Cover Letter Attachments for Controlled Correspondence and ANDA Submissions

Guidance for Industry

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

June 2023
Generic Drugs

Cover Letter Attachments for Controlled Correspondence and ANDA Submissions

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Additional copies are available from:
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Center for Drug Evaluation and Research
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Email: druginfo@fda.hhs.gov
https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs

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Contains Nonbinding Recommendations

Cover Letter Attachments for Controlled Correspondence and ANDA Submissions Guidance for Industry[1]

This guidance represents the current thinking of the Food and Drug Administration (FDA or the Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA office responsible for this guidance as listed on the title page.

I. INTRODUCTION

This guidance is intended to assist prospective applicants, applicants, and holders of abbreviated new drug applications (ANDAs) with optional attachments that can be used when preparing cover letters that accompany controlled correspondence,[2] original ANDAs, amendments to ANDAs, and supplements to approved ANDAs submitted to FDA. These attachments do not replace the recommendations for the content of cover letters provided in other FDA guidances.[3]

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

The Generic Drug User Fee Amendments of 2012 (GDUFA I)[4] amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to authorize FDA to assess and collect user fees to provide the

[1] This guidance has been prepared by the Office of Generic Drugs in the Center for Drug Evaluation and Research at the Food and Drug Administration.

[2] *Controlled correspondence* is correspondence submitted to the Agency, by or on behalf of a generic drug manufacturer or related industry, requesting information on a specific element of generic drug product development. See GDUFA Reauthorization Performance Goals and Program Enhancements fiscal years (FYs) 2023-2027 commitment letter (GDUFA III Commitment Letter), available at https://www.fda.gov/media/153631/download. See also the guidance for industry *Controlled Correspondence Related to Generic Drug Development* (December 2020). We update guidance periodically. For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

[3] Recommended content of cover letters (or first page of submission) is provided in the following guidances for industry: *Controlled Correspondence Related to Generic Drug Development* (December 2020); *ANDA Submissions—Content and Format* (June 2019); *ANDA Submissions—Amendments to Abbreviated New Drug Applications Under GDUFA* (July 2018); and *ANDA Submissions—Prior Approval Supplements Under GDUFA* (October 2017).

[4] Generic Drug User Fee Amendments of 2012, Title III of the Food and Drug Administration Safety and Innovation Act (Public Law 112-144, Title III).

Agency with resources[5] to help ensure patients have access to quality, affordable, safe, and effective generic drugs. GDUFA fee resources bring greater predictability and timeliness to the review of generic drug applications. GDUFA has been reauthorized every 5 years to continue FDA's ability to assess and collect GDUFA fees, and this user fee program has been reauthorized two times since GDUFA I, most recently in the Continuing Appropriations and Ukraine Supplemental Appropriations Act, 2023.[6] As described in the GDUFA III commitment letter applicable to this latest reauthorization,[7] FDA has agreed to performance goals and program enhancements regarding aspects of the generic drug assessment program that build on previous authorizations of GDUFA. New enhancements to the program are designed to maximize the efficiency and utility of each assessment cycle, with the intent of reducing the number of assessment cycles for ANDAs and facilitating timely access to generic medicines for American patients.

The enhancements described in the GDUFA III commitment letter include expansion of the types of correspondence that can be submitted as controlled correspondence,[8] as well as other submission and communication enhancements designed to improve the efficiency of ANDA assessment. The recommendations in this guidance are intended to aid applicants in preparing cover letters for controlled correspondence and common ANDA submissions to help ensure these cover letters include pertinent information to aid FDA's assessment of the submission. A cover letter is generally included with controlled correspondence to the Office of Generic Drugs (OGD) and submissions to an ANDA file. While a cover letter is not required content for an ANDA, the cover letter is a part of the electronic common technical document (eCTD) hierarchy and is included in Module 1 of an ANDA submission.[9]

The cover letter provides an overview of the submission and helps FDA ensure that the submission is properly triaged and assigned to the appropriate assessors. In an effort to ensure that submissions are effectively managed by FDA and acted upon within the performance review goal dates agreed to in the GDUFA III commitment letter, FDA has developed cover letter attachments to accompany, not replace, the applicant's[10] cover letter for the following common submissions: controlled correspondence, original ANDAs and amendments to ANDAs, and supplements to approved ANDAs. Use of the cover letter attachments contained in the appendices of this guidance is voluntary, and the absence of a cover letter attachment in a submission would not be a basis for a submission to be considered deficient or for a refuse-to-receive (RTR) determination.

