

CENTER FOR DRUG EVALUATION AND RESEARCH

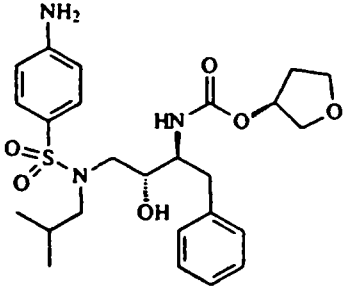
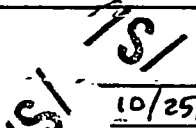
APPROVAL PACKAGE FOR:

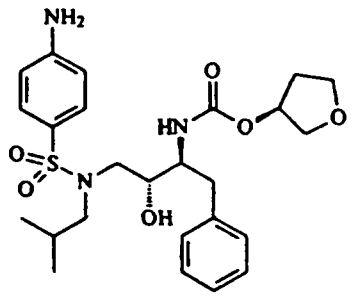
APPLICATION NUMBER

21-007/SE7-006

21-039/SE7-006

Chemistry Review(s)

SUPPLEMENTAL NDA CHEMIST'S REVIEW		1. ORGANIZATION HFD-530	2. NDA NUMBER 21-039
3. NAME AND ADDRESS OF APPLICANT (City and State) Glaxo Wellcome Inc. Five Moore Drive, P.O. Box 13398 Research Triangle Park, NC 27709		4. AF NUMBER	
		5. SUPPLEMENT(S)	
		NUMBER(S) SE7-006	DATE(S) 7/13/00
6. NAME OF DRUG AGENERASE™ Oral Solution		7. NONPROPRIETARY NAME Amprenavir oral solution	
8. SUPPLEMENT(S) PROVIDES FOR: Traditional approval.		9. AMENDMENTS / REPORTS	
10. PHARMACOLOGICAL CATEGORY Anti-HIV	11. HOW DISPENSED <input checked="" type="checkbox"/> Rx <input type="checkbox"/> OTC	12. RELATED IND/NDA/DMF(S)	
13. DOSAGE FORM(S) Oral solution		14. POTENCY(IES) 15 mg/mL	
15. CHEMICAL NAME AND STRUCTURE (3S)-tetrahydro-3-furyl N-((1S,2R)-3-(4-amino-N-isobutylbenzenesulfonamido)-1-benzyl-2-hydroxypropyl)carbamate 		16. MEMORANDA	
17. COMMENTS			
18. CONCLUSIONS AND RECOMMENDATIONS This Supplement provides for the traditional approval of AGENERASE (amprenavir) oral solution. No new CMC information has been submitted. From a CMC perspective it is therefore recommended that this Supplement be approved.			
19. REVIEWER			
NAME George Lunn, Ph.D.		SIGNATURE 	DATE COMPLETED 10/25/00
20. CONCURRENCE: HFD-530/SMiller			
DISTRIBUTION	<input checked="" type="checkbox"/> Original Jacket	<input checked="" type="checkbox"/> GLunn	<input checked="" type="checkbox"/> MTruffa
	<input checked="" type="checkbox"/> Division File	<input checked="" type="checkbox"/> SMiller	<input checked="" type="checkbox"/> Biopharm
	<input checked="" type="checkbox"/> HFD-830/CChen	<input checked="" type="checkbox"/> Med	<input checked="" type="checkbox"/> Micro

SUPPLEMENTAL NDA CHEMIST'S REVIEW		1. ORGANIZATION HFD-530	2. NDA NUMBER 21-007
3. NAME AND ADDRESS OF APPLICANT (City and State) Glaxo Wellcome Inc. Five Moore Drive, P.O. Box 13398 Research Triangle Park, NC 27709		4. AF NUMBER	
		5. SUPPLEMENT(S)	
		NUMBER(S) SE7-006	DATE(S) 7/13/00
6. NAME OF DRUG AGENERASE™ Capsules		7. NONPROPRIETARY NAME Amprenavir capsules	
8. SUPPLEMENT(S) PROVIDES FOR: Traditional approval.		9. AMENDMENTS / REPORTS	
10. PHARMACOLOGICAL CATEGORY Anti-HIV	11. HOW DISPENSED <input checked="" type="checkbox"/> Rx <input type="checkbox"/> OTC	12. RELATED IND/NDA/DMF(S)	
13. DOSAGE FORM(S) Capsules		14. POTENCY(IES) 50 mg, 150 mg	
15. CHEMICAL NAME AND STRUCTURE (3S)-tetrahydro-3-furyl N-((1S,2R)-3-(4-amino-N-isobutylbenzenesulfonamido)-1-benzyl-2-hydroxypropyl)carbamate		16. MEMORANDA	
			
17. COMMENTS			
18. CONCLUSIONS AND RECOMMENDATIONS This Supplement provides for the traditional approval of AGENERASE (amprenavir) capsules. No new CMC information has been submitted. From a CMC perspective it is therefore recommended that this Supplement be approved.			
19. REVIEWER			
NAME George Lunn, Ph.D.		SIGNATURE <i>[Signature]</i>	DATE COMPLETED 10/25/00
20. CONCURRENCE: HFD-530/SMiller			
DISTRIBUTION	<input checked="" type="checkbox"/> Original Jacket	<input checked="" type="checkbox"/> J Lunn	<input checked="" type="checkbox"/> M Truffa
	<input checked="" type="checkbox"/> Division File	<input checked="" type="checkbox"/> S Miller	<input checked="" type="checkbox"/> Biopharm
	<input checked="" type="checkbox"/> HFD-830/CChen	<input checked="" type="checkbox"/> Med	<input checked="" type="checkbox"/> Micro