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APPROVAL PACKAGE FOR:

APPLICATION NUMBER

50-794

Approval Letter(s)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-794

Pharmion Corporation
Attention: Gillian Ivers-Read, Vice President,
Clinical Development and Regulatory
2525 28th Street
Boulder, Colorado 80301

Dear Ms. Ivers-Read:

Please refer to your new drug application (NDA) dated December 26, 2003, received December 29, 2003, 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 in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

We acknowledge receipt of your submissions dated February 20; March 2, 12, 18 and 23 and April 22, 2004.

This new drug application provides for the use of Vidaza™ (azacitidine for injectable suspension) for the treatment of patients with the following myelodysplastic syndrome subtypes: refractory anemia or refractory anemia with ringed sideroblasts (if accompanied by neutropenia or thrombocytopenia and requiring transfusions), refractory anemia with excess blasts, refractory anemia with excess blasts in transformation, and chronic myelomonocytic leukemia.

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, immediate container and carton labels). 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.

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 50-794**." Approval of this submission by FDA is not required before the labeling is used.

We remind you of the postmarketing study commitment made in your submission dated May 18, 2004:

> As azacitidine and its metabolites are primarily excreted by the kidneys, you have agreed to conduct a formal pharmacokinetics and safety study in patients with varying degrees of renal impairment. The results of this study will support dosing recommendations for this patient population especially during the first course of therapy. Dose proportionality should also be explored in this study.
>
> You have agreed to the following schedule:
>
> | | |
> |---|---|
> | Protocol Submission: | by August 2004 |
> | Study Start: | by November 2004 |
> | Final Report Submission: | by May 2006 |

Clinical protocols should be submitted to your IND for Vidaza. Nonclinical and chemistry, manufacturing, and controls protocols and all study final reports should be submitted to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled "**Postmarketing Study Protocol**", "**Postmarketing Study Final Report**", or "**Postmarketing Study Correspondence**."

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

> Division of Drug Marketing, Advertising,
> and Communications, HFD-42
> Food and Drug Administration
> 5600 Fishers Lane
> Rockville, MD 20857

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).

The MedWatch-to-Manufacturer Program provides manufacturers with copies of serious adverse event reports that are received directly by the FDA. New molecular entities and important new biologics qualify for inclusion for three years after approval. Your firm is eligible to receive copies of reports for this product. To participate in the program, please see the enrollment instructions and program description details at www.fda.gov/medwatch/report/mmp.htm.

If you have any questions, call Amy Baird, Regulatory Project Manager, at (301) 594-5779.

Sincerely,

{See appended electronic signature page}

Robert Temple, M.D.
Director
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Robert Temple
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