

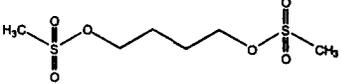
CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER

20-945/S-005

Chemistry Review(s)

CHEMIST'S REVIEW #1		1. ORGANIZATION HFD-150 DODP		2. NDA NUMBER 20-954	
3. NAME AND ADDRESS OF APPLICANT (City and State) Orphan Medical, Inc. 13911 Ridgedale Drive, Suite 475 Minnetonka, MN 55305.				4. AF NUMBER	
6. NAME OF DRUG Busulfex Injection				7. NONPROPRIETARY NAME Busulfan	
				5. SUPPLEMENT (S) NUMBER(S) DATES(S)	
		6. NAME OF DRUG Busulfex Injection		7. NONPROPRIETARY NAME Busulfan	
				SCP-005 05-10-2002	
8. SUPPLEMENT PROVIDES FOR: An alternate 5 micron syringe filter.					
10. PHARMACOLOGICAL CATEGORY Anti-neoplastic		11. HOW DISPENSED RX <input checked="" type="checkbox"/> OTC		12. RELATED IND/NDA/DMF	
13. DOSAGE FORM(S) Sterile liquid		14. POTENCY 60 mg ampoule			
15. CHEMICAL NAME AND STRUCTURE 1,4-butanediol-dimethylsulfonate esters				16. RECORDS AND REPORTS	
				CURRENT YES <input checked="" type="checkbox"/> NO <input type="checkbox"/> REVIEWED YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>	
7. COMMENTS The applicant has proposed an alternate 5 μ _____ syringe filter membrane to the currently used _____ filter membrane. A consult request was sent to Microbiology to evaluate proposed _____ filter membrane. They have recommended approval from microbiology standpoint (please refer to the e-mail from Dr. Peter Cooney, dated 11.13.02). The _____ filter will be manufactured by _____. The applicant has provided a letter of authorization from _____ to refer to their approved medical device under 510(k) #K960928. The applicant has provided data from a compatibility study of _____ filter with Busulfex. The drug product exposed to _____ filter for 4 hours and a control were evaluated by _____ for assay, impurities, absorption/stability. Particulate matter was evaluated using USP <788> light obscuration test. Filter extractable study was conducted using _____. Provided data from the above studies indicate that the drug product is compatible with _____ filters. The applicant has requested categorical exclusion from submitting an environmental assessment under 21 CFR 25.31(b). The applicant's request is found to be acceptable.					
18. CONCLUSIONS AND RECOMMENDATIONS Based on the above, this application is recommended for approval from the standpoint of chemistry, manufacturing and controls.					
19. REVIEWER					
NAME Nallaperumal Chidambaram, Ph.D.		SIGNATURE 			DATE COMPLETED 11-13-2002
DISTRIBUTION DNDC1/Division Dir. /DY, Director	ORIGINAL NDA	DIVISION FILE	Reviewer: N. Chidambaram HFD-110	CSO: S. Bradley HFD-150	Chemistry Team Leader: R. Lostritto HFD-150

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Nallaperumal Chidambaram
11/13/02 01:49:56 PM
CHEMIST

Richard Lostritto
11/13/02 02:01:24 PM
CHEMIST