DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

NDA 50-759

Food and Drug Administration
Rockville MD 20857

OCT - 1 1998

Roche Global Development
Attention: Carmen Rodriguez
Regulatory Affairs
3401 Hillview Avenue
Palo Alto, CA 94304

Dear Ms. Rodriguez:

Please refer to your new drug application (NDA) dated September 30, 1997, received October 1, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for CellCept (mycophenolate mofetil for suspension) Suspension. We note that this application is subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

We acknowledge receipt of your submissions dated as follows.

January 6, 1998	May 12, 1998	September 17, 1998
February 13, 1998	May 29, 1998	September 22, 1998
March 6, 1998	September 9, 1998	September 24, 1998

The user fee goal date for this application is October 1, 1998.

This new drug application provides for the use of CellCept® Oral Suspension (mycophenolate mofetil for suspension) for the prophylaxis of organ rejection in patients receiving allogeneic renal transplants and in patients receiving allogeneic cardiac transplants .

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert dated September 22, 1998). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved NDA 50-759." Approval of this submission by FDA is not required before the labeling is used.

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, contact Mary Dempsey, Project Manager, at (301) 837-2127.

Sincerely,

Mark J. Goldberger, M.D., M.P.H.
Director
Division of Special Pathogen and Immunologic
Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research