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[5] User fees are available for obligation in accordance with appropriations acts.
[6] See Division F, Title III of the Continuing Appropriations and Ukraine Supplemental Appropriations Act, 2023 (Public Law 117-180).
[7] The GDUFA III commitment letter, available at https://www.fda.gov/media/153631/download.
[8] See GDUFA III commitment letter at 11.
[9] See *The Comprehensive Table of Contents Headings and Hierarchy*, available at https://www.fda.gov/media/76444/download.
[10] Use of the term *applicant* in this guidance includes prospective ANDA applicants, ANDA applicants, and ANDA holders.

III. USING THE COVER LETTER ATTACHMENTS

The cover letter attachments provided in this guidance have been developed by the divisions that receive and respond to controlled correspondence and that assess ANDAs (including amendments and supplements). The cover letter attachments have been designed as a checklist to reflect common types of information applicants are expected to address in the cover letter for their submission. Please note that these checklists are not an exhaustive list of the information needed from applicants for a particular submission. There may be additional items that need to be submitted with a particular submission; for example, information related to patents and exclusivities may need to be submitted with some ANDA submissions.

Prospective ANDA applicants, ANDA applicants, and ANDA holders may complete and submit the appropriate attachment(s) along with their cover letter. Applicants are not required to submit an attachment with their cover letter; however, the optional cover letter attachment can be a useful guide to help applicants prepare their cover letters, particularly in situations covered in Appendices 2 and 3. The format of the cover letter attachment may be adapted by the applicant for their convenience. The main purpose of the cover letter attachment is to help applicants ensure that they are addressing relevant information in any cover letter submitted to FDA for the submissions covered in this guidance. Completing a relevant checklist and attaching it to the cover letter submission is helpful to FDA in the triage of applications and management of submissions.

The cover letter attachment provided in Appendix 1 of this guidance is intended for use with controlled correspondence submitted to OGD. The cover letter attachment provided in Appendix 2 of this guidance is intended for original ANDA submissions, amendments to original ANDAs, and any general correspondence associated with that original ANDA. The cover letter attachment provided in Appendix 3 of this guidance is for supplements to approved ANDAs, amendments to pending supplements, submissions to tentatively approved ANDAs under the President's Emergency Plan for AIDS Relief (PEPFAR) program,[11] and any general correspondence related to these submissions.

[11] Under PEPFAR, certain antiretroviral products that have been granted a tentative approval may be distributed for use outside of the United States, even when there is still patent and/or exclusivity protection in the United States. See FDA's PEPFAR web page, available at https://www.fda.gov/international-programs/presidents-emergency-plan-aids-relief-pepfar.

APPENDIX 1: COVER LETTER ATTACHMENT FOR CONTROLLED CORRESPONDENCE

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, Prospective Applicant, or 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	
Applicant or 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?		

Drug-Device Combination Product	**Yes**	**No or N/A**
Is the product or proposed product a drug-device combination product? Note: If this is a combination product, mark the corresponding box to identify it as such on line #24 of the FDA Form 356h.		

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

Related Submissions

- **If this is related to a submitted abbreviated new drug application (ANDA) or a pre-assigned ANDA, provide the information below.**

ANDA Number	Submission Date	Submission Status

Previous Meeting and PSG Teleconference (TCon) History • **If this is related to a previous meeting and/or PSG TCon, provide the assigned ANDA number, meeting type, and meeting date.** • **Include copies of all previous, related meeting and PSG TCon requests and the Agency's response(s).**		
ANDA Number	**Meeting Type**	**Meeting Date**

List of attachments provided:

1.
2.
3.

APPENDIX 2: COVER LETTER ATTACHMENT FOR ORIGINAL ANDAS, AMENDMENTS TO ORIGINAL ANDAS, AND GENERAL CORRESPONDENCE RELATED TO ORIGINAL APPLICATIONS[12]

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. 6), *Prioritization of the Review of Original ANDAs, Amendments, and Supplements*[13]	

[12] Note that there may be multiple submissions falling under this particular category related to a particular ANDA. Applicants should utilize the checklist for each specific submission and only include information relevant to the current submission, not previous submissions.

