DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-954/S-008

PDL BioPharma, Inc.
Attention: Robert J. Stagg, Pharm.D.
Vice President, Regulatory Affairs and Drug Safety
34801 Campus Drive
Fremont, CA 94555

Dear Dr. Stagg:

Please refer to your supplemental new drug application dated December 18, 2006, received December 19, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for IV Busulfex (busulfan) Injection.

We acknowledge receipt of your submissions dated March 1, April 18 (electronic) and 19, (electronic), 2007.

This supplemental new drug application provides for the addition of a new container/closure system and revised labeling for the IV Busulfex Injection product.

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

The final printed labeling (FPL) for this supplement S-008 must be identical to the enclosed labeling (text for the package insert, immediate container and carton labels). Please note that your final printed labeling submitted May 27, 2003, for S-004 has been superseded but will be retained in the file.

Submit content of labeling [21 CFR 601.14(b)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text. Upon receipt and verification, we will transmit that version to the National Library of Medicine for posting on the DailyMed website.

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-954/S-008.**" Approval of this submission by FDA is not required before the labeling is used.

We remind you that you must comply with the reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please call Frank H. Cross, Jr., Project Manger, at 301-796-0876.

Sincerely,

{See appended electronic signature page}

Ann T. Farrell, M.D.
Acting Deputy Division Director
Division of Drug Oncology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

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

/s/

Ann Farrell

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