DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-637/S-022

MGI Pharma
Attention: Nataskia Lampe
Manager, Regulatory Affairs
6611 Tributary Street
Baltimore, MD 21224

Dear Ms. Lampe:

Please refer to your supplemental new drug application dated June 30, 2006, received July 3, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Gliadel Wafer (polifeprosan 20 with carmustine implant).

We acknowledge receipt of your submissions dated August 15 and November 15, 2006.

This supplemental new drug application provides for changes to the Caution Card (new manufacturer) and CLINICAL STUDIES, Primary Surgery, and ADVERSE REACTIONS, Surgery for Recurrent Disease sections, and change of the listed manufacturer of the Package Insert.

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 (text for the package insert and caution card).

Please submit an electronic version of the FPL. 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 20-637/S-022**." 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
Food and Drug Administration
5515 Security Lane

HFD-001, Suite 5100
Rockville, MD 20852

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 question, call Paul Zimmerman, Regulatory Project Manager, at (301) 796-1489.

Sincerely,

{See appended electronic signature page}

Robert Justice, M.D.
Director
Division of Drug Oncology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

Enclosure

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

/s/

Robert Justice

12/26/2006 02:53:30 PM