DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-954/S-005

Orphan Medical, Inc.
13911 Ridgedale Drive, Suite 475
Minnetonka, MN 55305

Attention: Carol S. Curme, J.D., RAC
Senior Manager RA

Dear Ms. Curme:

Please refer to your supplemental new drug application dated May 10, 2002, received May 13, 2002, 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 an alternate 5-micron syringe filter and labeling changes.

We have completed our review of this application. 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 (text for the package insert) and immediate container and carton labels submitted May 10, 2002.

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 Lostritto, Ph.D.
Team Leader, Chemistry, Manufacturing and Controls
Division of Oncology Drug Products
Division of New Drug Chemistry-I
Office of New Drug Chemistry

Enclosure

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

/s/

Richard Lostritto

11/13/02 04:52:37 PM