# CENTER FOR DRUG EVALUATION AND RESEARCH

***APPLICATION NUMBER:***

# 50-722/S-009

# APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 50-722/S-009

Hoffmann-La Roche Inc.
Attention: Christine Hoogmoed
Associate, Drug Regulatory Affairs
340 Kingsland Street
Nutley, NJ 07110-1199

Dear Ms. Hoogmoed:

Please refer to your supplemental new drug application dated May 11, 2001, received May 14, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for CellCept (mycophenolate mofetil) Capsules, 250 mg.

We acknowledge receipt of your submissions dated October 26, 2001.

This "Changes Being Effected in 30 days" supplemental new drug application provides for the addition of a new bulk market drum for distribution within the United States to large-volume pharmacies to facilitate their repackaging operations, and the addition of an alternate contract packaging site [redacted] that may be used to package and label the product in the bulk market drum.

We have completed the review of this supplemental application, and it is approved.

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, call Matthew Bacho, Regulatory Project Manager, at (301) 827-2127.

Sincerely,

*{See appended electronic signature page}*

Norman R. Schmuff, Ph.D.
Chemistry Team Leader for the
Division of Special Pathogen and Immunologic Drug Products, (HFD-590)
DNDC III, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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/s/

Norman Schmuff
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APPEARS THIS WAY
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