

# Review Status Updates

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# What is New or Changed?

Background:

GDUFA II Commitment Letter (II.B.10)

*The Authorized Representative may periodically request a Review Status Update. In response to the Authorized Representative's request, the RPM will timely provide a Review Status Update.*

# What is New or Changed? *Cont'd*

- Specific Status Updates added to GDUFA II Commitment Letter
  - During GDUFA I, RPMs received many requests for status updates.
  - We progressed from “check back in 3 months” to provide detailed updates
  
- Tracking, logging and reporting system for all communications with Applicant as part of GDUFA II

# What Does it Mean?

- The Communications MAPP has been updated based on the GDUFA II Commitment Letter

## MAPP 5200.3

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POLICY AND PROCEDURES

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Office of Generic Drugs and Office of Pharmaceutical Quality

Communications with Industry with respect to  
Abbreviated New Drug Applications

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# What is the Impact?

- GDUFA II has an organized process for updates

# Who is Responsible to do what for Status Updates?

## APPLICANT SIDE:

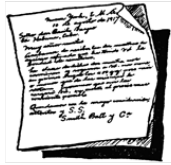
- Authorized representative's responsibility to request a status update
  - Point of contact identified on Form FDA 356h
  - Keep this updated

## FDA/OGD SIDE:

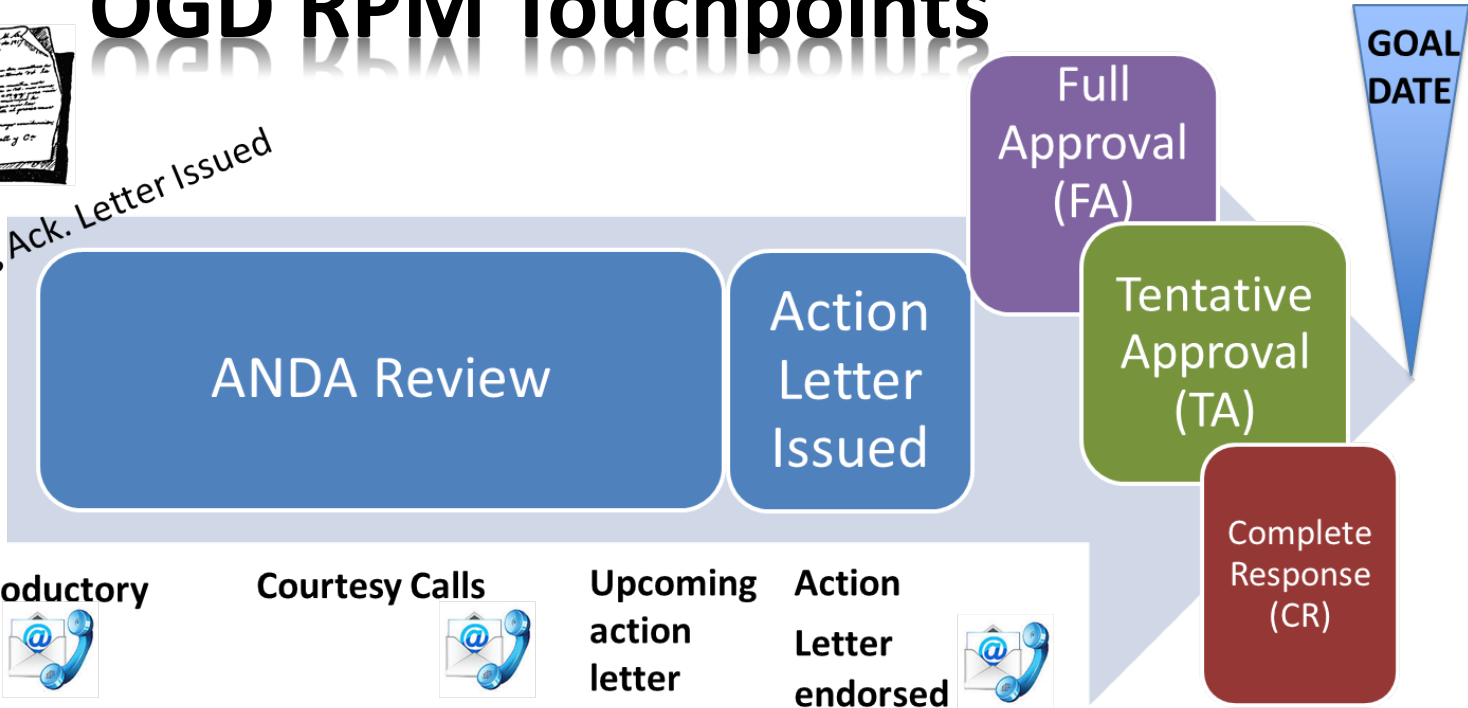
- Regulatory Project Managers (RPMs) to provide the response within 2 business days

# What Will The RPM's Do?

## OGD RPM Touchpoints



Filing Ack. Letter Issued



# What Will The RPM's Do?

## Other RPM Touchpoints

- Applicant Status Update requests
- Anticipate a missed Goal Date
- Informally notify applicant of a MAJOR deficiency
- Acknowledgement Letters



# How Will Status Updates be Evaluated?



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

# 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 5200.3, Communications with Industry with respect to Abbreviated New Drug Applications
- If the assigned RPM is out of the office, reach out to the covering RPM or their Team Leader

<https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM449543.pdf>

