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**POLICY AND PROCEDURES**

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**Office of Generic Drugs**

**Consolidation of ANDAs by the Office of Generic Drugs**

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**PURPOSE**

This MAPP describes the process for reviewing and approving or denying requests to consolidate previously approved abbreviated new drug applications (ANDAs) submitted by an ANDA applicant. This MAPP applies to the Office of Generic Drugs’ (OGD) ANDA Consolidation Coordinator (ACC), who coordinates requests for consolidation, makes the consolidation determination, and ensures ANDAs are properly consolidated. This MAPP also applies to OGD regulatory project managers (RPMs), who determine whether any of the ANDAs identified in the request for consolidation have associated open issues or pending reviews and Document Room staff who send consolidation requests to the OGD RPMs.

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**BACKGROUND**

Historically, ANDA applicants submitted a separate, original ANDA for each strength of a particular generic drug product for which they sought FDA approval. This practice resulted in multiple ANDA numbers for different strengths of the same drug product.

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**POLICY**

When appropriate, an ANDA applicant that owns several original ANDAs for different strengths of the same drug product may request a consolidation of the ANDAs into one “parent” ANDA. The parent ANDA is the ANDA associated with the strength upon which all in vivo bioequivalence (BE) studies were conducted and serves as the basis for

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BE waivers for the remaining strengths. Once these ANDAs are consolidated, the applicant may submit one prior approval supplement (PAS) or changes being effected (CBE) submission to the parent ANDA for any subsequent change to all strengths of the drug product and one annual report.

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## **RESPONSIBILITIES**

ANDA Consolidation Coordinator (ACC) will:

- Conduct preliminary review of requests for ANDA consolidation
- Make the determination to approve or deny the consolidation request
- Issue approvals or denials of requests for ANDA consolidation to applicants
- Advise OGD and other FDA staff of an approved request for consolidation to ensure that the ANDA consolidation is reflected in the Orange Book and review platform
- Serve as the point of contact (POC) for all industry inquiries on ANDA consolidation

OGD RPM will:

- Receive requests for ANDA consolidation via the Document Room
- Determine whether there are any open issues (e.g., a CBE submission requiring acknowledgement) or pending reviews associated with any of the ANDAs identified in the request for consolidation
- Determine whether there are any open issues or pending reviews associated with supplements to any of the ANDAs identified in the request for consolidation
- Send the request to the ACC for evaluation and include information on any open issues and/or pending reviews

Document Room staff will:

- Send requests for ANDA consolidation to the OGD RPMs via the RPM Shared Queue

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## **PROCEDURES**

### **RPM Triage of a Request for ANDA Consolidation**

- The OGD RPM receives the applicant's request for ANDA consolidation from the Document Room
- The OGD RPM reviews the ANDAs identified in the request for consolidation to determine whether any open issues or pending reviews are associated with any of the ANDAs identified
- The OGD RPM forwards the request for consolidation to the ACC, along with any information relevant to the ANDAs identified in the request

**ACC Review of a Request for ANDA Consolidation**

- *Review of Information Provided by the Applicant*
  - The ACC reviews the request to determine whether the applicant has provided all information necessary to review the request. Specifically, the ACC reviews the request to determine whether the applicant has:
    - submitted a separate copy of the request for consolidation to each ANDA applicable to the request (i.e., parent and child ANDAs);
    - properly identified the request as a “Request for Consolidation” to the ANDA files (i.e., the applicant has not submitted the request as a PAS, CBE-0 or CBE-30);
    - identified all formulations and ANDAs;
    - indicated that all inactive ingredients are the same and proportional for all formulations identified in the request by including a listing of all ingredients, the quantity of the ingredient per dosage form, and the weight to weight percentage (example below); and

Ingredient	Quantity per Tablet		Quantity per Tablet		Quantity per Tablet	
	50 mg		75 mg		100 mg	
	mg/unit	% (w/w)	mg/unit	% (w/w)	mg/unit	% (w/w)

- provided documentation that the applicant has performed BE studies on appropriate strength(s), as well as documentation of any BE waivers received.
- *Approval or Denial of the Request for Consolidation*
  - If the applicant has properly provided all information necessary to review the request, the ACC proceeds with the review of the request for consolidation.
  - If the applicant’s request for consolidation fails to provide any of the information listed above, the ACC denies the request.
    - The ACC drafts and issues a letter to the applicant explaining why the request was denied and the request for consolidation is closed. An applicant may submit a new request for consolidation with the necessary revisions, but may not amend the original request that was denied.
  - If there are open issues or pending reviews associated with any of the ANDAs identified in the request for consolidation, the ACC may either deny the request for consolidation or hold the request until an action is taken on the open issues or pending reviews. For example, the ACC may take into consideration the estimated time to action on a pending supplement.
    - If the ACC denies the request, the ACC drafts and issues a letter to the applicant explaining why the request was denied.

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- If there are no open issues or pending reviews associated with any of the ANDAs identified in the request for consolidation, the ACC approves the request.
    - The ACC drafts and issues a letter to the applicant approving the request for consolidation and identifying the new parent ANDA.
    - The ACC sends a copy of the letter to the OGD RPM for the ANDA, the Orange Book Staff (so the consolidation may be reflected in the Orange Book), and Integrity Services (so the consolidation may be reflected in the review platform).
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**EFFECTIVE DATE**

This MAPP is effective upon date of publication.

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