

CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER

9-386/S-019

Chemistry Review(s)

CHEMIST'S REVIEW		1. ORGANIZATION HFD-150 DODP		2. NDA NUMBER 9-386	
3. NAME AND ADDRESS OF APPLICANT <i>(City and State)</i> GlaxoSmithKline 5 Moore Dr. Research Triangle Park, N. Carolina 27709				4. AF NUMBER	
				5. SUPPLEMENT (S) NUMBER(S) DATES(S)	
6. NAME OF DRUG MYLERAN		7. NONPROPRIETARY NAME busulfan tablets		SCM-019	10-4-2001
8. SUPPLEMENT PROVIDES FOR: the manufacturing site change from NC to Dartford, NK.				9. AMENDMENTS DATES	
10. PHARMACOLOGICAL CATEGORY Antineoplastic		11. HOW DISPENSED RX <input checked="" type="checkbox"/> OTC		12. RELATED IND/NDA/DMF None	
13. DOSAGE FORM(S) Tablets		14. POTENCY 2 mg/tablet			
15. CHEMICAL NAME AND STRUCTURE 1,4-Butanediol dimethanesulfonate C ₆ H ₁₄ S ₂ O ₆ , MW = 246 CH ₃ SO ₂ O(CH ₂) ₄ OSO ₂ CH ₃				16. RECORDS AND REPORTS CURRENT YES <input checked="" type="checkbox"/> NO REVIEWED YES <input checked="" type="checkbox"/> NO	
17. COMMENTS (See Review Notes)					
18. CONCLUSIONS AND RECOMMENDATIONS Approval is recommended. However, company should satisfactorily address the Biopharm review comments.					
19. REVIEWER					
NAME Chengyi Liang, Ph.D.		SIGNATURE			DATE COMPLETED 1-30-2002
DISTRIBUTION	ORIGINAL NDA	DIVISION FILE	Reviewer: C.Y. Liang HFD-150	CSO: M. Pelosi HFD-150	Chemistry Team Leader R. Lostritto

Original NDA 9-386/SCM-019
HFD-150 Div. File
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/s/

Chengyi Liang
1/25/02 07:44:54 AM
CHEMIST

Richard Lostritto
1/30/02 05:49:42 PM
CHEMIST