



NDA 22234/S-010

## SUPPLEMENT APPROVAL

Hospira Inc.  
Attention: Maria Hinklin  
Associate Director, Global Regulatory Affairs, Pfizer Essential Health  
275 North Field Drive  
Lake Forest, IL 60045

Dear Ms. Hinklin:

Please refer to your Supplemental New Drug Application (sNDA) dated and received November 27, 2017, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Docetaxel Injection USP, 10mg/mL and 20 mg/mL.

This Prior Approval supplemental new drug application provides for labeling changes to the carton and immediate container labels for the drug product.

### APPROVAL & LABELING

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

### CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and immediate container labels that are identical to , as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (May 2015, Revision 3)*. For administrative purposes, designate this submission “**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 22234/S-010.**” Approval of this submission by FDA is not required before the labeling is used.

### 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 Adijat Abass-Fasuyi, Regulatory Business Process Manager, at (301) 796 - 3609.

Sincerely,

*{See appended electronic signature page}*

Ramesh Raghavachari, Ph.D.  
Chief, Branch I  
Division of Post-Marketing Activities I  
Office of Lifecycle Drug Products  
Office of Pharmaceutical Quality  
Center for Drug Evaluation and Research

Enclosure:  
Carton and Container Labeling



Ramesh  
Raghavachari

Digitally signed by Ramesh Raghavachari  
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