DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 50722/S-037
NDA 50723/S-037
NDA 50758/S-034
NDA 50759/S-042

SUPPLEMENT APPROVAL

Roche Palo Alto
c/o Genentech, Inc.
Attention: Barbara S. Taylor, PhD
Regulatory Agent
1 DNA Way MS# 241A
South San Francisco, CA 94080-4990

Dear Dr. Taylor:

Please refer to your Supplemental New Drug Applications (sNDAs) dated and received September 27, 2017, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

NDA Number	Supplement Number	Drug Name	Date Submitted and Received
50722	37	CellCept (mycophenolate mofetil) Capsules, 250 mg	September 27, 2017
50723	37	CellCept (mycophenolate mofetil) Tablets, 500 mg	September 27, 2017
50758	34	CellCept (mycophenolate mofetil hydrochloride) Intravenous	September 27, 2017
50759	42	CellCept (mycophenolate mofetil) Oral Suspension	September 27, 2017

These "Prior Approval" supplemental new drug applications provide for the addition of Dosing Instruction for Patients for the oral suspension product labeling.

APPROVAL & LABELING

We have completed our review of these supplemental applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text, which is identical to the labeling texts submitted on September 27, 2017 for the Dosing Instructions for Patients and on November 15, 2017, for the Package Insert.

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 http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert), with the addition of any labeling changes in pending "Changes Being Effected" (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 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 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 MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, 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 Ms. June Germain, Safety Regulatory Project Manager, at (301) 796-4024.

Sincerely,

{See appended electronic signature page}

Renata Albrecht, MD
Director
Division of Transplant and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure: Content of Labeling-Package Insert and Dosing Instructions for Patients

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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
12/18/2017