Application Communications:
RBPM Communication with Industry Throughout the IQA Process

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Objectives

- Update on communication enhancements under GDUFA II
- Provide an overview of the ANDA assessment timeline and identify when communications may occur
- Highlight important points for communications with OPQ

Communication During the Assessment

What is New/Changed?

- Request for additional information will be communicated via either:
  - Information Request (IR) Letter
  - Discipline Review Letter (DRL)

- Multiple IRs and DRLs can be issued in one GDUFA cycle

Communication During the Assessment

What is New/Changed?

Information Request (IR) Letters

- IR letters can be issued by a discipline or a sub-discipline
- Primarily used to request additional information/clarification needed to continue the assessment
- Can be issued as early as once Filing is found acceptable
- Will include a requested response date
- May be communicated by letter, e-mail, or phone

Communication During the Assessment

What is New/Changed?

Discipline Review Letters (DRL)

- DRL is issued when all Quality sub-disciplines have substantially completed their assessments
- Represent preliminary findings by the discipline upon review of submitted information to date
- May or may not represent management level review

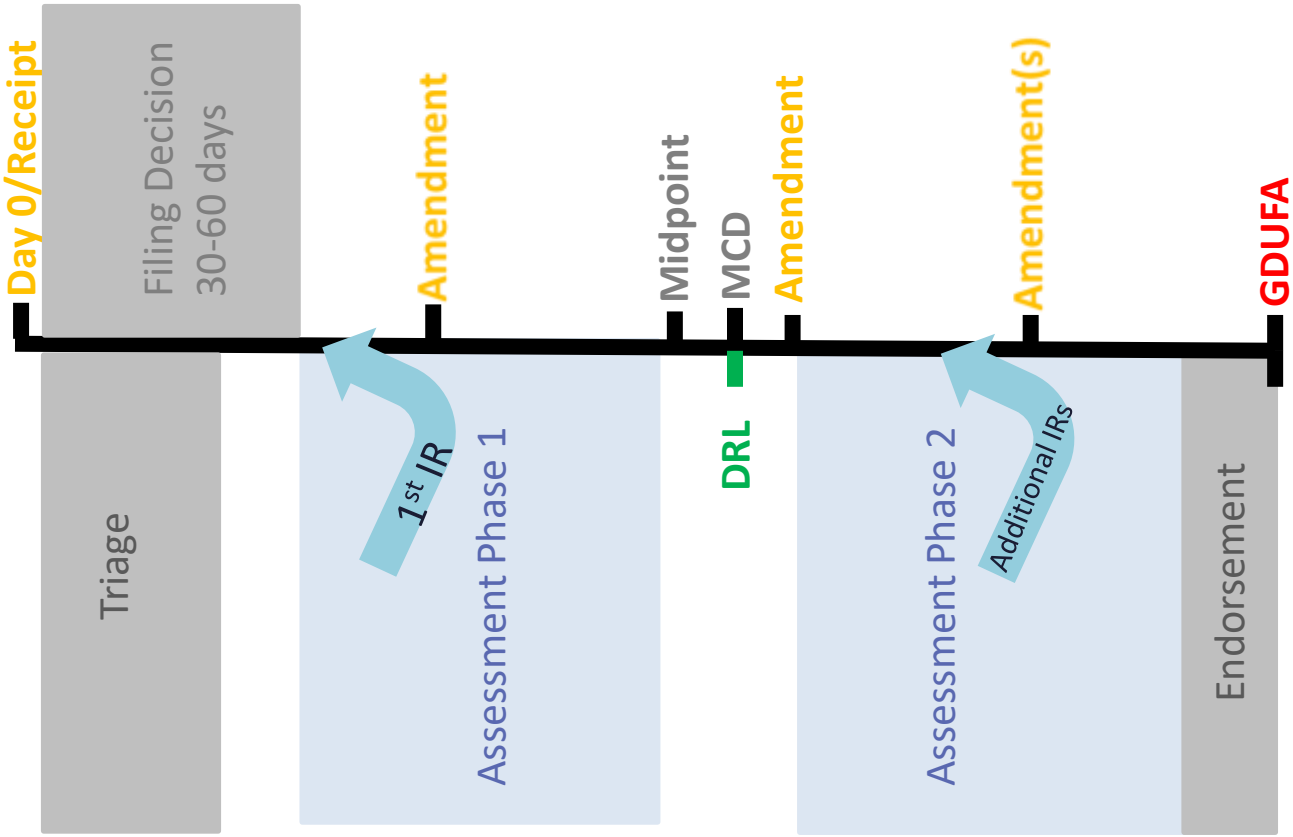
Communication During the Assessment

What is New/Changed?

