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RESEARCH**

APPLICATION NUMBER:
022234Orig1s000

CROSS DISCIPLINE TEAM LEADER REVIEW

Cross-Discipline Team Leader Review

Date	02-MAR-2011
From	Richard (Rik) Lostritto, Ph.D.
Subject	Cross-Discipline Team Leader Review
NDA/BLA #	222234
Supplement#	
Applicant	Hospira, Inc.
Dates of Submissions	<p>Amendments: 23-SEP-2010 full approval request (b) (4)</p> <p>03-NOV-2010 (b) (4)</p> <p>Labeling amendments: 15-NOV-2010, 23-NOV-2010, 24-DEC-2010, 27-JAN-2011.</p>
PDUFA Goal Date	23-MAR-2011
Proprietary Name / Established (USAN) names	Docetaxel Injection
Dosage forms / Strength	20 mg/2 mL, 80 mg/8 mL, and 160 mg/16 mL
Proposed Indication(s)	Multiple: See "Clinical" section herein
Recommended:	Approval

Introduction

This NDA amendment for docetaxel injection, in accordance with section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, was submitted by Hospira, Inc (Lake Forest, IL) to request approval of the therapeutic equivalence of the proposed product to Taxotere.

This CDTL memo serves to highlight the critical approvability issues across the involved disciplines and recommends an "Approval" action for this application. All individual discipline reviews may be found to be completed in DARRTS with the exception of DDMAC (see below).

Background

This application received tentative approval letters dated August 11, 2008 and December 11, 2009. The applicant provided a "Minor Amendment-Full Approval Requested" dated 23-SEP-2010. In the Summary of Changes document attached to this electronic submission, the applicant indicated (b) (4). Thus, as submitted and filed, this was a Class-2 resubmission with a six (6) month time clock. After filing and the Class-2 designation, Hospira submitted an amendment to withdraw the

(b) (4) on 03-NOV-2010. However, this (b) (4) withdrawal did not affect the already established time clock.

Several telecons with the applicant and several rounds of labeling reviews were conducted. Hospira has revised the package insert to align with the most recent RLD revisions that were approved in April and May 2010.

Dear Health Care Professional Letter

Per Agency request, on August 8, 2008 Hospira committed to provide a Dear Healthcare Professional Letter to inform healthcare practitioners about the differences in preparation of the proposed Docetaxel Injection. Hospira has drafted this letter and has provided a copy herein. Upon approval, Hospira will submit a copy of this letter to MedWatch.

DMEPA

In the review dated 28-JAN-2011, the DMEPA reviewer noted the following:

In a labeling meeting held by DDOP on November 18, 2010, DMEPA communicated their safety concerns with this product. The review team communicated these safety concerns to the Applicant in a teleconference held on November 23, 2010. At that time, the Applicant stated they had proactively revised the container labels and carton labeling that were submitted on September 23, 2010 in response to safety concerns raised in the November 18, 2010 ISMP Medication Safety Alert newsletter. These revised labels and labeling were submitted to the Agency for review on November 23, 2010.

DMEPA comments concerning the DHCP letter submitted by the Applicant on September 23, 2010 were forwarded to the Applicant on November 29, 2010. DMEPA communicated their container label and carton labeling recommendations to the Division in a labeling meeting held on December 14, 2010. DMEPA and the Division came to a consensus at that time and on December 20, 2010, Agency finalized recommendations were emailed to the Division for dissemination to the Applicant.

In response to these recommendations, the Applicant submitted revised container labels and carton on December 24, 2010. A revised DHCP letter was also submitted at this time.

DMEPA evaluated these revised labels and labeling and finds them acceptable.

DDMAC

The copy of the e-mail below serves to close the DDMAC review:

From: Salis, Olga
Sent: Tuesday, March 01, 2011 10:58 AM
To: Lostritto, Richard T
Cc: George, Adam
Subject: NDA 22234 Docetaxel Injection

Dear Dr. Lostritto,

According to the last labeling submitted by the sponsor on 2/18/2011, DDMAC agrees with the changes.

Thanks,
Olga Salis
DDMAC RPM

CMC

This review covers the changes made to the application since the product was tentatively approved on 11-DEC-2009.

The Applicant has resolved all outstanding CMC issues, and this application is recommended for approval. An overall acceptable recommendation was received from the Office of Compliance on 09-NOV-2010, and the microbiology reviewer recommended approval of this amendment on 10-DEC-2009 (see Microbiology Review). Hospira has addressed the CMC comments related to carton and container labels in Amendment dated 27-Jan-2011; see attached copies of revised carton and container labels.

Clinical

The Clinical Reviewer updated the review in DARRTS on 08-FEB-2011:

No new clinical data was submitted for this NDA. The Taxotere NDA 20449 has been previously reviewed for efficacy and safety. Therefore, the medical reviewer recommends approval for the indications cited in their updated review which include breast cancer, non-small cell lung cancer, prostate cancer, gastric adenocarcinoma, and head and neck cancer.

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

/s/

RICHARD T LOSTRITTO
03/02/2011