



NDA 21-618/S-003

Mission Pharmacal Company
Attention: Mary A. Walter, Ph.D.
Chief Scientific Officer
10999 IH 10 West, Suite 1000
San Antonio, TX 78230-1355

Dear Dr. Walter:

Please refer to your supplemental new drug application dated and received July 21, 2006, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Tindamax[®] (tinidazole tablets), 250 mg and 500 mg.

We acknowledge receipt of your submissions dated:

August 11, 2006	August 24, 2006	August 25, 2006
September 26, 2006	September 27, 2006	September 28, 2006
October 6, 2006	October 24, 2006	November 28, 2006
February 23, 2007	March 6, 2007	May 15, 2007

This supplemental new drug application provides for the use of Tindamax[®] for the treatment of bacterial vaginosis in non-pregnant females.

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

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, immediate container and carton labels). Marketing of the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved drug.

Within 21 days of the date of this letter, submit of labeling [21CFR 314.50(1) in structured product labeling (SPL) format as described at <http://www.fda.gov/oc/datacouncil/spl.html>. that is identical in content to the enclosed labeling text. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission "SPL for approved supplement NDA 21-618/S-003."

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We note that you have fulfilled the pediatric study requirement for the treatment of bacterial vaginosis in post-menarchal female patients. We are waiving the pediatric study requirement for the treatment of bacterial vaginosis in pre-menarchal female patients.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Special Pathogen and Transplant Products and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

If you issue a letter communicating important information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

Please submit one market package of the drug product when it is available.

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 question, please call Christina H. Chi, Ph.D., Regulatory Health Project Manager, at (301) 796-0695.

Sincerely,

{See appended electronic signature page}

Renata Albrecht, M.D.
Division Director
Division of Special Pathogen and Transplant Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure: Package insert, immediate container & carton labels

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Renata Albrecht
5/21/2007 05:02:17 PM