RPM Communications Associated with the "Take Action" Process

(Complete Responses and Approvals)

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Poll Question

For the majority of your ANDAs, what month of review are you in currently?

Generic Drug User Fee Amendments of 2012

ANDA Submitted ✓

Filing Acknowledgement Letter (ACK Letter) ✓

Now what???

Source of Discussion…

1) **GDUFA 2012 Commitment Letter**

2) **Manual of Policy and Procedures - MAPP 5200.3 Rev. 1**
Communications with Industry with respect to pre-GDUFA Year Three Abbreviated New Drug Applications

To improve review efficiency and ensure consistency, the Office of Generic Drugs (OGD) issued MAPP 5200.3 in September 2013, stating that OGD Regulatory Project Managers (RPMs) should field all applicant inquiries concerning review status of submissions. ***Revised 08/17/15***

OGD RPM Touchpoints

Filing Ack. Letter

Review

Action Letter Issued

Full Approval (FA)

Tentative Approval (TA)

Complete Response (CR)

Month 2

TAD for pre-CY-3

Month 15 for CY-3

Month 10 for CY-3>

ANDA Triaging

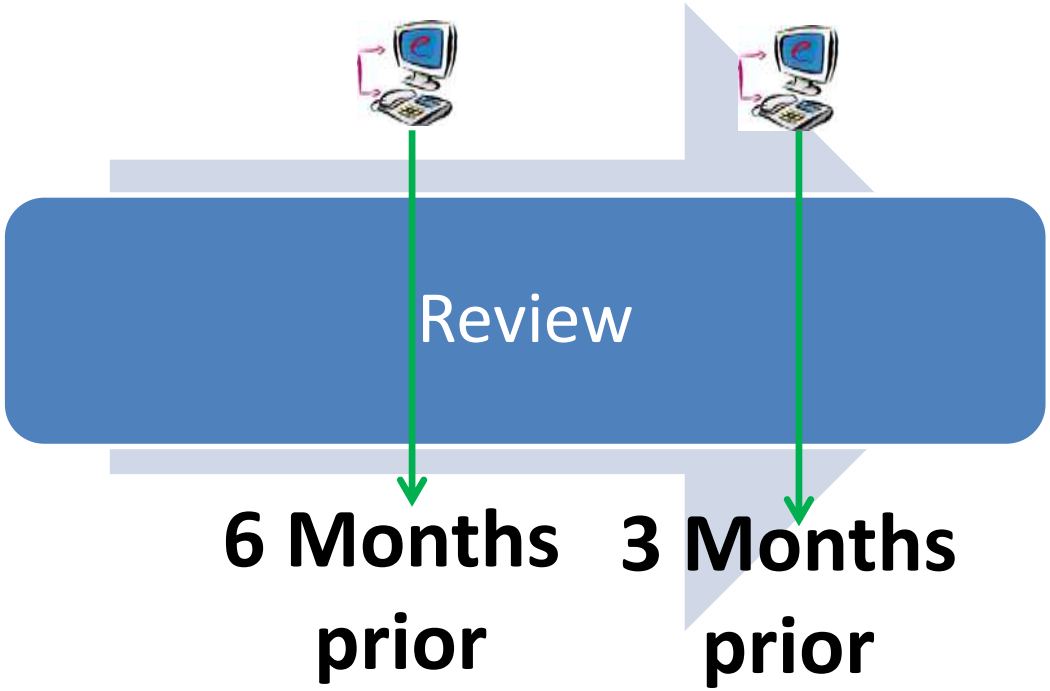
Filing Ack. Letter

Review

Month 2

- Division of Project Management (DPM) is notified
- Confirm disciplines are notified of acceptable ANDA
- RPM notes prioritization factors, REMS, policy factors or circumstances
- **Introductory Call / Email from the Regulatory Project Manager (RPM)**

During ANDA Review



- RPM ensures that disciplines are proceeding as planned
- Bi-weekly leadership high-level reviews → "On or Off track"
- **"Status update" 6 & 3 months prior to TAD / Goal Date**
- **Missed Goal Date call**

