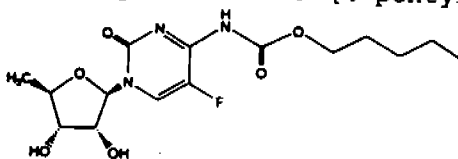


**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

**APPLICATION NUMBER:     NDA 20-896/S-006**

**CHEMISTRY REVIEW(S)**

Liang

<b>CHEMIST'S REVIEW</b>		1. ORGANIZATION HFD-150 DODP		2. NDA NUMBER 20-896	
3. NAME AND ADDRESS OF APPLICANT: Hoffmann-La Roche Inc. 340 Kingsland St. Nutley, NJ 07110-1199				4. AF NUMBER  JUN 27 2000	
				5. SUPPLEMENT (S) NUMBER(S) DATES(S):	
6. NAME OF DRUG XELODA Tablets		7. NONPROPRIETARY NAME Capecitabine		SE1-006	10/5/99 11/9/99
8. SUPPLEMENT PROVIDES FOR: an efficacy supplement for the new indication and a claim for categorical exclusion from the environmental assessment requirement for the approved drug Xeloda,				9. AMENDMENTS DATES	
10. PHARMACOLOGICAL CATEGORY		11. HOW DISPENSED RX <input checked="" type="checkbox"/> OTC <input type="checkbox"/>		12. RELATED IND/NDA/DMF	
13. DOSAGE FORM(S) Tablets		14. POTENCY 150 and 500mg/tablets			
15. CHEMICAL NAME AND STRUCTURE 5'-Deoxy-5-fluoro-N-(4-pentyloxycarbonyl)-cytidine				16. RECORDS AND REPORTS CURRENT YES <input checked="" type="checkbox"/> NO <input type="checkbox"/> REVIEWED YES <input type="checkbox"/> NO <input type="checkbox"/>	
 <p>C<sub>15</sub>H<sub>22</sub>FN<sub>3</sub>O<sub>6</sub>, MW = 359.35</p>					
17. COMMENTS Applicant provided for a claim for categorical exclusion from the environmental assessment requirement for the approved drug Xeloda, which is proposed to treat the patients with metastatic colorectal cancer in larger dose. All the CMC information for DS and DP remains unchanged from approved NDA.					
18. CONCLUSIONS AND RECOMMENDATIONS Approval is recommended.					
19. REVIEWER					
NAME Chengyi Liang, Ph.D.		SIGNATURE <i>ISI</i>		DATE COMPLETED 6/27/2000	
<u>DISTRIBUTION</u>	NDA 20-896/BC	DIVISION FILE	Reviewer C. Liang HFD-150	Project Manager: M. Pineda HFD-150	Chemistry Team Leader: E. Duffy HFD-150

ISI