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RESEARCH**

APPLICATION NUMBER: 20-547/S007

CHEMISTRY REVIEW(S)

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CHEMIST'S REVIEW		1. ORGANIZATION HFD-570 DPDP	2. NDA NUMBER 20-547
Zeneca Pharmaceuticals 1800 Concord Pike P.O. Box 15437 Wilmington, DE 19850-5437		4. AF NUMBER	
6. NAME OF DRUG: Accolate® tablets		5. SUPPLEMENT(S) NUMBER(S) DATES(S) SEI-007 9/17/98	
7. NONPROPRIETARY NAME Zafirlukast, USAN		9. AMENDMENT(S), REPORT(S), ETC. NUMBER(S) DATE(S) *SEI-007 9/3/99 *SEI-007 9/10/99 *SEI-007 9/13/99 *SEI-007 9/16/99 * subject of this review	
8. SUPPLEMENT PROVIDES FOR: The use of Accolate (zafirlukast) tablets in the prophylaxis and chronic treatment of asthma in pediatric patients 7 through 11 years of age		12. RELATED IND/NDA/DMF	
10. PHARMACOLOGICAL CATEGORY Leukotriene receptor antagonist	11. HOW DISPENSED RX <input checked="" type="checkbox"/> OTC <input type="checkbox"/>		
13. DOSAGE FORM(S) Tablets	14. POTENCY 10 mg in addition to approved 20 mg. The [redacted] is withdrawn		
15. CHEMICAL NAME AND STRUCTURE See USP		16. RECORDS AND REPORTS CURRENT YES <input type="checkbox"/> NO <input type="checkbox"/> REVIEWED YES <input type="checkbox"/> NO <input type="checkbox"/>	
17. COMMENTS: a. Previous chemist's review (j leak, 10/5/98) concluded that this supplement may be approved from manufacturing and control on receipt of a satisfactory report from compliance and receipt of an additional analytical method. The 11/19/98 submission provided the method and an acceptable report were received 10/26/98 from HFD-324.			
18. CONCLUSIONS AND RECOMMENDATIONS: From CMC standpoint, this supplement is approved. cc: Orig. NDA 20-547/SEI-007 HFD-570/div File HFD-570/HKhorshidi HFD-570/GPoochikian HFD-570/P Jani R/D Init. by: <u>Poochikian</u> F/T by: HKhorshidi <i>5/1/16/99</i> doc # N:\NDA\20-547\SEI-007\Chem\99-09-16 .REV			
19. REVIEWER NAME: Hossein S. Khorshidi	SIGNATURE [Signature]	DATE COMPLETED 9/16/99	

APPEARS THIS WAY
ON ORIGINAL


DEC - 2 1998

Jan 1

CHEMIST'S REVIEW #		1. ORGANIZATION HFD-570 DPDP		2. NDA NUMBER 20-547	
3. NAME AND ADDRESS OF APPLICANT (City and State) Zeneca Limited 1800 Concord Pike, PO Box 15437 Wilmington, DE 19850-5437				4. AF NUMBER	
				5. SUPPLEMENT (S) NUMBER(S)	
6. NAME OF DRUG Accolate		7. NONPROPRIETARY NAME zafirlukast tablets		SEI-007 9/17/98	
8. SUPPLEMENT PROVIDES FOR: the use of ACCOLATE® (zafirlukast) tablets in the prophylaxis and chronic treatment of asthma in pediatric patients [redacted] years of age.				9. AMENDMENTS DATES SUBJECT OF THIS REVIEW 11/19/98	
10. PHARMACOLOGICAL CATEGORY leukotriene receptor antagonist		11. HOW DISPENSED RX <input checked="" type="checkbox"/> OTC <input type="checkbox"/>		12. RELATED IND/NDA/DMF	
13. DOSAGE FORM(S) tablet		14. POTENCY [redacted] 10 mg in addition to the approved 20 mg			
15. CHEMICAL NAME AND STRUCTURE				16. RECORDS AND REPORTS CURRENT YES <input type="checkbox"/> NO <input type="checkbox"/> REVIEWED YES <input type="checkbox"/> NO <input type="checkbox"/>	
17. COMMENTS Previous chemist's review (JLeak, 10/5/98) concluded that this supplement may be approved from manufacturing and control on receipt of a satisfactory report from compliance and receipt of an additional analytical method. The 11/19/98 submission provided the method and an acceptable report was received 10/26/98 from HFD-324.					
doc # 20547S7a.SUP					
18. CONCLUSIONS AND RECOMMENDATIONS The supplement may be approved from manufacturing and control. The requested information has been received and the facilities are adequate. <i>IS/ GP 12/2/98</i>					
19. REVIEWER					
NAME John C. Leak, Ph.D.		SIGNATURE <i>IS/</i>		DATE COMPLETED 11/24/98	
DISTRIBUTION ORIGINAL JACKET <input type="checkbox"/> DIVISION FILE <input type="checkbox"/> REVIEWER <input type="checkbox"/> CSO <input type="checkbox"/> SUP. CHEMIST <input type="checkbox"/>					

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OCT 8 1998

CHEMIST'S REVIEW #		1. ORGANIZATION HFD-570 DDPD		2. NDA NUMBER 20-547	
3. NAME AND ADDRESS OF APPLICANT (City and State) Zeneca Limited 1800 Concord Pike, PO Box 15437 Wilmington, DE 19850-5437				4. AF NUMBER	
6. NAME OF DRUG Accolate		7. NONPROPRIETARY NAME zafirlukast tablets		5. SUPPLEMENT (S) NUMBER(S) DATES(S)	
				SUBJECT OF THIS REVIEW SEI-007 9/17/98	
8. SUPPLEMENT PROVIDES FOR: the use of ACCOLATE® (zafirlukast) tablets in the prophylaxis and chronic treatment of asthma in pediatric patients: _____ years of age.				9. AMENDMENTS DATES	
10. PHARMACOLOGICAL CATEGORY leukotriene receptor antagonist		11. HOW DISPENSED RX <input checked="" type="checkbox"/> OTC _____		12. RELATED IND/NDA/DMF	
13. DOSAGE FORM(S) tablet		14. POTENCY <input type="checkbox"/> 10 mg in addition to the approved 20 mg			
15. CHEMICAL NAME AND STRUCTURE				16. RECORDS AND REPORTS CURRENT YES _____ NO _____ REVIEWED YES _____ NO _____	
17. COMMENTS An EER was requested through EES. An evaluation of the material submitted in the supplement follows on the following pages of this review. This is an efficacy supplement. doc # 20547S7.SUP					
18. CONCLUSIONS AND RECOMMENDATIONS The supplement may be approved from manufacturing and control on receipt of a satisfactory report from compliance and receipt of an additional analytical method which was requested.					
19. REVIEWER					
NAME John C. Leak, Ph.D.		SIGNATURE 		DATE COMPLETED 10/5/98	
DISTRIBUTION ORIGINAL JACKET _____ DIVISION FILE _____ REVIEWER _____ CSO _____ SUP. CHEMIST					
(51) 10/8/98					