POLICY AND PROCEDURES

Office of Generic Drugs

Consolidation of ANDAs by the Office of Generic Drugs

Table of Contents

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, determines whether any of the ANDAs identified in the request for consolidation have associated open or outstanding issues (e.g., pending reviews), makes the consolidation determination, and ensures ANDAs are properly consolidated.

- This MAPP also applies to OGD regulatory project managers (RPMs) and document room staff who forward consolidation requests to the OGD RPMs.

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.

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.

- Generally, 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 BE waivers[1] for the remaining strengths.

- Once the request is approved by the Agency and the ANDAs are consolidated, the applicant may submit one prior approval supplement (PAS) or changes being effected (CBE) submission for any subsequent change to all strengths of the drug product and may submit any required postmarketing reports (e.g., annual reports, transfer of ownership) to the parent ANDA.

RESPONSIBILITIES

ANDA Consolidation Coordinator (ACC):

- Conducts preliminary review of requests for ANDAs consolidation.
- Determines whether there are any open or outstanding issues associated with any of the ANDAs identified in the request for consolidation.
- Makes the determination to approve or deny the consolidation request.
- Issues approvals or denials of requests for an ANDA consolidation to applicants.
- Advises OGD and other FDA staff of an approved request for consolidation to ensure that the ANDA consolidation is reflected in the FDA publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (Orange Book)[2] and review platform.
- Serves as the point of contact for all industry inquiries sent to the ANDA Consolidation mailbox (ANDAConsolidation@fda.hhs.gov).

OGD RPM:

- Receives requests for ANDAs consolidation from the document room.
- Sends the request to the ACC for evaluation and includes information on any open or outstanding issues.

[1] In addition to waiver of an in vivo BE requirement under 21 CFR 320.22, there are certain circumstances in which BE can be evaluated using in vitro approaches under 21 CFR 320.24(b)(6). In such circumstances, an in vivo data requirement is not waived, but rather, FDA has determined that in vitro data is the most accurate, sensitive, and reproducible for a product, as required under 21 CFR 320.24(a). Nonetheless, for ease of the reader, in this MAPP we will refer to either the decision to waive an in vivo BE requirement under 21 CFR 320.22 or the decision to accept in vitro BE data in accordance with 21 CFR 320.24(a) as a "BE waiver."

[2] FDA Orange Book website: https://www.accessdata.fda.gov/scripts/cder/ob/

Document room staff:

- Forwards requests for ANDAs consolidation to the OGD RPMs via the RPM Shared Queue.

PROCEDURES

OGD 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 forwards the request for consolidation to the ACC, along with information on any open or outstanding issues related 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:
        - Properly identified all ANDAs applicable to the request.
        - Properly identified the parent ANDA request as "Correspondence" and the child ANDA request(s) as a "Request for Consolidation" to the NDA files (i.e., the applicant has not submitted the request as a PAS, CBE-0, or CBE-30).
        - Submitted a separate copy of the request for consolidation to each ANDA applicable to the request (i.e., parent and child ANDAs).
        - Identified formulations for all ANDAs applicable to the request.
        - Provided documentation of performed BE studies on appropriate strength(s), as well as documentation of any BE waivers received.
        - Identified the same new drug application as the reference listed drug for the parent and child ANDAs.

- Approval or Denial 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 they may not amend the original request that was denied.

    - If there are no open or outstanding issues associated with any of the ANDAs identified in the request for consolidation and the applicant has properly provided all information necessary to review the request, the ACC proceeds with the review of the request for consolidation.

    - If there are open or outstanding issues 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 or outstanding issues. 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.

    - If there are no open or outstanding issues associated with any of the ANDAs identified in the request for consolidation and all requested information has been provided, the ACC approves the request.

        - The ACC drafts and issues a request approval letter, including a identified new parent ANDA.
        - The ACC sends a copy of the letter to the Orange Book Staff (so the consolidation may be reflected in the Orange Book) and CDER Informatics and Integrity Services (so the consolidation may be reflected in the review platform).

EFFECTIVE DATE

This MAPP is effective upon date of publication.

CHANGE CONTROL TABLE

Effective Date	Revision Number	Revisions
10/28/2015	N/A	Initial
8/19/2020	1	Revised to update responsibilities and clarify process
9/8/2025	N/A	Recertified, M. Nguyen's e-signature.