


**CENTER FOR DRUG EVALUATION AND RESEARCH**

*APPLICATION NUMBER:*

**50-722/S-006**

**CHEMISTRY REVIEW(S)**

APR 28 2000

SUPPLEMENTAL NDA CHEMIST'S REVIEW		1. ORGANIZATION HFD-590	2. NDA NUMBER 50-722
3. NAME AND ADDRESS OF APPLICANT (City and State) Hoffmann-La Roche Inc. 340 Kingsland Street Nutley, NJ 07110-1199		4. AF NUMBER	
		5. DOCUMENT(S) NUMBER(S) DATE(S) SCS-006 1/17/2000	
6. NAME OF DRUG CellCept		7. NONPROPRIETARY NAME mycophenolate mofetil	
8. SUPPLEMENT(S) 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.		9. AMENDMENTS AND OTHER (Reports, etc.) DATES BC 4/14/00	
10. PHARMACOLOGICAL CATEGORY Immunosuppressant	11. HOW DISPENSED <input checked="" type="checkbox"/> Rx <input type="checkbox"/> OTC		12. RELATED IND/NDA/DMF(S) DMF _____ DMF _____
13. DOSAGE FORM(S) Capsule		14. POTENCY(IES) 250 mg	
15. CHEMICAL NAME See current package insert		16. MEMORANDA Telephone conversation, April 3, 2000 (attached)	
17. COMMENTS This supplemental NDA 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, MMF) in CellCept Capsules.			
18. CONCLUSIONS AND RECOMMENDATIONS The applicant has adequately demonstrated the equivalence of _____ produced by the original and new strains of _____. It is, therefore, recommended that this supplemental application be approved as amended.			
19. REVIEWER			
NAME Mark R. Seggel		SIGNATURE 	DATE COMPLETED 4/28/00
20. CONCURRENCE: HFD-590/Nschmuff			
DISTRIBUTION	<input checked="" type="checkbox"/> Original Jacket	<input checked="" type="checkbox"/> MSeggel	<input checked="" type="checkbox"/> JKorvick
	<input checked="" type="checkbox"/> Division File	<input checked="" type="checkbox"/> NSchmuff	<input checked="" type="checkbox"/> MBacho
	<input checked="" type="checkbox"/> HFD-830/CChen		

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