DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-722/S-020
NDA 50-723/S-018
NDA 50-758/S-018
NDA 50-759/S-023

Roche Palo Alto LLC
c/o Hoffmann-La Roche, Inc.
Attention: Wendy L. Corbett, Ph.D., MBA
Associate Director, Pharma Development Regulatory
340 Kingsland Street
Nutley, NJ 07110-1199

Dear Dr. Corbett:

Please refer to your supplemental new drug applications submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

NDA Number	Drug Product	Supplement Number	Date of Supplement	Date of Receipt
50-722	CellCept® (mycophenolate mofetil) Capsules, 250 mg	S-020	October 1, 2008	October 2, 2008
50-723	CellCept® (mycophenolate mofetil) Tablets, 500 mg	S-018	October 1, 2008	October 2, 2008
50-758	CellCept® (mycophenolate mofetil hydrochloride for injection) Intravenous, 500 mg/ 20 mL	S-018	October 1, 2008	October 2, 2008
50-759	CellCept® (mycophenolate mofetil for oral suspension) Oral Suspension, 200 mg/mL	S-023	October 1, 2008	October 2, 2008

We acknowledge receipt of your submissions dated January 30, 2009.

These supplemental new drug applications provide for the following changes to the labels:

Carton Labels:
Addition of the statement: "Attention Pharmacist: Dispense the accompanying Medication Guide to each patient. For additional Medication Guides call 1-800-526-6367 or visit www.rocheusa.com/products/CellCept."

Bottle Labels:
Addition of the statement: "Attention Pharmacist: Dispense the accompanying Medication Guide to each patient."

We completed our review of these applications, as amended. These applications are 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 (immediate container and carton labels).

As soon as possible, but no later than 14 days from the date of this letter, please submit the final printed immediate container and carton labels. For administrative purposes, please designate these submissions, "**Carton and Container Labels for approved supplements NDA 50-722/S-020, NDA 50-723/S-018, NDA 50-758/S-018, NDA 50-759/S-023."**

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
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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 Hyun Son, Pharm.D., Acting Safety Regulatory Project Manager, at (301) 796-1600.

Sincerely,

{See appended electronic signature page}

Ozlem Belen, M.D., MPH
Deputy Director for Safety
Division of Special Pathogen and Transplant Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure

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

/s/

Ozlem Belen

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