



NDA 20-954/S-003

Orphan Medical, Inc.  
13911 Ridgedale Drive, Suite 250  
Minnetonka, MN 55305

Attention: Carol S. Curme, J.D., RAC  
Senior Manager of Regulatory Affairs

Dear Ms. Curme:

Please refer to your supplemental new drug application dated June 19, 2000, received June 20, 2000, and submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Busulfex® (busulfan) Injection.

This "Changes Being Effected in 30 days" supplemental new drug application provides for revisions to the DOSAGE AND ADMINISTRATION section, Preparation for Intravenous Administration subsection, to better ensure the safe use of Busulfex. In addition, there were minor editorial revisions to the CLINICAL PHARMACOLOGY, CLINICAL STUDIES, WARNINGS, PRECAUTIONS, ADVERSE REACTIONS, OVERDOSAGE, HOW SUPPLIED, and HANDLING AND DISPOSAL sections.

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert submitted June 19, 2000). Accordingly, the supplemental application is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2  
FDA  
5600 Fishers Lane  
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

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If you have any questions, call Dianne Spillman, Regulatory Project Manager, at (301) 594-5746.

Sincerely,

*{See appended electronic signature page}*

Richard Pazdur, M.D.

Director

Division of Oncology Drug Products

Office of Drug Evaluation I

Center for Drug Evaluation and Research

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Richard Pazdur

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