



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 50-723/S-021

Roche Palo Alto, LLC  
Attention: Dawn Jennemann  
Senior Program Manager  
340 Kingsland Street  
Nutley, NJ 07110

Dear Ms. Jennemann:

Please refer to your supplemental new drug application dated March 23, 2009, received March 24, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cellcept® (mycophenolate mofetil) Tablets.

This supplemental new drug application provides for addition of an alternate packaging site (Roche in Kaiseraugst, Switzerland) and an alternate testing site (Roche in Basel, Switzerland) for the drug product.

We completed our review of this application. This application is 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 submitted labeling (immediate container and carton labels) submitted March 23, 2009.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 50-723/S-021.**" Approval of this submission by FDA is not required before the labeling is used.

If you have any questions, call Althea Cuff, Regulatory Project Manager, at (301) 796-4061.

Sincerely,

*{See appended electronic signature page}*

Hasmukh B. Patel, Ph.D.  
Branch Chief  
Branch 8, Division of Post-Marketing Evaluation  
Office of New Drug Quality Assessment  
Center for Drug Evaluation and Research

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/s/

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Hasmukh Patel

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