Discipline Review Letters (DRL) *Cont'd*

- DRL is expected to be issued by mid-cycle date (MCD):
  - Standard 5 months + 30 days
  - Priority 4 months + 30 days
- Will include a requested response date
- May be communicated by letter, e-mail, or phone
- If no deficiencies are identified by the MCD, a No Comments DRL will be issued

GDUFA II Approach and Assessment Timeline



What is the Impact?

- Assessments of ANDAs will begin earlier in the assessment cycle
- Applicants will receive feedback on their application around the mid-point of the assessment period
- Applicants have an opportunity to resolve issues in the same assessment cycle
- The concept is to improve assessment efficiency and reduce assessment cycles (get generics faster to market)

What Can Industry Do to Assist?

- Submit high quality submissions at the start
- Respond to the IR and DRL promptly (date in letter)
- Don’t add unsolicited info in responses
- Learn from previous requests

Important Points to Consider

- Contact the RBPM for all questions related to Quality-only correspondences received
- Continue to use the OGD RPM as the point of contact for overall application status and other inquiries
- Be aware of the IR/DRL response deadlines
- Only respond to IRs/DRLs with requested information. Additional unsolicited information may impact assessment time and goal dates
- Correctly code all submissions and amendments to ensure accurate triage and goal dates are applied

Application Communications

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Roles and Responsibilities

OGD RPM

- Manages the entire ANDA
- Industry contact for all review status updates

Discipline PM

- Issues Discipline Review Letters (DRLs)/Information Requests (IRs)
- Industry contact for questions related to DRLs/IRs ONLY
- All other ANDA related-inquiries go the OGD RPM

GDUFA II Commitment Letter

- Review Status Update(II.B.10)
- Anticipated Missed Goal Date (II.B.9)
- Informal Notification of a MAJOR Deficiency (II.B.8)

Review Status Update(II.B.10)

GDUFA I:

- RPMs received many requests for status updates.
- RPMs provide updates to Industry
  - Check back in 3 months

GDUFA II:

- RPMs provide detailed status updates
- RPM touchpoints

Who is Responsible?

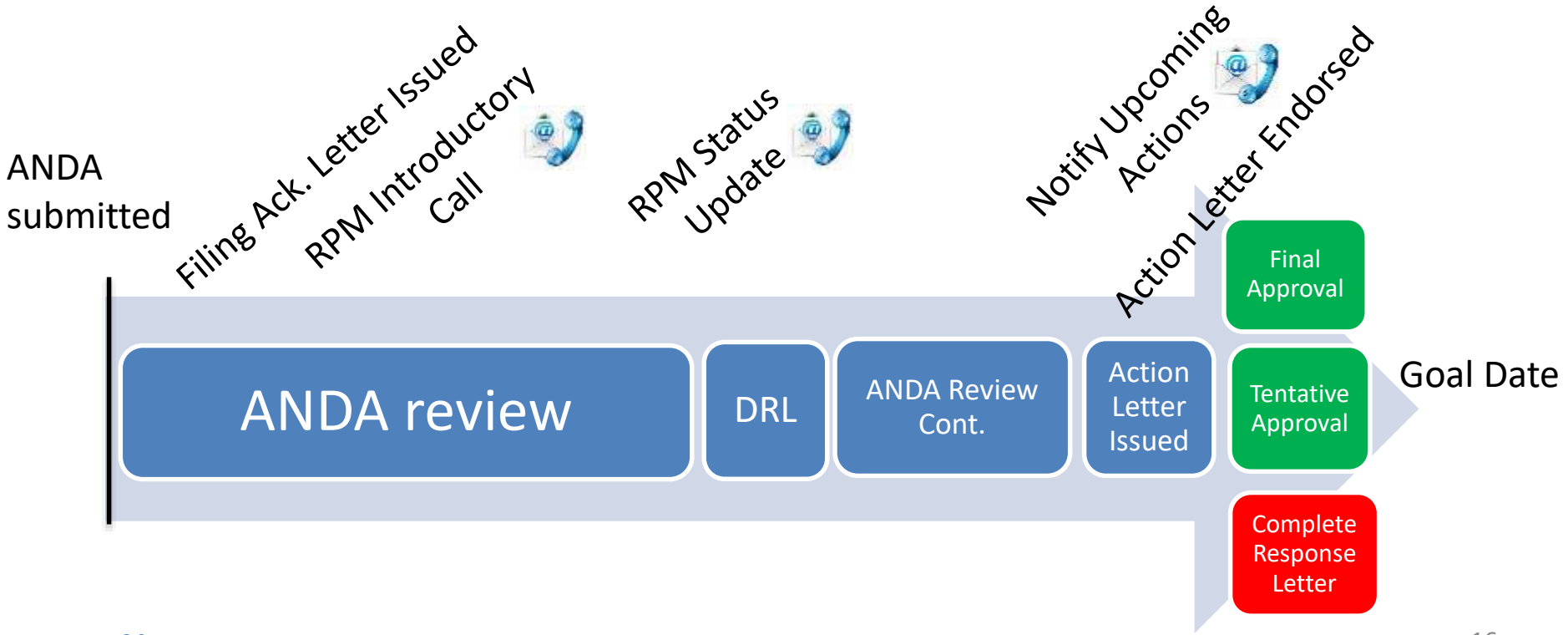
APPLICANT SIDE:

