



ANDA 65-413

Roxane Laboratories, Inc.
Attention: Elizabeth Ernst
Director, Drug Regulatory Affairs and Medical Affairs
1809 Wilson Rd.
Columbus, OH 43228

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated May 24, 2006, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Mycophenolate Mofetil Tablets, 500 mg. We note that this product is subject to the exception provisions of section 125 (d)(2) of Title I of the Food and Drug Administration Modernization Act of 1997.

Reference is also made to your amendments dated October 12, October 24, and November 17, 2006; February 28, March 9, April 20, September 24, October 5, November 2, November 29, and December 21, 2007; and January 31, February 29, March 17, June 4, July 7, and July 8, 2008.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the ANDA is approved. The Division of Bioequivalence has determined your Mycophenolate Mofetil Tablets, 500 mg to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, CellCept® Tablets, 500 mg, of Roche Palo. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

Under section 506A of the Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made. We note that if FDA

requires a REMS for the list drug, an ANDA citing that listed drug also will be required to have a REMS. See 505-1(i).

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert(s) directly to:

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

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Division of Drug Marketing, Advertising, and Communications with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,

{See appended electronic signature page}

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

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

/s/

Robert L. West
7/29/2008 02:16:20 PM
Deputy Director, for Gary Buehler