

Review Process Definitions in GDUFA II

- **Discipline Review Letter (DRL)** – communication of *at least the primary reviewer's thoughts* on the application
- **Discipline Review Date (DRD)** – tool for managers to use to provide reviewers clarity on when primary reviews are needed; controlled by the discipline (aka task date)
- **Mid-Review Date (MRD)** – date all discipline reviews should be turned over to the discipline Project Managers for inclusion in the DRL; controlled by the discipline
- **Mid-cycle Date (MCD)** – GDUFA II mid-point plus 1 month goal (priority ANDA 5 months & standard ANDA 6 months) for communicating the primary reviewer's thoughts to the applicant; controlled by the Commitment Letter (Regulatory Project Manager can adjust for unsolicited amendments)
- **Mid-review Cycle T-Con** – CDER initiated t-con with applicant to discuss review thoughts, needs, clarifications, etc.; coordinated by the Regulatory Project Manager and conducted by the MCD; for **Pre-ANDA...Complex Program meeting applications only**
- **Owner Due Date (ODD)** – date *all reviews* need to be **complete** to allow action letter (CR, AP, TA) issuance in advance of the GDUFA II goal; controlled by the owner:
 - For original ANDA – turned over to the Regulatory Project Manager (RPM)
 - For cross cutting Prior Approval Supplement (PAS) submissions – turned over to Regulatory Project Manager (RPM)
 - For labeling only PAS submissions – turned over to Labeling Project Manager (PM)
 - Quality only PAS submissions – turned over to the Office of Pharmaceutical Quality Regulatory Business Process Manager (RBPM)

9/18/17