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information), with the addition of any labeling changes in pending “Changes Being Effectuated” (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.²

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

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 Alison Rodgers, Regulatory Project Manager, at 301-796-0797.

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

¹ <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

² We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

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
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