Review Status Updates

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Commitment Letter Language

- Section [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.

Work Group Organization

- Chair: OGD, ORO
- Project Manager: OGD, ORO
- Informatics Lead: OGD, ORO
- Members: OGD, ORO; OPQ, OPRO; OGD, OGDP

What is New/Changed?

- 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?

- Communications MAPP has been issued based on 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

What is the Impact?

- GDUFA II has an organized process for status update requests

Who is Responsible?

Applicant

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

FDA/OGD

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

What Will The RPM Do?

OGD RPM Touchpoints

Filing Ack. Letter Issued

ANDA Review

Action Letter Issued

Full Approval (FA)

Tentative Approval (TA)

Complete Response (CR)

GOAL DATE

Introductory Call

Courtesy Calls

Upcoming action letter

Action Letter endorsed

What Will The RPM Do?
Other RPM Touchpoints

- Applicant Status Update requests
- Anticipate a missed Goal Date
- Informally notify applicant of a MAJOR deficiency
- Acknowledgement Letters
- Mid-review cycle meetings (if applicable)

What Should Industry Expect?

- RPM will contact the authorized representative regarding the ANDA at various touchpoints
- There will be more frequent and predictable communications between industry and the Agency regarding ANDA status
- RPM or an alternate (in case of absence) will respond to status update requests within 2 business days

What Can Industry Do to Assist?

- Familiarize yourself with 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
    - E.G., After the introductory touchpoint, there will be limited information available while the reviewers are beginning their review and before they issue Information Requests or Discipline Review Letters
    - E.G., Two weeks after a status update, unlikely that new information will be available

Tips for Industry

- Keep Authorized Representative on 356h updated
- Please reach out only to the assigned RPM for your ANDA for status updates or questions relating to your ANDA
- The RPM will route your inquiries to the appropriate discipline or sub-discipline, if needed
- Please contact your RPM if you have not heard from him/her in 3 months

Resources

- GDUFA II Commitment Letter
- MAPP 5200.12, Communicating Abbreviated New Drug Application Review Status Updates with Industry

  https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ManualofPoliciesProcedures/UCM579339.pdf

External Contact

DPM Organization Chart:

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

* If the assigned RPM is out of the office, reach out to the covering RPM or their Team Leader


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ADMINISTRATION