

# CENTER FOR DRUG EVALUATION AND RESEARCH

## Approval Package for:

### *APPLICATION NUMBER:*

**201525Orig1s000**

*Trade Name:* Docetaxel Injection 20 mg/2 mL, 80 mg/8 mL and 160 mg/16 mL

*Generic Name:* Docetaxel

*Sponsor:* Sandoz Inc.

*Approval Date:* June 29, 2011

*Indications:* For the use of docetaxel Injection, 20 mg/2 mL, 80 mg/8 mL and 160 mg/16 mL in locally advanced or metastatic breast cancer, locally advanced or metastatic non-small cell lung cancer and hormone refractory metastatic prostate cancer, gastric adenocarcinoma and squamous cell carcinoma of the head and neck cancer.

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## 201525Orig1s000

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**APPROVAL LETTER**



NDA 201525

**NDA APPROVAL**

Sandoz Inc.  
Attention: Bernadette Attinger  
Director, Regulatory Affairs  
506 Carnegie Center  
Suite 400  
Princeton, NJ 08540

Dear Ms. Attinger:

Please refer to your New Drug Application (NDA) dated September 16, 2010, received September 17, 2010, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Docetaxel Injection 20 mg/2 mL, 80 mg/8 mL and 160 mg/16 mL.

We acknowledge receipt of your amendments dated October 6, 2010; November 15, 2010; December 15, 2010; January 14, 2011; March 22, 2011; April 25, 2011; April 29, 2011; May 6, 2011; May 13, 2011; May 17, 2011; May 18, 2011; May 19, 2011; May 24, 2011 and June 1, 2011.

This new drug application provides for the use of docetaxel Injection, 20 mg/2 mL, 80 mg/8 mL and 160 mg/16 mL in locally advanced or metastatic breast cancer, locally advanced or metastatic non-small cell lung cancer and hormone refractory metastatic prostate cancer, gastric adenocarcinoma and squamous cell carcinoma of the head and neck cancer.

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

Based on the stability data provided, an 18-month expiration dating period is granted for the drug product, when stored at the proposed conditions (between 2°C and 25°C).

**CONTENT OF LABELING**

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the enclosed labeling. 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.

### **CARTON AND IMMEDIATE CONTAINER LABELS**

We acknowledge your June 1, 2011, submission containing final printed carton and container labels.

### **PROPRIETARY NAME**

If you intend to have 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 a request for a proposed proprietary name review. (See the guidance for industry titled, “Contents of a Complete Submission for the Evaluation of Proprietary Names”, at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm075068.pdf> and “PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2008 through 2012”.)

### **REQUIRED PEDIATRIC ASSESSMENTS**

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

### **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.

### **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 Jamila Mwidau, RN, BSN, MPH, Regulatory Project Manager, at (301) 796-4989.

Sincerely,

*{See appended electronic signature page}*

Anthony J. Murgo, M.D.  
Acting Deputy Director  
Division of Drug Oncology Products  
Office of Oncology Drug Products  
Center for Drug Evaluation and Research

### **ENCLOSURES:**

Content of Labeling  
Carton and Container Labeling

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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ANTHONY J MURGO  
06/29/2011