

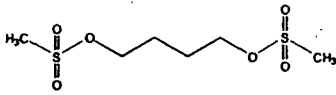
CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER

20-954/S-004

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 250 Minnetonka, MN 55305.				4. AF NUMBER	
				5. SUPPLEMENT (S) NUMBER(S) DATES(S)	
6. NAME OF DRUG Busulfex [®] (busulfan) Injection		7. NONPROPRIETARY NAME Busulfan		SE2-004	01-11-2002
8. SUPPLEMENT PROVIDES FOR: A labeling supplement to incorporate pediatric information on dosing, pharmacokinetics and safety.				9. AMENDMENTS DATES BZ 02.25.2002	
10. PHARMACOLOGICAL CATEGORY Anti-neoplastic		11. HOW DISPENSED RX <input checked="" type="checkbox"/> OTC		12. RELATED IND/NDA/DMF	
13. DOSAGE FORM(S) Injection		14. POTENCY 10 mL (6 mg/mL)			
15. CHEMICAL NAME AND STRUCTURE 				16. RECORDS AND REPORTS CURRENT YES <input checked="" type="checkbox"/> NO REVIEWED YES <input checked="" type="checkbox"/> NO	
17. COMMENTS The prior approval supplement provides for a labeling change to incorporate pediatric information on dosing, pharmacokinetics and safety. The Chemistry, manufacturing and controls information has been cross-referenced to original NDA. No changes have been made to the manufacture of the drug substance and the drug product. There is no pediatric formulation and no changes have been made to Description and How Supplied Section. A claim for categorical exclusion from filing an environmental assessment under 21 CFR 25.31 (b) has been submitted. The applicant's claim is found to be acceptable.					
18. CONCLUSIONS AND RECOMMENDATIONS: Provided information is found to be adequate. This supplement is recommended for approval from the standpoint of chemistry, manufacturing and controls.					
19. REVIEWER					
NAME Nallaperumal Chidambaram, Ph.D.		SIGNATURE <i>/S/</i>		DATE COMPLETED 05-01-2002	
DISTRIBUTION DNDCI/Division Dir. /DY. Director	ORIGINAL NDA	DIVISION FILE	Reviewer: N. Chidambaram Ph.D., HFD-150	CSO: D. Spillman HFD-150	Chemistry Team Leader: R. Lostritto, Ph.D.

**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
5/2/02 03:48:43 PM
CHEMIST

Richard Lostritto
5/2/02 04:07:57 PM
CHEMIST