

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

20-658/S-012

CHEMISTRY REVIEW(S)

CHEMIST'S REVIEW		1. ORGANIZATION HFD-120 DNDP	2. NDA NUMBER 20-658
3. NAME AND ADDRESS OF APPLICANT <i>(City and State)</i> GlaxoSmithKline, Research Triangle Park, NC		4. AF NUMBER	
6. NAME OF DRUG REQUIP® Tablets		7. NONPROPRIETARY NAME ropinirole hydrochloride	5. SUPPLEMENT (S) NUMBER(S) DATES(S) SCS-012CBE 09-DEC-2002 (letter Date) assigned 05-JUN-2003
8. SUPPLEMENT PROVIDES FOR: a change in the number of tablets and the strength of tablets in the patient starter pack as well as a change from blister packaging to HDPE bottles with child-resistant closures		9. AMENDMENTS DATES 08-MAY-2003 to provide a desk copy as per PM's request	
10. PHARMACOLOGICAL CATEGORY anti-parkinsonian	11. HOW DISPENSED RX <input checked="" type="checkbox"/> OTC		12. RELATED IND/NDA/DMF
13. DOSAGE FORM(S) oral film coated IR tablets	14. POTENCY. 0.25 mg, 0.5, 1,2,3,4,5 mg		
15. CHEMICAL NAME AND STRUCTURE see 2001 USAN page 766		16. RECORDS AND REPORTS CURRENT YES ___ NO ___ REVIEWED YES ___ NO ___	
17. COMMENTS cc: Orig. NDA # 20-658 HFD-120/Div. File HFD-150/R.Lostritto HFD-120/M. Guzewska HFD-120/T.Wheelous R/D Init. by: _____ F/T by: RTLostritto HFD-150 doc # n20658S12.doc			
18. CONCLUSIONS AND RECOMMENDATIONS. From a CMC viewpoint, this supplement may be APPROVED. There are no additional comments to the applicant.			
19. REVIEWER			
NAME Richard T. Lostritto, Ph.D. Team Leader HFD-150		SIGNATURE.	DATE COMPLETED 06-JUN-2003
DISTRIBUTION ORIGINAL JACKET ___ DIVISION FILE ___ REVIEWER ___ CSO ___ TEAM LEADER			

2 Page(s) Withheld

✓ § 552(b)(4) Trade Secret / Confidential

 § 552(b)(4) Draft Labeling

 § 552(b)(5) Deliberative Process

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/s/

Richard Lostritto
6/6/03 04:51:11 PM
CHEMIST

Maryla Guzewska
6/9/03 08:52:07 AM
CHEMIST

RECEIVED MAY
6 11 2003