[13] The cover letter should clearly state "Priority Review Requested"; reference the ANDA number; provide the basis for the request, including the prioritization factor(s); and include sufficient supporting documentation for the request. For additional information, see FDA's MAPP 5240.3 (Rev. 6), available at https://www.fda.gov/media/89061/download.

<table>
<tr><th colspan="4">Select all applicable information included in the submission</th></tr>
<tr><td>☐ Administrative General Correspondence[14]
☐ Scientific General Correspondence[15]</td><td>☐ Bioequivalence</td><td>☐ Biopharmaceutics</td><td>☐ Clinical</td></tr>
<tr><td>☐ Drug Substance
(Drug Master File) DMF #: _____</td><td>☐ Drug Product</td><td>☐ Labeling
☐ Carve-out[16]
☐ Patent (Section viii statement)
☐ Exclusivity
☐ Dosage Form</td><td>☐ Microbiology</td></tr>
<tr><td>☐ Patent or Exclusivity
☐ Request for Reconsideration</td><td>☐ Pharm/Tox</td><td colspan="2">☐ Manufacturing:
☐ Facility
☐ Active Pharmaceutical Ingredient (API)
☐ Finished Dosage Form (FDF) (including packaging and labeling)
☐ Testing
☐ Other (e.g., storage, device constituent)
☐ Ready for Inspection[17]
☐ Process</td></tr>
<tr><td colspan="2">☐ Facility-Based Major CRL Amendment Request for Reclassification</td><td colspan="2"></td></tr>
</table>

[14] An *administrative general correspondence* is a general correspondence to FDA that does not include information required for review of the ANDA. For example, it may include a change in the point of contact, applicant address, etc.

[15] A *scientific general correspondence* is a general correspondence from an applicant to FDA requesting scientific advice after a complete response letter has been issued by the Agency.

[16] Labeling carve-outs should be prominently identified (e.g., bolded) in the cover letter for these types of submissions.

[17] FDA recommends that applicants state in their cover letters "**Facility Ready For Inspection**" along with the ANDA number, if applicable.

Additional background	**Yes**	**No or N/A**
1. Is the email secure? If no, apply for a secure email with the FDA by contacting secureemail@fda.hhs.gov		
2. Was a Pre-Submission Facility Correspondence (PFC) submitted?		
3. If a PFC was submitted, have any significant changes been made to the pre-submitted facility information?		
4. Does the submission contain any technology that has been accepted into or may qualify for the Emerging Technology Program[18]?		
5. For all submissions: Was a Competitive Generic Therapy (CGT) designation granted for a drug product or drug products under this ANDA?		
6. For original ANDAs: Is a CGT designation request being made concurrently with the original ANDA submission? If yes, please refer to the guidance for industry *Competitive Generic Therapies* (March 2020) for additional information on what to include in the cover letter.[19]		
Drug-device combination product	**Yes**	**No or N/A**
7. Is the proposed product a drug-device combination product? If yes, answer questions #8 and #9. Note: If this is a combination product, mark the corresponding box to identify it as such on line #24 of the FDA Form 356h.		
8. Does the submission include comparative analyses for a drug-device combination product? If yes, then specify location in the submission: _____		
9. Does the submission include additional data and/or information, such as data from a comparative use human factors study, to support differences in user interface? If yes, then specify location(s) in the submission: _____:_____:_____		

[18] See the guidance for industry *Advancement of Emerging Technology Applications for Pharmaceutical Innovation and Modernization* (September 2017).

[19] This guidance recommends including a statement supporting the request for designation and information supporting the assertion that there is inadequate generic competition for the drug product under section 506H of the FD&C Act (21 U.S.C. 356h).

