



NDA 50-722/S-019
NDA 50-723/S-017
NDA 50-758/S-017
NDA 50-759/S-022

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

Dear Dr. Corbett:

Please refer to your supplemental new drug application (NDA) dated October 1, 2008, and received on October 2, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

NDA Number	Supplement No.	Drug Product
50-722	S-019	CellCept [®] (mycophenolate mofetil) Capsules, 250 mg
50-723	S-017	CellCept [®] (mycophenolate mofetil) Tablets, 500 mg
50-758	S-017	CellCept [®] (mycophenolate mofetil hydrochloride for injection), Intravenous, 500 mg/ 20 mL
50-759	S-022	CellCept [®] (mycophenolate mofetil for oral suspension), Oral Suspension, 200 mg/ mL

We acknowledge receipt of your submissions dated December 3, 2008, and December 10, 2008.

Reference is also made to the FDA letter dated September 4, 2008, notifying you, under section 505(o)(4) of the Federal Food, Drug and Cosmetic Act (FDCA) that you are required to make safety related labeling changes to the labeling of CellCept[®] to address the risk of congenital malformations in offspring of patients exposed to mycophenolate mofetil (MMF) during pregnancy based on new safety information about the risk of congenital malformations identified since the drug was approved.

On October 2, 2008, FDA received your prior-approval labeling supplements that contained your proposed Medication Guide. Section 505(o) requires FDA to promptly review the supplements and if we disagree with the proposed changes, initiate discussions with you on the content of the changes. These discussions are to be completed within 30 days, unless FDA determines that an extension is warranted. On October 30, 2008, we sent you a letter informing you that an extension was warranted for these supplements, extending the discussion period to end on December 1, 2008.

We have completed our review of the Medication Guide. These supplements are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit content of labeling [21 CFR 314.50(l)] 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 and verification, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate these submissions “**SPL for approved supplements NDA 50-722/S-019, NDA 50-723/S-017, NDA 50-758/S017, and NDA 50-759/S-022.**”

In addition, within 21 days of the date of this letter, amend any pending applications for these NDAs with content of labeling in SPL format to include the changes approved in these applications.

Marketing the product with FPL that is not identical to the approved labeling text and in the required format may render the product misbranded and an unapproved new drug.

We request that this revised labeling approved today be available on your website within 10 days of receipt of this letter and that the revised labeling be reflected in the next printing of the labeling. While you may use labeling already printed as of the date of this letter until May 15, 2009, after that date, we request that the revised labeling accompany any newly shipped product.

Failure to make these changes promptly could make your product misbranded under Sections 201(n) and 502(a) of FDCA.

Please note that you must comply with the Medication Guide Regulations as specified in 21 CFR208.

LETTERS TO HEALTH CARE PROFESSIONALS

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

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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}

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

Enclosure: Medication Guide

**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
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