DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-794/S-001

Pharmion Corporation
Attention: Robert Nelson
Regulatory Affairs Senior Submissions Specialist
2525 28th Street, Suite 200
Boulder, CO 80301

Dear Mr. Nelson:

Please refer to your supplemental new drug application dated September 1, 2004, received September 2, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Vidaza™ (Azacitidine for Injectable Suspension).

This application is subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

We acknowledge receipt of your submission dated January 24, 2005.

This "Changes Being Effected" supplemental new drug application provides for clarification to the instructions for appropriate dosage and administration of Vidaza™. Also, provided in this supplement, is a change to the **CLINICAL STUDIES** section to accurately reflect that the pivotal study was conducted at 53 U.S. sites.

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 submitted January 24, 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 50-794/S-001**." 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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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 Amy Baird, Consumer Safety Officer, at (301) 594-5779.

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

6/29/05 09:29:19 AM