POLICY

OFFICE OF THE CENTER DIRECTOR

NDAs/BLAs: Using the 21st Century Review Process Desk Reference Guide[1]

Table of Contents

PURPOSE **1**
BACKGROUND **1**
POLICY **2**
RESPONSIBILITIES **2**
REFERENCES **2**
EFFECTIVE DATE **2**

PURPOSE

- This MAPP is intended to inform review staff in the Center for Drug Evaluation and Research (CDER) about the availability and use of the Desk Reference Guide during the 21st Century Review process for new drug applications/biologics license applications (NDAs/BLAs) and efficacy supplements.

BACKGROUND

- The 21st Century Review process was established in September 2008 to make the marketing/licensing application review process more organized and integrated. The 21st Century Review process is designed to allow sufficient time at the end of the process to be sure all concerns have been heard and addressed by the decision makers.

- The foundation of this process included the creation of standard instructions that are consistent with good review management practices and that review teams can use to manage their work. These instructions have been compiled into the Desk Reference Guide. The guide describes the activities that comprise the review process for NDAs, BLAs, and efficacy supplements. In addition to explaining the steps in the process, the guide outlines expectations for reviewer conduct and provides timelines in which the reviewer should

[1] To view the guide, click on the words *Desk Reference Guide* within this MAPP.

perform his or her review. The guide also includes suggestions for working in a team environment and with team leaders and regulatory project managers to complete a timely, high-quality review to support action.

- The objectives of the guide are to:

  – Describe the steps and expected timeline for the review process
  – Provide an information resource for both new and seasoned CDER staff members

POLICY

- The guide is considered the current review procedure for NDA/BLA and efficacy supplement review in accordance with the 21st Century Review process.

- The guide is available through the hyperlinks within this MAPP and/or through the desktop shortcut, and will be updated as needed.

RESPONSIBILITIES

- CDER review staff are responsible for following the procedures in the guide during NDA/BLA and efficacy supplement review.

- The Review Process Transformation Team is responsible for keeping the guide up to date.

REFERENCES

- Guidance for review staff and industry *Good Review Management Principles and Practices for PDUFA Products* (http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm065015.htm)

EFFECTIVE DATE

This MAPP is effective upon date of publication.