CDER Small Business & Industry Assistance (SBIA) 2022 Generic Drugs Forum

Strategies for Communication with FDA

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Learning Objectives

- Address commonly seen issues
- Review best practices
- Provide tips for success
- Provide resources

Agenda

- Cover Letters
- Requests for Prioritization
- Tentative Approval to Final Approval
- Patent History
- Deferred Submissions

Purpose of Cover Letters

- To summarize contents of the submission
- To identify the purpose of the submission
- To highlight the key elements of the submission
- To provide required regulatory statements
- To help the FDA route and manage the submission effectively

Cover Letters (cont.)

1. Provide regulatory description of the submission, including appropriate regulatory information
2. Highlight significant elements of your submission in the beginning of your cover letter
3. Make sure all required components are included
4. Include all new or major changes or labeling updates in header/reference
5. Separate each item in its own paragraph

Cover Letters (cont.)

6. Be concise, especially if more detail is provided within other modules

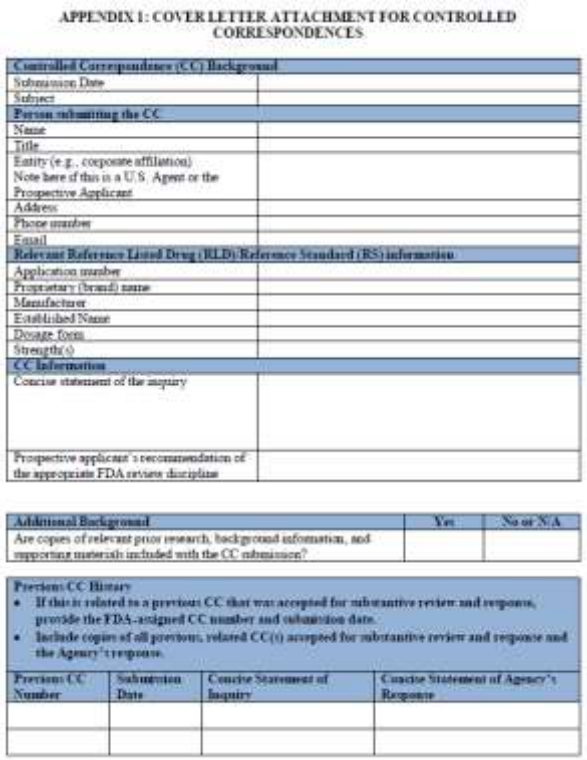
7. Use key words rather than vague and lengthy descriptions of content

8. Become familiar with the types of changes that can affect the review of your application and ensure those changes are always communicated on your cover letter

9. Bold the text of any administrative requests that are combined with data submitted for review

Cover Letters (cont.)

- Utilize cover letter attachment checklist found in [Cover Letter Attachments for Controlled Correspondences and ANDA Submissions Guidance for Industry : Draft Guidance for Industry]



APPENDIX 1: COVER LETTER ATTACHMENT FOR CONTROLLED CORRESPONDENCES

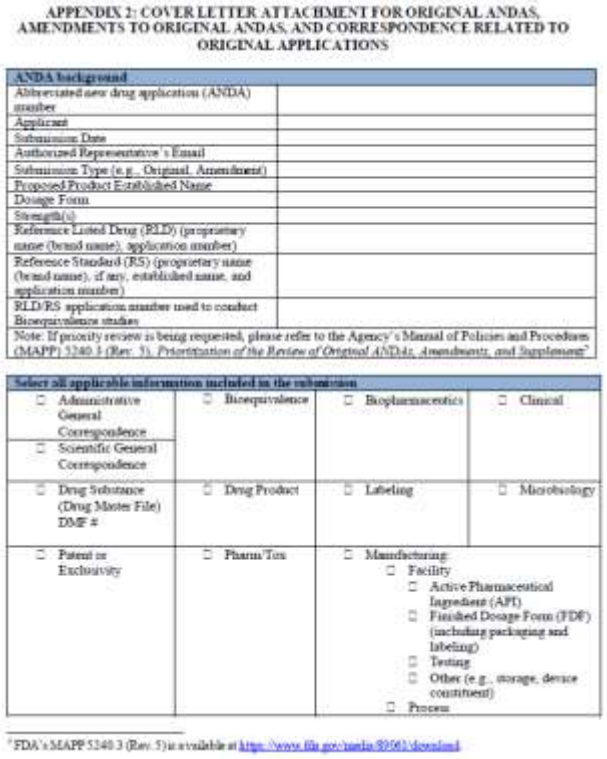
Controlled Correspondence (CC) Background	
Submission Date	
Subject	
Person submitting the CC	
Name	
Title	
Entity (e.g., corporate affiliation) Note here if this is a U.S. Agent or the Prospective Applicant	
Address	
Phone number	
Email	
Relevant Reference Listed Drug (RLD)/Reference Standard (RS) information	
Application number	
Proprietary (brand) name	
Manufacturer	
Established Name	
Dosage form	
Strength(s)	
CC Information	
Concise statement of the inquiry	
Prospective applicant's recommendation of the appropriate FDA review discipline	

Additional Background	Yes	No or N/A
Are copies of relevant prior research, background information, and supporting materials included with the CC submission?		