Study Information	Yes	No or N/A
10. Does the submission include an alternate method for demonstrating bioequivalence (BE) (e.g., modeling, in vitro testing) that deviates from the current recommendations in a Product-Specific Guidance?		
11. Does the submission include a request for a waiver under 21 CFR 320.22? If yes and referencing a BE study submitted under a different application, then include the original BE study's ANDA number, submission date, and the module for the BE study referenced in support of the waiver request in the current submission: _____		
12. Are there any additional data and/or information from comparative studies (e.g., in vitro studies, failed BE studies) included in other modules besides module 5? If yes, then specify study type and location in the submission: _____ _____		
13. Does the submission include a Pharmacology/Toxicology (safety) justification, for example, nonclinical studies as defined in 21 CFR 58.3(d)? If yes, then specify justification/study type and location in the submission: _____		

Proposed product development history

- **For original ANDAs: ensure that copies of all related pre-ANDA communications accepted for substantive review and the Agency's response (e.g., controlled correspondence, pre-ANDA meeting written responses) are included in your submission**
- **For subsequent amendments: only include updates or new information since last submission, as applicable**

Complete this section to document any prior FDA communications for this ANDA, as appropriate	Yes	No or N/A
1. Controlled correspondence(s) If yes, include #(s) and date(s): _____		
2. Protocol review(s) If yes, include #(s) and date(s): _____		
3. Bio-investigational new drug (Bio-IND) protocol review(s) If yes, include #(s) and date(s): _____		
4. Approved suitability petition for the basis of submission, as per 21 CFR 314.94(a)(3)(iii)		

If yes, include docket number and a copy of FDA's correspondence approving the petition: _____		
5. Approved citizen petition requesting a specific basis of submission[20] If yes, include docket number: _____		
6. Pre-ANDA meeting(s) If yes, include #(s) and date(s): _____		
7. Scientific General Correspondence(s) after complete response letter (CRL) response (for amendments only) If yes, include #(s) and date(s): _____		
8. Device related communication(s) (for drug-device combination product only) If yes, include #(s) and date(s): _____		

For Amendments Only			
Type of amendment	**Date of FDA correspondence or action that elicited the amendment (e.g., CRL, discipline review letter (DRL), information request (IR), or tentative approval (TA)**	**Is this a response to a CRL?**	
		Yes	**No or N/A**
Unsolicited			
Solicited			
Post-TA amendment			
Post-TA Request for Final Approval			
Request For Reconsideration (RFR)			
Facility-Based Major CRL Amendment to Minor Reclassification Request			

Patent Certification/Statement	**Yes**	**No[21]**
1. Does the submission contain any of the following changes? (i) To add a new indication or other condition of use; (ii) To add a new strength; (iii) To make other than minor changes in product formulation; or		

[20] See section III.C.3 in FDA's guidance for industry *Referencing Approved Drug Products in ANDA Submissions* (October 2020).

[21] "N/A" does not apply for Patent Certification/Statement. Under 21 CFR 314.96(d), an amendment to an unapproved ANDA must contain either (1) an appropriate patent certification or statement (or recertification), or (2) a verification that the proposed changes described in the amendment is not one of the types of amendments described in 21 CFR 314.96(d)(1).

(iv) To change the physical form or crystalline structure of the active ingredient If yes, please address this according to 21 CFR 314.96(d)(1) If no, please provide a statement according to 21 CFR 314.96(d)(2) within the cover letter		
Does the amendment submission include any of the following?	**Yes**	**No or N/A**
2. New strength (including new fill volume for parenteral products)		
3. Modified formulation		
4. New batch		
5. Specification change(s)		
6. New container closure system		
7. Active Pharmaceutical Ingredient (API) source change If yes, then include Drug Master File (DMF) #: _____		
8. Changes or additions to the manufacturing/quality facilities?		
9. For a request for final approval, is new data being submitted?		
10. New bioequivalence (BE) study/studies If yes, then specify the following for each new BE study: a. Select study type: in vivo or in vitro, including failed study b. Study number: _____ c. Study site (clinical, analytical, in vitro testing) Name and address: _____ d. Location of new BE study in the submission: _____		
11. Updated labeling due to a new or revised patent or exclusivity currently listed in the Orange Book[22]		

[22] The publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the Orange Book) identifies drug products approved on the basis of safety and effectiveness by FDA under the FD&C Act and related patent and exclusivity information. For more information on the Orange Book, see the Agency's web page https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book.

