DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 200197

Gordon Johnston Regulatory Consultants LLC
U.S. Agent for: Alkem Laboratories Limited
Attention: Gordon Johnston
3631 Martins Dairy Circle
Olney, MD 20832

Dear Sir:

This letter corrects the ANDA Approval Letter issued by this office on June 13, 2013, within which we inadvertently did not include the Risk Evaluation and Mitigation Strategy Requirements for your drug product. Please note that the effective date of action will remain as June 13, 2013, the date of the original action letter.

This is in reference to your abbreviated new drug application (ANDA) dated September 4, 2009, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Mycophenolate Mofetil Capsules USP, 250 mg.

Reference is also made to your amendments dated November 24, 2009; February 8, February 24, and October 19, 2010; September 7, 2011; February 7, April 25, August 17, and September 21, 2012.

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, effective on the date of this letter. The Division of Bioequivalence has determined your Mycophenolate Mofetil Capsules, 250 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, CellCept Capsules, 250 mg, of Roche Palo Alto, LLC. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

Section 505-1 of the Act authorizes FDA to require the submission of a risk evaluation and mitigation strategy (REMS), if FDA becomes aware of new safety information and makes a determination that such a strategy is necessary to ensure that the benefits of the drug outweigh the risks [section 505-1(a)]. The details of the REMS requirements were outlined in our REMS notification letter dated September 21, 2011. In that letter, you were also notified that in the interest of public health and to minimize the burden on the healthcare delivery system of having

multiple unique REMS programs, a single, shared system should be used to implement the REMS for all members of the class of Mycophenolate Mofetil and Mycophenolic Mofetil products.

We remind you that section 505-1(f)(8) of the Act prohibits holders of an approved covered application with elements to assure safe use from using any element to block or delay approval of an application under section 505(b)(2) or (j). A violation of this provision in 505-1(f) could result in enforcement action.

Your proposed REMS, appended to this letter, is approved. The REMS consists of a Medication Guide and elements to assure safe use.

This REMS will use a single, shared system for the elements to assure safe use and the REMS assessments. The individual sponsors who are part of the single shared system are collectively referred to as "mycophenolate sponsors." This single, shared system is known as the Mycophenolate REMS program. Other products may be added in the future if additional NDAs or ANDAs are approved.

Under section 505-1(g)(2)(C), FDA can require the submission of a REMS assessment if FDA determines that an assessment is needed to evaluate whether the approved REMS should be modified, or if FDA determines that there may be a cause for action by FDA under section 505(e). Additionally, the details for what should be included in any joint assessments completed under the Mycophenolate REMS Program are listed in Appendix 1.

Prominently identify the submission containing the REMS or any REMS assessments or proposed modifications with the following wording in bold capital letters at the top of the first page of the submission:

ANDA 200197
REMS ASSESSMENT

NEW SUPPLEMENT FOR ANDA 200197
PROPOSED REMS MODIFICATION

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.

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 directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale 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 Office of Prescription Drug Promotion with a completed Form FDA 2253 at the time of their initial use.

The Generic Drug User Fee Amendments of 2012 (GDUFA) (Public Law 112-144, Title III) established certain provisions with respect to self-identification of facilities and payment of annual facility fees. Your ANDA identifies at least one facility that is subject to the self-identification requirement and payment of an annual facility fee. Self-identification must occur by June 1 of each year for the next fiscal year. Facility fees must be paid each year by the date specified in the Federal Register notice announcing facility fee amounts. All finished dose forms (FDFs) or active pharmaceutical ingredients (APIs) manufactured in a facility that has not met its obligations to self-identify or to pay fees when they are due will be deemed misbranded. This means that it will be a violation of federal law to ship these products in interstate commerce or to import them into the United States. Such violations can result in prosecution of those responsible, injunctions, or seizures of misbranded products. Products misbranded because of failure to self-identify or pay facility fees are subject to being denied entry into the United States.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical in content to the approved labeling (including the package insert, and any patient package insert and/or Medication Guide that may be required). Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf. The SPL will be accessible via publicly available labeling repositories.

Sincerely yours,

{See appended electronic signature page}

Kathleen Uhl, M.D.
Acting Director
Office of Generic Drugs
Center for Drug Evaluation and Research

Enclosure: Appendix 1
REMS