

**POLICY AND PROCEDURES**

**Office of Generic Drugs**

**Review of ANDA Amendments and Supplements by the Division of Filing Review**

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**PURPOSE**

This MAPP outlines the policies and procedures for review by the Office of Generic Drugs (OGD), Office of Regulatory Operations (ORO), Division of Filing Review (DFR) of 1) certain amendments to original abbreviated new drug applications (ANDAs) and 2) certain prior approval supplements (PASs). This MAPP delineates responsibilities among staff from the Document Room, OGD, and the Office of Pharmaceutical Quality (OPQ) to ensure timely review of these submissions.

**POLICY**

ANDAs and PASs submitted to FDA must be substantially complete to permit a substantive review (21 CFR 314.101(b)(1)). DFR evaluates each ANDA and certain PASs (as defined below) submitted to OGD to determine whether the ANDA may be received. FDA will refuse to receive (RTR) a submission that is not substantially complete to permit a substantive review. FDA’s regulations at 21 CFR 314.101 provide the regulatory authority by which FDA may in certain cases, and will in others, RTR an ANDA.

In addition to reviewing each original ANDA submitted to OGD, DFR reviews every amendment to an original ANDA and every PAS in which an applicant requests approval for one of the following changes:

- new strength of a solid oral dosage-form drug product

- change in concentration for a parenteral dosage-form drug product
  - change in vial size, fill volume, and/or package size to a parenteral dosage-form drug product (i.e., total drug content)
  - change in concentration of an oral liquid, ophthalmic, otic, transdermal, or topical drug product
  - change in the formulation for any dosage form
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## RESPONSIBILITIES AND PROCEDURES

### Document Room Staff will:

- Review the cover letter and the FDA Form 356h in accordance with the checklist (Attachment 1) to determine whether DFR should review the submission.
  - Review the cover letter in accordance with the checklist, focusing on the following key terms:
    - Addition of
    - New strength added
    - Change
    - Updated
    - New formulation
  - Review the following fields on the FDA Form 356h:
    - Field 13: Strength
    - Field 25: Reasons for Submission
- If the answer to any question on the checklist is “yes,” ensure the submission is routed to DFR for filing review.
- If the answers to all questions on the checklist are “no,” ensure the submission is routed to the OGD regulatory project manager (OGD RPM) or the OPQ regulatory business process manager (OPQ RBPM), as appropriate based on the subject of the submission (e.g., multidisciplinary submissions are directed to the OGD RPM, product-quality only submissions are directed to the OPQ RBPM) .
- Contact the DFR technical information specialist (TIS) for assistance in accurately identifying the submission based on the criteria listed above and the checklist.

### OGD RPM and/or OPQ RBPM will:

- For every amendment and supplement the Document Room sends directly to the OGD RPM or OPQ RBPM, review the cover letter during the triage stage in accordance with the checklist to confirm whether a filing review is necessary.
- If the answer to any question on the checklist is “yes,” confirm in the Generic Drug Review Platform whether a filing review was performed for the submission.
- Contact DFR’s lead project manager if a filing review is needed but has not been performed.

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- Contact the DFR TIS for assistance in accurately identifying the submission based on the above criteria and the checklist.
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**EFFECTIVE DATE**

This MAPP is effective upon date of publication.

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**CHANGE CONTROL TABLE**

Effective Date	Revision Number	Revisions

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**ATTACHMENT 1: Checklist: Should DFR Review This Submission?**

If the answer to any of the following questions is “Yes,” route submission to DFR for filing review

- |   |                          |                          |
|---|--------------------------|--------------------------|
| 1. Does the cover letter* or Form 356h (at Field 13 and/or Field 25) include any of the following terms:  | YES                      | NO                       |
| a. Addition of  | <input type="checkbox"/> | <input type="checkbox"/> |
| b. New strength added   |                          |                          |
| c. Change   |                          |                          |
| d. Updated  |                          |                          |
| e. New formulation  |                          |                          |
| 2. If the submission is for a solid oral dosage form, are additional and/or new strengths of the drug product being proposed?   | YES                      | NO                       |
|   | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. If the submission is for a parenteral dosage form, are there any changes in concentration (e.g., mg/mL or percent) and/or vial size, fill volume, or package size of the drug product? | YES                      | NO                       |
|   | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. If the submission is for an oral liquid, ophthalmic, otic, topical, or transdermal drug product, are there any changes in concentration of the drug product?                           | YES                      | NO                       |
|   | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. For all dosage forms, are there any changes in the formulation?  | YES                      | NO                       |
|   | <input type="checkbox"/> | <input type="checkbox"/> |

\*Read the cover letter in its entirety.

Contact the DFR technical information specialist (TIS) for assistance in accurately identifying the submission based on the checklist criteria.