APPENDIX 3: COVER LETTER ATTACHMENT FOR SUPPLEMENTS TO APPROVED ANDAS, AMENDMENTS TO PENDING SUPPLEMENTS, AMENDMENTS TO TENTATIVELY APPROVED PEPFAR ANDAS, AND GENERAL CORRESPONDENCE RELATED TO THESE SUBMISSIONS[23]

ANDA Background	
Abbreviated new drug application (ANDA) number	
Applicant	
Submission Date	
Email	
Established Name	
Dosage Form	
Strength(s)	
Reference Listed Drug (RLD) (proprietary name (brand name) and application number)	
Reference Standard (RS) (proprietary name (brand name), if any, established name, and application number)	
If priority review is being requested, please refer to FDA's Manual of Policies and Procedures (MAPP) 5240.3 (Rev. 6), *Prioritization of the Review of Original ANDAs, Amendments, and Supplements*[24]	

Select all applicable information included in the submission			
☐ Administrative General Correspondence[25]	☐ Bioequivalence	☐ Biopharmaceutics	☐ Clinical
☐ Scientific General Correspondence[26]			

[23] Note that there may be multiple submissions falling under this particular category related to a particular ANDA. Applicants should utilize the checklist for each specific submission and only include information relevant to a particular application, not previous submissions.

[24] The cover letter should clearly state "Priority Review Requested"; reference the ANDA number; provide the basis for the request, including the prioritization factor(s); and include sufficient supporting documentation for the request. For additional information, see FDA's MAPP 5240.3 (Rev. 6), available at https://www.fda.gov/media/89061/download.

[25] An *administrative general correspondence* is a general correspondence to FDA that does not include information required for review of the ANDA. For example, it may include a change in the point of contact, applicant address, etc.

[26] A *scientific general correspondence* is a general correspondence from an applicant to FDA requesting scientific advice after a complete response letter has been issued by the Agency.

<table>
<tr><td>☐ Drug Substance
DMF #:
_____</td><td>☐ Drug Product</td><td>☐ Labeling
☐ Carve-out[27]
☐ Patent (Section viii statement)
☐ Exclusivity
☐ Dosage Form</td><td>☐ Microbiology</td></tr>
<tr><td>☐ Patent or Exclusivity</td><td rowspan="2">☐ Pharm/Tox</td><td colspan="2" rowspan="2">☐ Manufacturing:
☐ Facility
☐ Active Pharmaceutical Ingredient (API)
☐ Finished Dosage Form (FDF) (including packaging/labeling)
☐ Testing
☐ Other (e.g., storage warehouse, device constituent parts)
☐ Ready for Inspection[28]
☐ Process</td></tr>
<tr><td>☐ Request for Reconsideration</td></tr>
<tr><td colspan="2">☐ Facility-Based Major CRL Amendment Request for Reclassification</td><td colspan="2"></td></tr>
<tr><td colspan="4">☐ Notice of Commercial Marketing</td></tr>
</table>

[27] Labeling carve-outs should be prominently identified (e.g., bolded) in the cover letter for these types of supplements and amendments.

[28] FDA recommends that applicants state in their cover letters "**Facility Ready For Inspection**" along with the ANDA number, if applicable.

Additional Background	**Yes**	**No or N/A**
1. Is the email secure? If no, apply for a secure email with the FDA by contacting secureemail@fda.hhs.gov.		
2. Was a Pre-Submission Facility Correspondence (PFC) submitted?		
3. If a PFC was submitted, have any significant changes been made to the pre-submitted facility information?		
4. Does the submission contain any technology that has been accepted into or may qualify for the Emerging Technology Program[29]?		
Drug-device combination product	**Yes**	**No or N/A**
5. Is the proposed product a drug-device combination product? If yes, answer questions #6 through #9.		
6. Does the supplement propose a change to the drug-device combination product that may impact quality or labeling?		
7. Does the supplement propose a change to the drug-device combination product that may impact the user interface?		
8. Does the submission include comparative analyses for a drug-device combination product? If yes, then specify location in the submission: _____		
9. Does the submission include additional data and/or information, such as data from a comparative use human factors study, to support differences in user interface? If yes, then specify location(s) in the submission: _____		
Does the submission (supplement or amendment to the supplement) include any of the following?	**Yes**	**No or N/A**
10. New strength (including new fill volume for parenteral products)		
11. Modified formulation		
12. Specification change(s)		
13. New container closure system		

[29] See the guidance for industry *Advancement of Emerging Technology Applications for Pharmaceutical Innovation and Modernization* (September 2017).

