

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

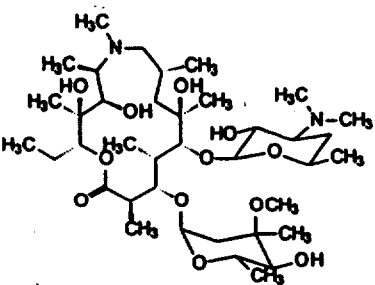
APPLICATION NUMBER:

50-670/S-015

50-693/S003

50-730/S005

CHEMISTRY REVIEW(S)

SUPPLEMENTAL NDA CHEMIST'S REVIEW		1. ORGANIZATION: HFD-590	2. NDA NUMBER: 50-730
3. NAME AND ADDRESS OF APPLICANT: (City and State) Pfizer, Inc. Eastern Point Road Groton, CT 06340-		4. AF NUMBER:	
		5. SUPPLEMENT(S):	
		NUMBER(S): SE1-005 SLR-006	DATE(S): 13-JAN-2000
6. NAME OF DRUG: Zithromax®		7. NONPROPRIETARY NAME: Azithromycin	
8. SUPPLEMENT(S) PROVIDES FOR: Use of Zithromax 600 mg tablets, in combination with ethambutol, for the treatment of disseminated <i>Mycobacterium avium</i> Complex (MAC) in patients with AIDS, or with other anti-mycobacterial agents to treat pulmonary MAC infections in non-HIV infected patients.		9. AMENDMENTS/REPORTS: SE1-005 (BC) 13-OCT-2000 SE1-006 (BC) 13-OCT-2000	
10. PHARMACOLOGICAL CATEGORY: Antibacterial (macrolide)	11. HOW DISPENSED: <input checked="" type="checkbox"/> Rx <input type="checkbox"/> OTC	12. RELATED IND/NDA/DMF(S): NDA 50-670; 50-693; 50-710; 50-711; 50-733	
13. DOSAGE FORM(S): Tablets	14. POTENCY(IES): 600 mg		
15. CHEMICAL NAME AND STRUCTURE: [2R-(2R*,3S*,4R*,5R*,8R*,10R*,11R*,12R*,13R*,14R*)]-13-[(2,6-Dideoxy-3-C-methyl-3-O-methyl-α-L-ribo-hexopyranosyl)oxy]-2-ethyl-3,4,10-trihydroxy-3,5,6,8,10,12,14-heptamethyl-11-[[3,4,6-trideoxy-3-(dimethylamino)-β-D-xylo-hexopyranosyl]oxy]-1-oxa-6-azacyclopentadecan-15-one CAS: 117772-70-0		16. MEMORANDA:	
			
17. COMMENTS: Please see page 2.			
18. CONCLUSIONS AND RECOMMENDATIONS: Other than labeling and environmental assessment, this supplement contains no CMC information. This supplement may be approved from a CMC perspective.			
19. REVIEWER: Gene W. Holbert, Ph.D.		SIGNATURE: <i>GS</i>	DATE COMPLETED: 17-Oct-2000
20. CONCURRENCE: Norman R. Schuff, Ph.D.		SIGNATURE: <i>GS</i>	DATE COMPLETED: 11/6/00
DISTRIBUTION:	<input checked="" type="checkbox"/> Original NDA 50-730	<input checked="" type="checkbox"/> HFD-590: NSchuff	<input checked="" type="checkbox"/> HFD-590: LBernato
	<input checked="" type="checkbox"/> Division File HFD-590	<input checked="" type="checkbox"/> HFD-590: GHolbert	<input checked="" type="checkbox"/> HFD-830: CChen