DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 79-183

Hospira, Inc.
Attention: Khaled M. Mohamed
Senior Regulatory Associate
Dept. 0389, Bldg H-2
275 North Field Dr.
Lake Forest, IL 60045-5046

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated August 24, 2007, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Gemcitabine for Injection USP, 2 grams per vial.

Reference is made to your amendments dated May 6, July 2, August 20, October 22, and October 27, 2008. Reference is also made to the ANDA Suitability Petition (2006P-0145/CP1) approved by the agency on August 22, 2007. This petition allowed you to file this ANDA for a drug product that differs in strength (total drug content) from that of the listed drug product (i.e. from Gemzar for Injection, 1 gram per vial, marketed by Eli Lilly and Co. (Lilly), to provide for a vial containing 2 grams of Gemcitabine for Injection, USP). In addition, we acknowledge receipt of your correspondence dated September 30, 2008, addressing patent issues associated with this ANDA.

We have completed the review of this ANDA, and based upon the information you have presented to date we have concluded that the drug is safe and effective for use as recommended in the submitted labeling. However, we are unable to grant final approval to your ANDA at this time because of the patent issue noted below. Therefore, the ANDA is **tentatively approved**. This determination is based upon information available to the agency at this time (i.e., information in your ANDA and the status of current good manufacturing practices (cGMPs) of the facilities used in the manufacture and testing of the drug product). This determination is subject to change on the basis of new information that may come to our attention. This letter does

not address notice issues related to the 180-day exclusivity provisions under section 505(j)(5)(B)(iv) of the Act.

The reference listed drug (RLD) upon which you have based your ANDA, Lilly's Gemzar for Injection, 1 gram per vial, is subject to periods of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S. Patent Nos. 4,808,614 (the '614 patent) and 5,464,826 (the '826 patent) are scheduled to expire (with pediatric exclusivity added) on November 15, 2010, and May 7, 2013, respectively.

With respect to both patents, your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that each patents is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Gemcitabine for Injection USP, under this ANDA. Section 505(j)(5)(B)(iii) of the Act provides that approval of an ANDA shall be made effective immediately, unless an action was brought against Hospira, Inc. (Hospira) for infringement of one or more of these patents that were the subjects of the paragraph IV certifications. You notified the agency that Hospira complied with the requirements of section 505(j)(2)(B) of the Act, and that litigation for infringement of the '614 and '826 patents was brought against Hospira within the statutory 45-day period in the United States District Court for the Southern District of Indiana, Indianapolis Division [Eli Lilly and Company v. Mayne Pharma Limited et al, Civil Action No. 1:08-cv-00037-SEB-JMS].

With respect to the I-499 exclusivity listed in the "Orange Book" for Lilly's Gemzar for Injection, your ANDA contains a statement under section 505(j)(4)(D)(iii) of the Act indicating that you will not market your drug product under this ANDA until the exclusivity has expired.

Therefore, final approval of this ANDA cannot be granted until:

1. a. the expiration of the 30-month period provided for in section 505(j)(5)(B)(iii)[1]

[1] Because information on the '614 and '826 patents was submitted to FDA before August 18, 2003, this reference to section 505(j)(5)(B)(iii) is to that section of the Act as in effect prior to December 8, 2003, when the Medicare Prescription Drug, Improvement and Modernization Act (MMA) (Public Law 108-173) was enacted. See MMA § 1101(c)(3).

b. the date the court decides[2] that the patents are invalid or not infringed (see sections 505(j)(5)(B)(iii)(I), (II), and (III) of the Act) or

c. the listed patents have expired, and

2. The agency is assured there is no new information that would affect whether final approval should be granted.

To reactivate your ANDA prior to final approval, please submit a "MINOR AMENDMENT – FINAL APPROVAL REQUESTED" 90 days prior to the date you believe that your ANDA will be eligible for final approval. This amendment should provide the legal/regulatory basis for your request for final approval and should include a copy of a court decision, or a settlement or licensing agreement, as appropriate. It should also identify changes, if any, in the conditions under which the ANDA was tentatively approved, i.e., updated information such as final-printed labeling, chemistry, manufacturing, and controls data as appropriate. This amendment should be submitted even if none of these changes were made, and it should be designated clearly in your cover letter as a MINOR AMENDMENT – FINAL APPROVAL REQUESTED.

In addition to the amendment requested above, the agency may request at any time prior to the date of final approval that you submit an additional amendment containing the requested information. Failure to submit either or, if requested, both amendments may result in rescission of the tentative approval status of your ANDA, or may result in a delay in the issuance of the final approval letter.

Any significant changes in the conditions outlined in this ANDA as well as changes in the status of the manufacturing and testing facilities' compliance with current good manufacturing practices (cGMPs) are subject to agency review before final approval of the application will be made. Such changes should be categorized as representing either "major" or "minor" changes, and they will be reviewed according to OGD policy in effect at the time of receipt. The submission of multiple amendments prior to final approval may also result in a delay in the issuance of the final approval letter.

---

[2] This decision may be either a decision of the district court or the court of appeals, whichever court is the first to decide that the patent is invalid or not infringed.

This drug product may not be marketed without final agency approval under section 505 of the Act. The introduction or delivery for introduction into interstate commerce of this drug product before the final approval date is prohibited under section 301 of the Act. Also, until the agency issues the final approval letter, this drug product will not be deemed to be approved for marketing under section 505 of the Act, and will not be listed in the "Orange Book."

For further information on the status of this application, or prior to submitting additional amendments, please contact Esther Chuh, Project Manager, at (240) 276-8530.

Sincerely yours,

{See appended electronic signature page}

Gary Buehler
Director
Office of Generic Drugs
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/

Robert L. West
2/23/2009 06:59:41 AM
Deputy Director, for Gary Buehler