Previous CC History

- If this is related to a previous CC that was accepted for substantive review and response, provide the FDA-assigned CC number and submission date.
- Include copies of all previous, related CC(s) accepted for substantive review and response and the Agency's response.

Previous CC Number	Submission Date	Concise Statement of Inquiry	Concise Statement of Agency's Response



APPENDIX 2: COVER LETTER ATTACHMENT FOR ORIGINAL ANDAS, AMENDMENTS TO ORIGINAL ANDAS, AND CORRESPONDENCE RELATED TO ORIGINAL APPLICATIONS

ANDA background	
Abbreviated new drug application (ANDA) number	
Applicant	
Submission Date	
Authorized Representative's Email	
Submission Type (e.g., Original, Amendment)	
Proposed Product Established Name	
Dosage Form	
Strength(s)	
Reference Listed Drug (RLD) (proprietary name (brand name), application number)	
Reference Standard (RS) (proprietary name (brand name), if any, established name, and application number)	
RLD/RS application number used to conduct Bioequivalence studies	

Note: If priority review is being requested, please refer to the Agency's Manual of Policies and Procedures (MAPP) 5240.3 (Rev. 5), *Prioritization of the Review of Original ANDAs, Amendments, and Supplements*[*]

Select all applicable information included in the submission			
☐ Administrative General Correspondence	☐ Bioequivalence	☐ Biopharmaceutics	☐ Clinical
☐ Scientific General Correspondence			
☐ Drug Substance (Drug Master File) DMF #	☐ Drug Product	☐ Labeling	☐ Microbiology
☐ Patent or Exclusivity	☐ Pharm/Tox	☐ Manufacturing ☐ Facility ☐ Active Pharmaceutical Ingredient (API) ☐ Finished Dosage Form (FDF) (including packaging and labeling) ☐ Testing ☐ Other (e.g., storage, device constituent) ☐ Process	

[*] FDA's MAPP 5240.3 (Rev. 5) is available at https://www.fda.gov/media/89563/download.

Challenge Question 1

True or False: The FDA cover letter template provides information that is required for each submission.

A. True

B. False

Requests for Prioritization

- Explicitly request priority at the time of submission, to include the prioritization factor(s) for which the submission qualifies
- Request priority review with **each** submission
- Clearly state “Priority Review Requested” and reference the ANDA number in the cover letter to the submission
- Include sufficient supporting documentation for the request

Tentative Approval to Final Approval

- Clearly state “Request for final approval” in the cover letter and provide adequate documentation showing the application will be eligible for final approval at or before the goal date

- Clearly identify all new or major changes or labeling updates since tentative approval was granted

Tentative Approval to Final Approval

- Monitor for reference listed drug (RLD) updates, newly issued product specific guidance's (PSG), and unsolicited Drug Master File (DMF) amendments as these may cause a delay. If any questions arise, contact the Regulatory Project Manager (RPM)

- Utilize ANDA Submissions – Amendments and Requests for Final Approval to Tentatively Approved ANDAs: Guidance for Industry

Patent History

- Submit litigation information in a timely fashion
- Open communication with the RPM is strongly encouraged
- Creating a table that chronologically describes patent/exclusivity information is helpful and encouraged

Deferred Submissions

- FDA may defer assessment of an unsolicited amendment if the discipline assessments are close to completion and either:
  - The submitted amendment contains a significant amount of new information to be assessed
  - The amendment is submitted after the relevant assessments have been completed and while an IR, DRL, or CRL is being prepared
- Generally, amendments submitted during closed cycle will be reviewed upon receipt of Complete Response or request for final approval.
- If there is uncertainty regarding a submission during a closed cycle, contact the RPM for guidance

Challenge Question 2

All of following can cause a delay to the issuance of an action letter EXCEPT.

A. RLD updates

B. Newly issued PSG

C. Administrative amendment

D. Unsolicited DMF amendment

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

Concluding Remarks

- Submit high quality submissions
- Share information with RPMs and discipline PMs so they can help navigate the best path forward
- Let’s work together to approve more applications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