



NDA 11-719/S-108

Mayne Pharma (USA) Inc.
Attention: Steve Richardson
Director, Regulatory and Medical Affairs
Mack-Cali Centre II
650 From Road, Second Floor
Paramus, NJ 07652

Dear Mr. Richardson:

Please refer to your supplemental new drug application dated March 9, 2005, received March 11, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Methotrexate Injection.

We acknowledge receipt of your submissions dated March 31, April 6 and 8, 2005.

This supplemental new drug application provides for a new drug substance source and new formulations for Methotrexate Injection, Preservative Free, in the following new strengths: 2.5 g/100 mL, 1 g/40 mL, 500 mg/20 mL, and 20 mg/ 2 mL.

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 submitted labeling (package insert, immediate container and carton labels) submitted March 9, 2005, and amended March 31, 2005.

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 11-719/S-108.**" Approval of this submission by FDA is not required before the labeling is used.

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 Paul Zimmerman, Regulatory Project Manager, at (301) 594-5775.

Sincerely,

{See appended electronic signature page}

Richard Pazdur, M.D.
Director
Division of Oncology Drug Products
Office of Drug Evaluation I
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/

Richard Pazdur
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