Action Package is Prepared

Action Letter Issued

2 – 4 weeks prior

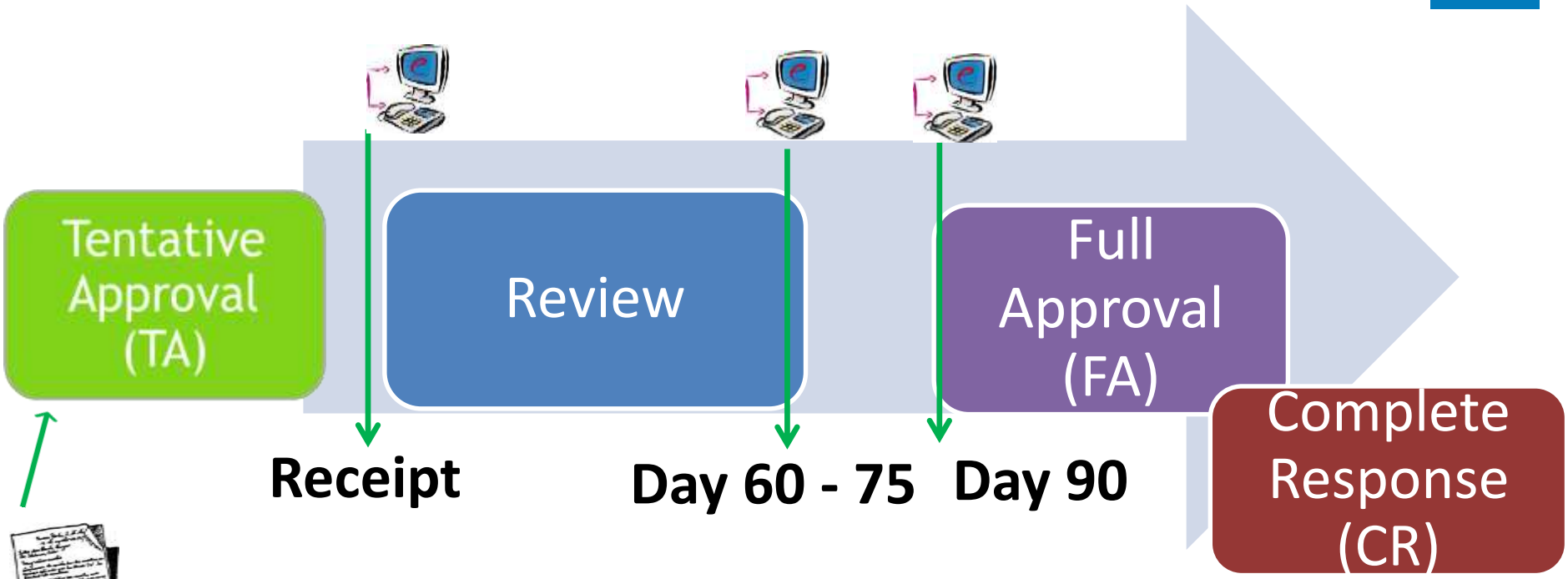
Once signed on/before TAD/Goal date

Full Approval (FA)

Tentative Approval (TA)

- Generate Approval package – review multiple to prep FA or TA letter
- Clearance phase – Policy and individual disciplines
- **Anticipated Action Letter call**
- Final Signature
- **Call & Courtesy Action Letter**

If Action Letter is a TA:



Request Final Approval 90 Days prior

- Review includes any updates, guidances, etc.
- Clearance phase – Policy and individual disciplines
- **Anticipated Action Letter call**
- Final Signature
- **Contacted when Approved & Courtesy Action Letter**

If Action Letter is a CR:

Action Letter Issued

Complete Response (CR)

Month 10, 15 or TAD

- RPM Generates Action package – multiple documents
- Clearance phase
- Final Signature
- **Courtesy Action Letter**

If CR, Cycle 2 review

CR Response

Review

Action Letter Issued

Full Approval (FA)

Tentative Approval (TA)

Complete Response (CR)

Month 1

TAD reset Notification
Goal Date Ack

Month 3-10

Watch Outs That Can Slow Actions…

- Quality of the submission – data structure & content
- 356h errors & secure e-mails
- Omissions of data requested in newly issued Draft Guidances
- Finalized Guidances

Watch Outs That Can Slow Actions…

- RLD Labeling updates
- Litigation outcomes
- Contacting disciplines unprompted throughout the review
- Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) Certifications

MMA /Patent recertification

CFR 314.96(d)

- Amendments submitted after December 5, 2016
- Final ruling on Abbreviated New Drug Applications and 505(b)(2) Applications; Final Rule, 81 FR 69580 (Oct. 6, 2016).

This rule revised 21 CFR 314.96(d), which concerns amendments to unapproved ANDAs. In part, the rule now requires an amendment to an unapproved ANDA to contain an appropriate patent certification or section viii statement described in 21 CFR 314.94(a)(12), or a recertification for a previously submitted paragraph IV certification, if approval is sought for changes described in any of the following types of amendments:

(i) To add a new indication or other condition of use;
(ii) To add a new strength;
(iii) To make other than minor changes in product formulation; or
(iv) To change the physical form or crystalline structure of the active ingredient.