- Authorized representative's responsibility to request a status update
  - Point of contact identified on Form FDA 356h
  - Keep this updated

FDA/OGD SIDE:

- Regulatory Project Managers (RPMs) provide response to inquiry within 2 business days
- Response may be just an acknowledgement of your call while RPM obtains detailed information

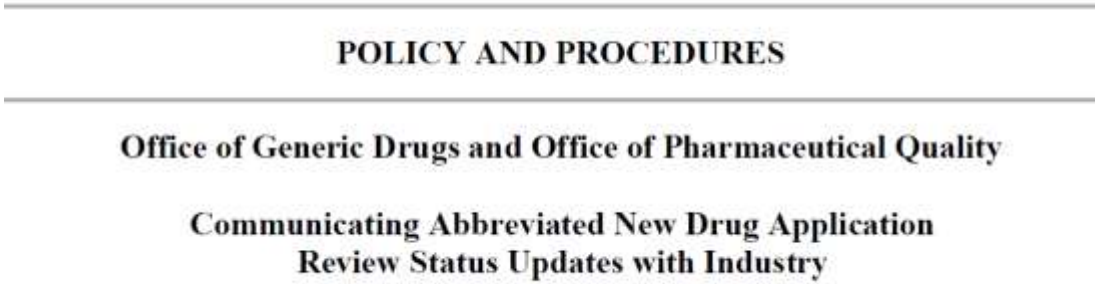
OGD RPM Touchpoints



Communications MAPP

- New MAPP issued on October 6, 2017 to reflect the GDUFA II Commitment Letter

MAPP 5200.12



POLICY AND PROCEDURES

Office of Generic Drugs and Office of Pharmaceutical Quality

Communicating Abbreviated New Drug Application
Review Status Updates with Industry

Tracking and Evaluations

- RPMs will log all communications
- Periodic communication evaluations
  - Status update requests do not impede the RPMs' workload or progress of other ANDA actions
  - Applicant requests are value-added

Anticipated Missed Goal Date (II.B.9)

- RPMs notify the Authorized Representative of the delay
- If Available, RPMs provide update
- If Available, RPMs provide estimated timeframe for completion

MAJOR Deficiency Notification (II.B.8)

- When Major deficiency has been preliminarily identified
  - RPMs notify the Authorized Representative that a major deficiency is likely forthcoming.

What Can Applicants Do to Assist?

- Please note the RPM touchpoints where you will be contacted regarding your ANDA
- If you need a status update outside of those touchpoints, please contact the RPM
  - We ask you do not excessively reach out to the RPM

Resources

- MAPP 5200.12, Communicating Abbreviated New Drug Application Review Status Updates with Industry
- If the assigned RPM is out of the office, reach out to the covering RPM or their Team Leader
- OGD Division of Project Management Org Chart
  - https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm119463.htm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