Best Practices and Strategies for Communicating with FDA

Robert Gaines, PharmD, MBA
Captain, US Public Health Service
Deputy Director, Office of Program and Regulatory Operations
CDER | US FDA

SBIA Generic Drug Forum – April 27, 2022

Learning Objectives

- Review OPQ communications during ANDA assessment cycle.
- Review best practices for communicating with OPQ.
- Provide resources to give additional details on the topics discussed.

OPQ Communications - POC

- Regulatory Business Process Manager (RBPM)
  - Primary point of contact (POC) for ALL OPQ-related communications internally and for industry
  - Works closely with OPQ assessment team and disciplines on your applications
  - Issues all communications related to the quality assessment during the assessment cycle

OPQ Communications - IR

- Information Request (IR) Letter
  - Further information/clarification needed to complete assessment throughout the assessment cycle
  - Single Quality sub-discipline or multiple Quality sub-disciplines
  - Requested response date
  - Communicated by letter, e-mail, or phone

OPQ Communications - DRL

- Discipline Review Letter (DRL)
  - Preliminary findings by the assessment team
    - May or may not represent management level assessment
  - Requested response date
  - Issued when Quality sub-disciplines have substantially completed assessments at around mid-point of the assessment cycle (Mid-Cycle Date)

Challenge Question #1

You've just received a Quality-related Information Request from OPQ. There is a comment that you are unclear about. Who should you contact first?

A. Dr. Mike Kopcha – Director, OPQ

B. Regulatory Project Manager (RPM, OGD)

C. Regulatory Business Process Manager (RBPM, OPQ)

D. Drug Product Assessor (OPQ)

Best Practices

Responding to IR/DRLs

- Responses to IR/DRLs should be complete and timely.
- Partial responses will not be accepted.
- Late responses may impact goal date or could be deferred until the next assessment cycle.
- Responses should only include information related to the IR/DRL. Additional/gratuitous information could impact timelines.

What if I need an extension to respond?

- Extension requests should be made as soon as possible by contacting the RBPM.
- The RBPM and assessment team will work together to determine if an extension will be granted.
- Your extension request should be done in a manner that provides you enough time to completely respond to the IR/DRL. Multiple extensions are not recommended.

Other Considerations

- Clearly outline all OPQ sub-disciplines impacted by the submission.
- Actively communicate with the Drug Master File (DMF) holder to anticipate submission timing.
- DMF submissions can impact that ANDA goal date.
- Ensure that ALL current facilities (including all relevant DMF facilities) and responsibilities are clearly listed on the 356h Form.

Other Considerations (cont.)

- Ensure that your cover letter for post-marketing submissions clearly indicate the type of change being submitted.
- For group supplements, be mindful of the implications of requesting changes to one application as it may impact all applications listed in the group.
- Ensure your e-mail is secure so communications can be timely. Request for secure e-mail can be sent to SecureEmail@fda.hhs.gov.

Challenge Question #2

Which of the following is true?

A. Sending partial responses to IR/DRLs has no impact on goal dates.

B. You do not need to communicate with the DMF holder after the application is acceptable for filing.

C. Facility responsibilities don't need to be on the 356h.

D. Having a secure email will ensure timely communication.

Summary

- Reach out to the RBPM for ALL Quality-related communications.
- Completely respond to all Quality IRs/DRLs by the requested response date.
- Be familiar with your ANDA assessment timeline and all possible communications.
- Reach out to the RBPM for ALL Quality-related communications.

Resources

- CDER Guidance Webpage: https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs
- GDUFA Webpage: https://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/default.htm
- Good ANDA Submission Practices Guidance for Industry: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/good-anda-submission-practices-guidance-industry
- CDER Small Business & Industry Assistance (SBIA): https://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/default.htm

Resources (cont.)

- Cover Letter Attachments for Controlled Correspondences and ANDA Submissions Draft Guidance for Industry : https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cover-letter-attachments-controlled-correspondences-and-anda-submissions-guidance-industry
- ANDA Submissions – Amendments and Requests for Final Approval to Tentatively Approved ANDAs Guidance for Industry: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/anda-submissions-amendments-and-requests-final-approval-tentatively-approved-andas

Resources (cont.)

- Guidance for Industry: Information Requests and Discipline Review Letters Under GDUFA
  - https://www.fda.gov/media/109915/download
- MAPP 5220.5: Issuance of Information Request and/or Discipline Review Letters for ANDAs
  - https://www.fda.gov/media/109649/download
- MAPP 5015.6: Review of Grouped Product Quality Supplements
  - https://www.fda.gov/media/72531/download

U.S. FOOD & DRUG ADMINISTRATION

Questions?

Robert Gaines, PharmD, MBA
Captain, US Public Health Service
Deputy Director, Office of Program and Regulatory Operations
CDER | US FDA

Robert.gaines@fda.hhs.gov


FDA
U.S. FOOD & DRUG
ADMINISTRATION