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APPLICATION NUMBER:

50-722/S-006

APPROVAL LETTER

NDA 50-722/S-006

Hoffmann-LaRoche Inc.
Attention: Debra Iorio
Program Manager
Drug Regulatory Affairs
340 Kingsland Street
Nutley, NJ. 07110-1199

Dear Ms. Iorio:

Please refer to your supplemental new drug application dated January 17, 2000, received January 18, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for CellCept® (mycophenolic mofetil, RS #61443) Capsules.

We acknowledge receipt of your submission dated April 14, 2000.

This supplemental new drug application provides for a new strain of microorganism to be used in the fermentation of the ——————— which is used to produce the active ingredient (mycophenolate mofetil) in CellCept Capsules.

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, Project Manager, at 301-827-2336.

Sincerely yours,

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