DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-234

Hospira, Inc.
Attention: Judith Zutkis
Director, Global Regulatory Affairs
275 N. Field Drive
D-0389, Bldg H2-2N
Lake Forest, IL 60045-5046

Dear Ms. Zutkis:

Please refer to your new drug application dated July 9, 2007, received July 11, 2007, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Docetaxel Injection, 20 mg/2 mL single-dose vial, 80 mg/8 mL multi-dose vial, 160 mg/16 mL multi-dose vial.

Please also refer to your submission dated April 24, 2008, received April 28, 2008, which extended the due date for this application to August 11, 2008.

We acknowledge receipt of your submissions dated September 14, 27, October 22, November 15, and 20 (2), 2007; March 14, April 24 (2), May 8, July 30 (2), August 8 (two electronic submissions), and 11 (electronic), 2008.

This NDA provides for the use of Docetaxel Injection, 20 mg/2 mL single-dose vial, 80 mg/8 mL multi-dose vial, and 160 mg/16 mL multi-dose vial for locally advanced or metastatic breast cancer after failure of prior chemotherapy, in combination with doxorubicin and cyclophosphamide as adjuvant treatment of operable node-positive breast cancer, locally advanced or metastatic non-small lung cancer after failure of prior platinum-based chemotherapy, in combination with cisplatin for unresectable, locally advanced or metastatic untreated non-small cell lung cancer, in combination with prednisone for androgen independent (hormone refractory) metastatic prostate cancer.

We completed our review of this application, as amended. It is tentatively approved under 21 CFR 314.105 for use as recommended in the agreed upon labeling (refer to the enclosed text for the package insert, enclosed text for the patient package insert, enclosed immediate container and carton labels). This determination is contingent upon information available to the Agency at this time (i.e., information in your application and the status of current good manufacturing practices of the facilities used in manufacturing and testing of the drug product) and is, therefore, subject to change on the basis of any new information that may come to our attention.

Your application contains certifications to each of the patents under section 505(b)(2)(A)(iv) of the Act stating that the patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of, this drug product under this application ("Paragraph IV certifications").

Section 505(c)(3)(C) of the Act provides that approval of a new drug application submitted pursuant to section 505(b)(2) of the Act shall be made effective immediately, unless an action is brought for infringement of one or more of the patents that were the subject of the paragraph IV certifications. This action must be taken prior to the expiration of forty-five days from the date the notice provided under section 505(b)(3) is received by the patent owner/approved application holder. You notified us that you complied with the requirements of section 505(b)(3) of the Act. In addition, you have notified the Agency that the patent owner and/or approved application holder has initiated a patent infringement suit against you with respect to patent 5,714,512 B1, and patent 5,750,561 B1 in the United States District Court for the District of Delaware (Aventis Pharma S.A., and sanofi-aventis U.S., LLC (collectively, "sanofi-aventis") vs. Hospira, Inc. [Civil Action Case No. 07-721]).

Therefore, final approval cannot be granted until:

1. a. expiration of the 30-month period provided for in Section 505(c)(3)(C) beginning on the date of receipt of the 45-day notice required under Section 505(b)(3), unless the court has extended or reduced the period because of the failure of either party to reasonably cooperate in expediting the action, or

   b. the date the court decides that the patent(s) is/are invalid or not infringed as described in section 505(c)(3)(C)(i), (ii), (iii,) or (iv) of the Act, or,

   c. the listed patent(s) has/have expired, and

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

In addition, the listed reference drug product upon which you base your application is subject to a period of patent protection and exclusivity protection and therefore, final approval of your application under section 505(c)(3) of the Act [21 U.S.C. 355(c)(3)] may not be made effective until the period has expired, i.e., September 28, 2010.

No more than 60 days prior to September 28, 2010, or when requested, submit an amendment to this application identifying changes, if any, in the conditions under which your product was tentatively approved. This information should include updated labeling, chemistry, manufacturing and controls data, and a safety update.

Failure to submit this amendment will prompt a review of the application that may result in rescission of the tentative approval letter.

Promotional materials should be submitted, in duplicate, directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

We note your plan, at the time of product launch, to inform healthcare practitioners about the differences in the preparation of the proposed Docetaxel Injection versus other docetaxel products (e.g., Dear Healthcare Professional letter), as per your August 8, 2008, correspondence.

Before we issue a final approval letter, this NDA is not deemed approved. If you believe that there are grounds for issuing the final approval letter before September 28, 2010, you should amend your application accordingly.

This product may be considered misbranded under the Federal Food, Drug, and Cosmetic Act if it is marketed with this change before final approval.

If you choose to use a proprietary name for this product, the name and its use in the labels must conform to the specifications under 21 CFR 201.10 and 201.15. We recommend that you submit any proprietary name to the Agency for our review prior to its implementation.

If you have any questions, please call Frank Cross, Regulatory Project Manager, at (301) 796-0876.

Sincerely,

{See appended electronic signature page}

Ramzi Dagher, M.D.
Deputy Division Director
Division of Drug Oncology Products
Office of Oncology Drug Products
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/

Ramzi Dagher

8/11/2008 04:52:02 PM