CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 20-896/S-006

CHEMISTRY REVIEW(S)
## CHEMIST’S REVIEW

### 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

### 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.

### 10. PHARMACOLOGICAL CATEGORY

### 11. HOW DISPENSED
RX ✓ OTC

### 12. RELATED IND/INDA/DME

### 13. DOSAGE FORM(S)
Tablets

### 14. POTENCY
150 and 500mg/tablets

### 15. CHEMICAL NAME AND STRUCTURE
5'-Deoxy-5-fluoro-N-[4-pentyloxycarbonyl]-cytidine

\[
\begin{align*}
\text{C}_{15}\text{H}_{22}\text{FN}_{3}\text{O}_{6}, & \quad \text{MW} = 359.35
\end{align*}
\]

### 16. RECORDS AND REPORTS
CURRENT ✓ NO
REVIEWED YES NO

### 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 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
/S/

DATE COMPLETED
6/27/2000

### DISTRIBUTION
NDA 20-896/RC

### DIVISION FILE
Reviewer: C. Liang  
Project Manager: M. Adler  
Chemistry Team Leader: E. Duffy  
HFD-150

### REVIEWER
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### PROJECT MANAGER
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### CHEMISTRY TEAM LEADER
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