If an amendment to an unapproved ANDA does not contain a patent certification or section viii statement, or a recertification, the applicant must verify that the proposed change described in the amendment is not one of the types of amendments described above.

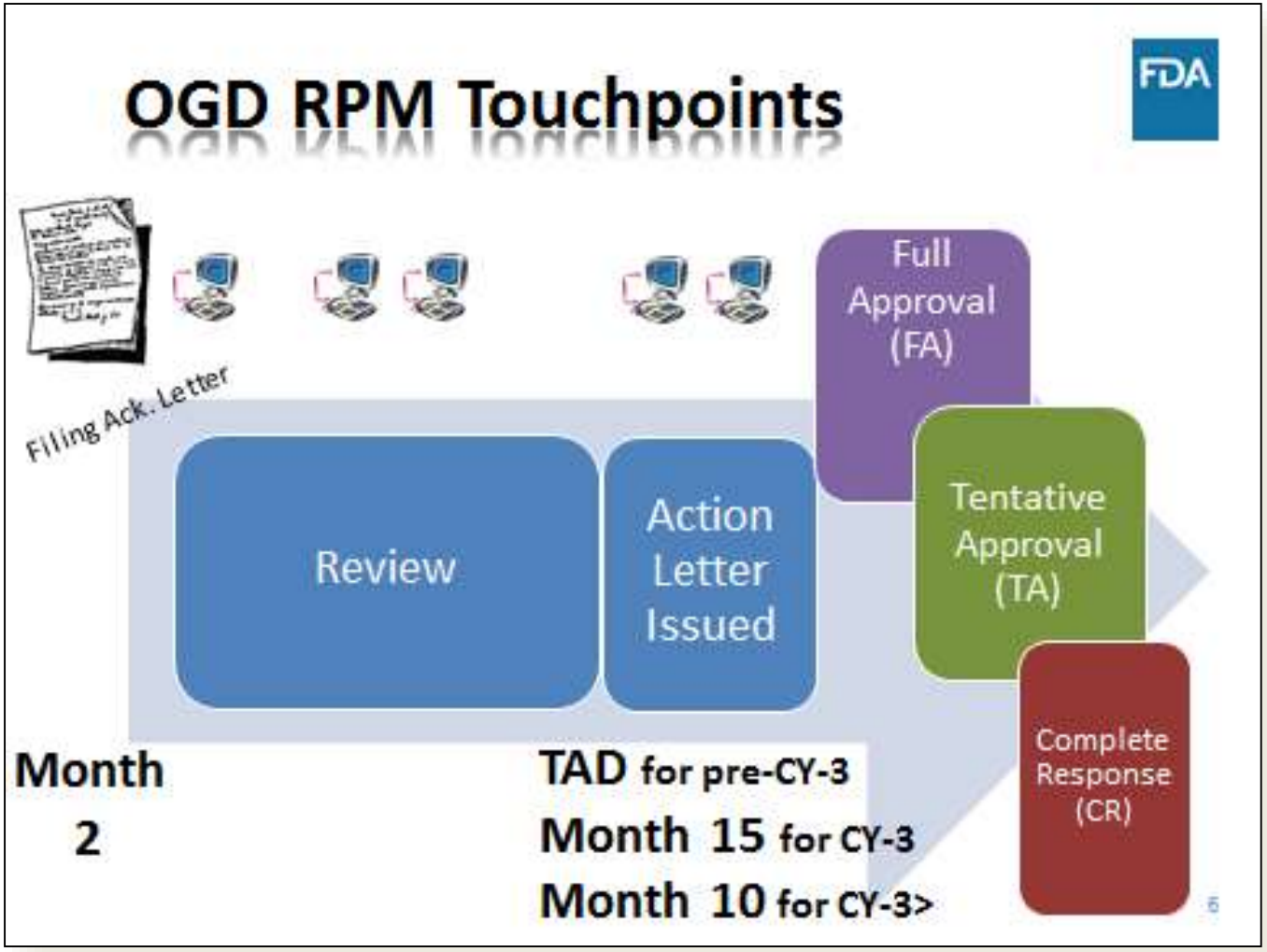
Other Helpful Tips…

- Division of Proj. Management = 45+ RPMs
  - Here to help answer questions and provide updates.
    - https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm119463.htm
- To ensure questions/comments are part of permanent record → Enroll your RPM
- Pre-Launch Activities Importation Requests (PLAIR)

  * https://www.fda.gov/downloads/drugs/guidances/ucm362177.pdf

  * Submit to: CDER-OC-PLAIR@fda.hhs.gov

In Summary…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Thank You!

Please complete the session survey:

surveymonkey.com/r/GDF-D2S03