DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 8-107/S-055

Mayne Pharma
Attention: Steve Richardson
Director, Regulatory Affairs
650 From Road
Mack-Cali Centre II, 2nd Fl.
Paramus, NJ 07652

Dear Mr. Richardson:

Please refer to your supplemental new drug application dated May 6, 2003, received May 8, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Leucovorin Calcium for Injection.

We acknowledge receipt of your submission dated September 18, 2003.

Your submission of September 18, 2003 constituted a complete response to our September 3, 2003 action date.

This supplemental new drug application provides for an alternate site of manufacturing, packaging and testing for Leucovorin Calcium for Injection and new packing components listed.

We have 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 dated September 18, 2003.

The final printed labeling (FPL) must be identical to the labeling (text for the package insert, immediate container and carton label).

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "**FPL for approved supplement NDA 8-107/S-055**." Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communication 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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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 Patty Garvey, Regulatory Project Manager, at (301) 594-5766.

Sincerely,

{See appended electronic signature page}

Richard Lostritto, Ph.D.
Chemistry Team Leader, DNDC I for the
Division of Oncology Drug Products, (HFD-150)
DNDC I, Office of New Drug Chemistry
Center of 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 Lostritto

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