14. Request for a Prescription (Rx) to over-the-counter (OTC) switch		
15. A reactivation/reintroduction request as noted in MAPP 5200.7 (Rev. 1)[30]		
16. Revised and/or new patent certification and/or exclusivity statement		
17. Updated labeling due to a new or revised patent or exclusivity currently listed in the Orange Book		
18. A new facility that has never been inspected for similar operations to those proposed in the supplement		
19. Removal of a facility		
20. Active Pharmaceutical Ingredient (API) source change If yes, then include Drug Master File (DMF) #: _____		
21. A Pharmacology/Toxicology (safety) justification for example nonclinical studies as defined in 21 CFR 58.3(d) If yes, then specify justification/study type and location in the submission: _____		
22. New bioequivalence (BE) study/studies If yes, then specify the following for each new BE study: a. Select Study type: in vivo or in vitro, including failed study b. Study Number: _____ c. Study Site (clinical, analytical, in-vitro testing) Name and Address: _____ d. Location of new BE study in the submission: _____		
23. An alternate method for demonstrating BE (e.g., modeling, in vitro testing) that deviates from the current recommendations in a Product-Specific Guidance		
24. A waiver request under 21 CFR 320.22? If yes, include the module where your waiver is located: _____		

Select one filing category corresponding to the highest risk of all proposed supplemental changes, ranked by supplement filing category (PAS, CBE-30, CBE-0) per 21 CFR 314.70		
☐ PAS	☐ CBE-30	☐ CBE-0

[30] FDA's MAPP 5200.7 (Rev. 1), *ANDA Amendments and Supplements Reviewed by the Division of Filing Review*, is available at https://www.fda.gov/media/94417/download.

For Amendments Only				
Type of amendment	**Supplement #**	**Date of FDA correspondence or action that elicited the amendment (e.g., Complete Response Letter (CRL), discipline review letter (DRL), information request (IR), or tentative approval (TA)):**	**Is this a response to a CRL?**	
			Yes	**No or N/A**
Unsolicited				
Solicited				
President's Emergency Plan for AIDS Relief Program (PEPFAR) Post-TA[31]				
Request for Reconsideration (RFR)				
Facility-Based Major CRL Amendment Reclassification Request				

[31] Under PEPFAR, certain antiretroviral products that have been granted a tentative approval may be distributed for use outside of the United States, even when there is still patent and/or exclusivity protection in the United States. See FDA's PEPFAR web page, available at https://www.fda.gov/international-programs/presidents-emergency-plan-aids-relief-pepfar.

Proposed Changes				
• **For all supplemental changes proposed, populate the table below, ranked by supplement filing category (PAS, CBE-30, CBE-0) per 21 CFR 314.70**				
#	**Change description**	**Filing category**	**Scale-Up and Post Approval Changes (SUPAC) level (1, 2 or 3), as applicable[32]**	**Justification for filing category based on current guidances and/or risk assessment** **If the same change has been previously approved, include ANDA # and approval date for the same change.**
1				
2				
3				
4				
5				

[32] SUPAC guidances are available for modified-release solid oral dosage forms, immediate-release solid oral dosage forms, and nonsterile semisolid dosage form products (see the guidances for industry *SUPAC-MR: Modified Release Solid Oral Dosage Forms Scale-Up and Postapproval Changes: Chemistry, Manufacturing, and Controls; In Vitro Dissolution Testing and In Vivo Bioequivalence Documentation* (October 1997); *SUPAC-IR: Immediate-Release Solid Oral Dosage Forms: Scale-Up and Post-Approval Changes: Chemistry, Manufacturing and Controls, In Vitro Dissolution Testing, and In Vivo Bioequivalence Documentation* (November 1995); and S*UPAC-SS: Nonsterile Semisolid Dosage Forms; Scale-Up and Post-Approval Changes: Chemistry, Manufacturing and Controls; In Vitro Release Testing and In Vivo Bioequivalence Documentation* (May 1997)). These guidances define levels of change (i.e., SUPAC levels 1, 2, and 3) for the covered products, along with recommended tests and documentation that should support the change.