

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-722/S-009

CHEMISTRY REVIEW(S)

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) SCP-009 5/11/01	
6. NAME OF DRUG CellCept	7. NONPROPRIETARY NAME mycophenolate mofetil capsules		
8. SUPPLEMENT(S) 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 _____ that may be used to package and label the product in the bulk market drum.		9. AMENDMENTS AND OTHER (Reports, etc.) DATES BL 10/26/01	
10. PHARMACOLOGICAL CATEGORY Immunosuppressant	11. HOW DISPENSED <input checked="" type="checkbox"/> Rx <input type="checkbox"/> OTC	12. RELATED IND/NDA/DMF(S) N18-225/S-020	
13. DOSAGE FORM(S) Capsule	14. POTENCY(IES) 250 mg		
15. CHEMICAL NAME See current package insert		16. MEMORANDA	
17. COMMENTS <p>This Bundled "Special Supplement – Changes Being Effected in 30 Days" is part of a group of supplement submitted by Roche covering the addition of a new bulk market drum for distribution of product to large-volume pharmacies within the United States to facilitate their repackaging operations. The supplement also provides for the addition of an alternate contract packaging and labeling site for product in the proposed market drum. The lead review for the supplement bundle was provided by S. Zimmerman, HFD-110 (NDA 18-225/SCP-020). The proposed changes were found to be acceptable provided product-specific issues were satisfied.</p> <div style="border: 1px solid black; height: 100px; width: 100%;"></div> <p>bulk market drum. In support of the proposed bulk market drum, the applicant has provided detailed information on the container/closure system and supporting stability data. _____ based on profile; see attached EER report).</p> <p>The proposed container label has been revised (BL 10/26/01) per recommendations to Roche from S. Zimmerman.</p>			
18. CONCLUSIONS AND RECOMMENDATIONS The suitability of the bulk market drum has been adequately demonstrated. The contract packaging site has acceptable cGMP status. It is, therefore, recommended that this supplemental application, as amended, be approved.			
19. REVIEWER Mark R. Seggel	SIGNATURE {See appended electronic signature page}		DATE COMPLETED November 9, 2001
20. CONCURRENCE: HFD-590/NSchmuff {See appended electronic signature page}			