DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-954/S001

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

Attention: Carol S. Curme, J.D., R.A.C.
Senior Manager of Regulatory Affairs

Dear Ms. Curme:

Please refer to your supplemental new drug application dated February 16, 1999, received February 17, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Busulfex® (busulfan) Injection.

We acknowledge receipt of your submission(s) dated June 7, July 27, and October 16, 2002.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling, including any revisions approved since 1999, i.e. S-003.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-954/S-001." Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), 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 reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Sean Bradley, R.Ph., Regulatory Project Manager, at (301) 594-5770.

Sincerely,

{See appended electronic signature page}

Richard Pazdur, M.D.
Director
Division of Oncology Drug Products
Office of Drug Evaluation 1
Center for Drug Evaluation and Research

Enclosure

Updated FDA Approved Labeling

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

/s/

Richard Pazdur

12/23/02 02:34:21 PM