

Transparency Pilot for Enhanced Communications

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Learning Objectives

FDA

- Recognize historical background of status updates for Abbreviated New Drug Applications (ANDA) within OGD
- Provide overview of OGD's transparency pilot and enhanced communications
- Describe benefits of pilot and increased transparency
- Outline helpful hints beneficial to the communications process between applicants and Regulatory Project Managers (RPM)

History of ANDA status communications



History of ANDA status updates

- Occurred during open review cycle
- Emails and phone calls often applicant initiated
- Use of common phrases to describe discipline review status
- Missed goal dates and complex regulatory issues

History of ANDA status updates

- Timing is known/predictable
 - Provided an estimated completion date
- Timing is unknown/not predictable
 - Provided an estimated timing for additional update
 - Short term vs. long term

Steps to Increase Communication Transparency



- Per the GDUFA III Commitment Letter, section II.B.6.c:

“If an RPM learns that FDA is likely to miss the goal date for an ANDA, the RPM will notify the applicant of the delay in taking an action, identify the general reason for the delay including the outstanding discipline(s), if any, and the estimated time for FDA’s action on the application.”

Steps to Increase Communication Transparency



- Applicant centric process
 - Increased frequency, teleconferences, and management/leadership participation
- Enhanced language, where applicable, for pending and missed goal date ANDAs

Benefits of pilot and increased transparency of communications



- OGD's response to industry's growing requests for increased transparency
- Recognition of every ANDA, regardless of review status (e.g., missed goal date ANDAs)
- Increased frequency, content, and interaction, when applicable, at pre-scheduled intervals

Benefits of pilot and increased transparency of communications



- Seek to build and strengthen trust and collaboration
- Unified process across RPMs, supervisory RPMs, Team Leaders, and office leadership

Helpful Hints: What can applicants do to facilitate timely communications?



- Ensure accuracy of most recent 356h on file with the ANDA
 - Authorized U.S. Agent or Responsible Official
- Secure email required for all FDA informal communications containing commercial confidential information
- Microsoft Teams – platform for teleconferences

Challenge Question #1

Which of the following statements is NOT true?

- A. The Office of Generic Drugs transparency pilot was designed to further enhance collaborative, informative interactions between generic drug applicants and the Agency.
- B. There may be instances when RPMs cannot provide additional information regarding application status to U.S. Agents when such information is unknown or not predictable.
- C. Representatives or attorneys of a generic drug applicant may openly communicate with RPMs via email or phone regarding ANDA review status.
- D. The transparency pilot applies to ANDAs with a future goal date (pending action) as well as applications whose goal date was missed.

Challenge Question #2



For ANDAs whose goal date has passed (missed goal date), how frequently, on average, should applicants expect interaction from an RPM?

- A. 7 days
- B. 14 days
- C. 30 days
- D. Only after the applicant calls or emails

Final Thoughts

- OGD's communications transparency pilot is currently live
- Primary goal is to enhance applicant, RPM, and leadership collaboration within the generic drug review program
- Applicants are encouraged to speak to the RPM managing the ANDA to learn more about the transparency pilot
- To date, OGD has received positive feedback from applicants and will continue to strive to meet the pilot's objectives in the future



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Questions?

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