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RESEARCH**

APPLICATION NUMBER: 20-121/S009

CHEMISTRY REVIEW(S)

JUN - 2 1998

CHEMIST'S REVIEW		1. ORGANIZATION HFD-570 DPDP	2. NDA NUMBER 20-121
3. NAME AND ADDRESS OF APPLICANT (City and State) Glaxo Wellcome, Inc. Research Triangle Park, NC 27709		4. AF NUMBER	5. SUPPLEMENT(S) NUMBER SE-009 DATE 12/17/97
6. NAME OF DRUG Flonase™ Nasal Spray		7. NONPROPRIETARY NAME fluticasone propionate nasal suspension	
8. SUPPLEMENT PROVIDES FOR: Support indication for perennial nonallergic rhinitis		9. AMENDMENT(S), REPORT(S), ETC.	
10. PHARMACOLOGICAL CATEGORY glucocorticosteroid with anti-inflammatory and anti-allergic properties for treatment of seasonal and perennial allergic rhinitis		11. HOW DISPENSED RX <input checked="" type="checkbox"/> OTC <input type="checkbox"/>	12. RELATED IND/NDA/DMF
13. DOSAGE FORM(S) Metered nasal pump spray (suspension)		14. POTENCY 50 µg per actuation through the nasal adapter	
15. CHEMICAL NAME AND STRUCTURE S-(Fluoromethyl)6,9-difluoro-11-hydroxy-16-methyl-3-oxo-17-propionyloxyandrosta-1,4-diene-17-carbothioate (for structure see USAN)		16. RECORDS AND REPORTS CURRENT YES_ NO_ REVIEWED YES_ NO_	
17. COMMENTS: cc: Orig. NDA #20-121 HFD-570/div. File <u>HFD-570/BRogers/5/29/98</u> HFD-570/GPoochikian HFD-570/SBarnes HFD-570/RMeyer R/D Init. by <u>5/26/98</u> F/T by: B. Rogers/5/29/98 doc # 20121.S09.DOC			
18. CONCLUSIONS AND RECOMMENDATIONS: This supplemental application is approvable from a CMC viewpoint.			
19. REVIEWER NAME Brian D. Rogers, Ph.D.		20. SIGNATURE <u>/s/</u>	21. DATE COMPLETED 5/29/98

APPEARS THIS WAY
ON ORIGINAL