DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022234

NDA APPROVAL

Hospira, Inc.
Attention: Laurie Wojtko
Senior Associate, Global Regulatory Affairs
275 North Field Drive Dept. 389, Bldg. H2-2
Lake Forest, IL 60064

Dear Ms. Wojtko:

Please refer to your New Drug Application (NDA) 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 and 160 mg/16 mL multi-dose vial.

We acknowledge receipt of your amendments dated October 27, November 3, 8, 9, 11, 15, and 23, December 2, and 24, 2010; January 27; February 16 and 18, 2011.

Please also refer to our tentative approval letter dated December 11, 2009.

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; for 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, and in combination with prednisone for androgen independent (hormone refractory) metastatic prostate cancer.

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 enclosed agreed-upon labeling text.

As soon as possible, but no later than 14 days from the date of this letter, submit, via the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical to the enclosed labeling text for the package insert, and text for the patient package insert, Information on submitting SPL files using eLIST may be found in the guidance for industry titled “SPL Standard for Content of Labeling Technical Qs and As” at

http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert 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

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

METHODS VALIDATION

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

LETTERS TO HEALTH CARE PROFESSIONALS

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA to the following address:

MedWatch Program
Office of Special Health Issues
Food and Drug Administration
10903 New Hampshire Ave
Building 32, Mail Stop 5353
Silver Spring, MD 20993

REPORTING REQUIREMENTS

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 Modupe Fagbami Regulatory Project Manager, at (301) 796-1348.

Sincerely,

{See appended electronic signature page}

Robert L. Justice, M.D., M.S.
Director
Division of Oncology Products
Office of Oncology Products
Center for Drug Evaluation and Research

ENCLOSURES:
Package Insert
Patient Package Insert
Carton and Container Labeling

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 JUSTICE
03/08/2011