CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

205934Orig1s000

MEDICAL REVIEW(S)

Memo to the File:

Re: NDA 205934/0005 Filing Review

From: Genevieve A. Schechter, MD

NDA 205934 for a 505(b)(2) application for a docetaxel product which contains no alcohol in the formulation. No clinical information is included in this NDA application. There are no clinical issues. No filing list will be submitted by clinical review team. Clinical defers to the Product reviewer for filability of this application.

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.
/s/
GENEVIEVE A SCHECHTER 05/05/2015

Reference ID: 3748181