Communication with FDA: Best Practices

CDR Lana Rossiter, Ph.D.
Supervisor, Unit 6, DRBPM III
Office of Program and Regulatory Operations (OPRO)

OPQ | CDER | US FDA
Generics + Biosimilars Conference
November 2, 2026

OUTLINE

Best Practices for Cover Letters

Common Issues with submissions

Reminder: Grouped submissions

Communications and Inquires

Cover Letter Best Practices

- State all proposed changes in the entire submission (including all facility changes noted in module 3)
  - Using a bulleted list increases clarity
- Include filing category for each change (CBE-0, CBE-30 or PAS)
- Include the Drug Master File (DMF) number for all referenced DMFs
  - Reference the DMF amendment letter to the agency or submission date in the cover letter if submission is based on a specific DMF amendment
- If other pending submissions are pending or have been approved with the same/similar proposed change(s)- Include this information in the cover letter
- Cleary identify on first page:
  - Prioritization request
  - Grouped submission
  - If any Established Conditions are being added or changed

Common Issues Impacting Efficient Review

- Ambiguous Cover Letters- change to be implemented is not clear
- Errors with 356h form
  - Form is not the newest version
  - Missing facilities, combination products not indicated as such in box 24, other missing information
- Insufficient information submitted to eCTD modules
- Drug Substance manufacturing process changes – No Drug Product Manufacturer CoA included in submission
- Incorrectly Grouped Supplements
  - E.g.: different data needed for review of each submission, different dosage forms
- Postapproval Changes —Analytical Testing Laboratory Sites (PAC-ATLS) submissions:
  - Submission does not clearly state that all requirements listed in Guidance are met
  - Incorrect filing category for addition of analytical testing sites
- Submitting facility related change without verifying that facility is currently in acceptable status
- Responding to Complete Response (CR) letter containing facility deficiencies before verifying that issues have been resolved

Grouped Supplements

- Refer to MAPP 5015.6 Rev 1 – Office of Pharmaceutical Quality Review of Grouped Product Quality Supplements
- Identical CMC post-approval changes that affect multiple approved applications
  - Reviewed and processed as a group, one acknowledgement, one action letter
  - Improved efficiency for review
- Submit cover letter and module 3 information ***to each supplement within the group***
  - The cover letter for the supplements should clearly state the purpose of the proposed CMC changes and indicate that the supplement is one of multiple submissions for the same change
- **The supporting data necessary for the review of the CMC changes should be the same for each of the grouped supplements**
  - Any supplement that provides for the same CMC changes but necessitates the review of data that is unique to that supplement (e.g., product specific data) should not be grouped – However, should be mentioned in the cover letter

Supplement Acknowledgements

- New Process for CMC only CBE supplements:
  - FDA reviews and determines the categorization for the submission in line with Guidance
  - By day 30, RBPM issues the acknowledgement email to convey the categorization (CBE 0 or CBE 30), name and contact info for future inquires
    - Applicant will also be notified of decision that submission is not appropriate for a CBE and must be resubmitted as a PAS; a formal letter will be issued in these cases
  - Categorization of submission as a CBE 0/CBE 30 is equivalent to “granting” as CBE 0/CBE 30
  - If FDA evaluates and determines the proposed change(s) are annual reportable, an acknowledge and retain letter will be issued, closing out that supplement
  - If action is taken before day 30, the action letter will also serve as the acknowledgement
- Prior Approval Supplements, Acknowledgement Letter issued generally no later than day 30 from FDA receipt date
  - Goal date included in acknowledgement letter
- FDA POC listed in the acknowledgement email (CBEs) or letter (PAS)

SECURE EMAIL

- FDA communications via unsecure email cannot include commercial confidential information (e.g. application numbers or information, trade secrets, manufacturing, or patient information). Therefore, sponsors/applicants should establish secure email with FDA to allow for informal communications that may include commercial confidential information
- This applies to all applicants and DMF holders
- Unsecure email leads to communication delays
- If you have not already established secure email with the FDA and would like to set it up, send an email request to SecureEmail@fda.hhs.gov

Additional Post-Marketing Inquiries

- Controlled Correspondence Guidance
  - https://www.fda.gov/media/164111/download
  - Controlled Correspondences can be submitted to ask for clarifications after a Complete Response letter is issued
  - Can also be submitted for questions about other postmarketing activities, including future submissions
  - Submitted through the CDER Direct NextGen Collaboration Portal (the portal, https://edm.fda.gov).
  - Website for more info: https://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/ucm411122.htm#submitting_controlled
- ANDA Transfer of Ownership, Withdrawal and Consolidation are managed by the Office of Generic Drugs - genericdrugs@fda.hhs.gov
- CMC post-approval submission requirements which do not qualify as controlled correspondence and not covered under any of the CDER post-approval guidances: CDER-OPQ-Inquiries@fda.hhs.gov
- Labeling Supplements: - Druginfo@fda.hhs.gov.


FDA
U.S. FOOD & DRUG
ADMINISTRATION