DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-790

MGI PHARMA, INC.
5775 West Old Shakopee Road, #100
Bloomington, MN 55437

Attention: Timothy K. Ressler, MS, MT, (ASCP)
Vice President Regulatory Affairs

Dear Mr. Ressler:

Please refer to your new drug application (NDA) dated November 14, 2005, received November 15, 2005, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Dacogen™ (decitabine) for Injection 50 mg/vial.

We acknowledge receipt of your submissions dated November 18, 2005, February 21, 2006; and March 20, March 23, and March 31, 2006; and April 11,2006. The November 14, 2005 submission constituted a complete response to our August 31, 2005 action letter.

This new drug application provides for the use of Dacogen™ (decitabine) for Injection 50 mg/vial for myelodysplastic syndrome (MDS).

We have completed our review of this application, as amended. It 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 the immediate container and carton labels (submitted March 23, 2006). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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 NDA 21-790**." Approval of this submission by FDA is not required before the labeling is used.

Although not considered post-marketing commitments, we have the following recommendations.

1. Please provide the results of the following study when complete: EORTC 06011 Phase III randomized trial of intravenous low-dose decitabine versus supportive care in elderly patients with primary MDS, secondary MDS or Chronic Myelomonocytic Leukemia (CMML) who are not eligible for intensive therapy.

2. We recommend that you conduct *in vitro* studies in human hepatic microsomes to evaluate if decitabine inhibits CYP2C8.

Updates to the above recommendations and the Clinical Pharmacology and Biopharmaceutic's recommendations listed in your November 14, 2005 letter should be included in your annual reports to the NDA.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Drug Oncology Products and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
Food and Drug Administration
5901-B Ammendale Road
Beltsville, MD 20705-1266

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

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 Brenda Atkins, Regulatory Project Manager at (301) 796-1324.

Sincerely,
{See appended electronic signature page}

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

Enclosures – Approved Labeling, Immediate Container and Carton labels

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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

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