



**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration  
Silver Spring MD 20993

September 2, 2020

Sara W. Koblitz  
HYMAN, PHELPS & MCNAMARA, P.C.  
700 THIRTEENTH STREET, N.W. SUITE 1200  
WASHINGTON, DC 20005

Sent via email to: [SKoblitz@hpm.com](mailto:SKoblitz@hpm.com)

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting that FDA designate NDA 205934 listed in the Orange Book for Docetaxel Injection, 20mg/ml, 80mg/4ml, and 160mg/8ml, as both an RLD and a RS for purposes of submitting an Abbreviated New Drug Application (ANDA) for a generic version of the drug product was received in this office on 09/02/2020.

It was assigned docket number FDA-2020-P-1844. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter and in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Bigby  
Supervisory Administrative Proceedings Officer  
Dockets Management Staff  
FDA/Office of Operations (OO)