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RESEARCH**

APPLICATION NUMBER:

21-150/S007

CHEMISTRY REVIEW(S)

CHEMIST'S REVIEW		1. ORGANIZATION : FDA, CDER, OPS, ONDQA, DIV. II, Branch VII	2. NDA NUMBER 21-150
3. NAME AND ADDRESS OF APPLICANT (City and State) Pfizer Inc. 235 East 42nd Street New York, NY 10017		4. AF NUMBER	5. SUPPLEMENT(S) NUMBER DATE SE6-007 1/10/07 S/A 4/27/07 S/A 8/23/07
6. NAME OF DRUG Zyrtec-D™ Extended-release Tablets	7. NONPROPRIETARY NAME cetirizine hydrochloride and pseudoephedrine hydrochloride extended-release tablets		
8. SUPPLEMENT PROVIDES for the OTC marketing of this product with the same strength, dose, duration of use, dosage form, population and route of administration as the approved prescription NDA drug product.		9. AMENDMENT(S), REPORT(S), ETC. NUMBER DATE	
10. PHARMACOLOGICAL CATEGORY Histamine H1-receptor antagonist/decongestant for treatment of symptoms associated with seasonal allergic rhinitis	11. HOW DISPENSED RX X OTC _	12. RELATED IND/NDA/DMF Related bundled NDAs 19-621/S-022 and 21-835/S-005; DMFs _____ . There is also the related syrup dosage form, NDA 22-155 (20-346) that is reviewed apart from the tablets.	
13. DOSAGE FORM(S) Aq. film-coated Extended-release Tablet	14. POTENCY 5 mg immediate-release cetirizine HCl and 120 mg extended-release pseudoephedrine HCl		
15. CHEMICAL NAME AND STRUCTURE (±)-[2-[4-(p-chloro-α-phenylbenzyl)-1-piperazinyl]ethoxy] acetic acid dihydrochloride and [S-(R*,R*)]-α-[1-(Methylamino)ethyl]-benzenemethanol HCl (for structures see USAN)		16. RECORDS AND REPORTS CURRENT YES_ NO_ REVIEWED YES_ NO_	
17. COMMENTS: This provides for a type SE6/PA submission. It is considered as a bundled submission along with those for two other tablet dosage forms (i.e., NDAs 19-621/S-022 and 21-835/S-005)., Certain basic CMC issues were identified and voiced to Pfizer in an information request letter that was then answered in the amendment of 4/27/07. This response was then reviewed and several issues were again identified and conveyed to Pfizer that were then resolved as in the submission dated 23-AUG-2007 as noted in this review as respective assessment topic sections. One, DMF _____, has been reviewed (i.e., Chemistry Review #2 date of 28-AUG-2007) relative to this specific supplement _____ . Another facility, McNeil Consumer Healthcare, was added for testing. It is acceptable by OC.			
18. CONCLUSIONS AND RECOMMENDATIONS: This supplement for NDA 21-150/SE6 may be approved from a CMC standpoint. It should be included with the other bundled tablet submissions in the action letter.			
19. REVIEWER NAME Stuart Zimmerman, Ph.D. Branch Chief: James Vidra, Ph.D.	20. SIGNATURES _____		21. DATES COMPLETED/Endorsed 8-30-2007

16 Page(s) Withheld

8 Trade Secret / Confidential

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/s/

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9/5/2007 01:12:53 PM
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