



NDA 50-794/S-010

Pharmion Corporation  
Attention: Mary Vandekauter, M.S., RAC  
Manager, Regulatory Affairs  
9900 West 109<sup>th</sup> Street, Suite 300  
Overland Park, KS 66210

Dear Ms. Vandekauter:

Please refer to your supplemental new drug application dated October 19, 2007, received October 22, 2007, and submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Vidaza® (azacitidine) for Injection.

We acknowledge receipt of your submission dated February 8, 2008.

This supplemental new drug application provides for adding a drug product manufacturing site and updated labeling.

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 content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format submitted on October 19, 2007.

### **CONTENT OF LABELING**

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format as described at <http://www.fda.gov/oc/datacouncil/spl.html> that is identical to, except for including the revisions listed, the submitted labeling (package insert submitted October 19, 2007). These revisions are terms of the NDA approval. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission "SPL for approved NDA 50-794/S-010."

**CARTON AND IMMEDIATE CONTAINER LABELS**

Submit final printed carton and container labels that are identical to the submitted carton and immediate container labels as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission “**Final Printed Carton and Container Labels for approved NDA 50-794/S-010.**” Approval of this submission by FDA is not required before the labeling is used.

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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 questions, call Susan Jenney, Regulatory Health Project Manager, at (301) 796-0062.

Sincerely,

*{See appended electronic signature page}*

Hasmukh B. Patel, Ph.D.  
Branch Chief  
Branch VIII, Division of Post-Marketing Evaluation  
Office of New Drug Quality Assessment  
Center for Drug Evaluation and Research

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/s/

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Hasmukh Patel  
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