

OFFICE OF GENERIC DRUGS

---

Review Order of Original ANDAs, Amendments, and Supplements

---

CONTENTS

**PURPOSE**  
**BACKGROUND**  
**POLICY**  
**RESPONSIBILITIES**  
**PROCEDURES**  
**AUTHORITY**  
**EFFECTIVE DATE**

---

**PURPOSE**

- This MAPP describes the review order for original abbreviated new drug applications (ANDAs), amendments and supplements in the Office of Generic Drugs (OGD). It also describes when the review order for certain applications may be revised to reflect public health considerations. This MAPP is a revision of MAPP 5240.3 (*Restatement of the Office of Generic Drugs' "First-In, First-Reviewed" Policy and Modification of the Exceptions to the Policy Regarding Minor Amendments*) dated November 1, 1995. Information from that MAPP is also contained in the Guidance for Industry: Major, Minor and Telephone Amendments to Abbreviated New Drug Applications.
- 

**BACKGROUND**

- Since 1990, OGD has been reviewing ANDAs (and related submissions) on a “first-in, first-reviewed” basis as a means to assure fair and even-handed treatment of applicants. This approach established that, to the extent possible, chemists would review original ANDAs in the order in which they were received. OGD remains committed to this “first-in, first-reviewed” approach unless there are specific reasons to expedite an application.
  - In December 2001, the expectations for major and minor amendments were published in a guidance to industry on *Major, Minor, and Telephone Amendments to Abbreviated New Drug Applications*.
  - Since 2002, the number of ANDAs submitted has continued to grow. OGD expects that the increased number of ANDAs, plus additional workload from citizen petitions and the submission of ANDAs for more complex drug products, could potentially cause delays in the approval of ANDAs, including ANDAs for drug products that are particularly important to the public health.
-

- Currently, OGD's growth and migration toward an enhanced science/risk-based review process are leading to refinement of the basic policy on review order. The increased number and complexity of applications require the use of mechanisms that foster review efficiencies.
- 

## POLICY

- Review of original ANDAs, amendments and supplements is expected to be completed in the order received (first-in, first-reviewed), to the extent possible, except as noted below. The initial review done at the time of submission may identify instances when an exception to the "first-in, first-reviewed" approach is appropriate and the review should be expedited.
  1. Certain applications may be identified at the time of submission for expedited review. These include products to respond to current and anticipated public health emergencies, products under special review programs such as the President's Emergency Plan for AIDS Relief (PEPFAR), products for which a nationwide shortage has been identified, and first generic products for which there are no blocking patents or exclusivities on the reference listed drug. These applications will be the highest priority in a reviewer's work queue.
  2. After expedited applications, the usual review order priorities will be as follows:
    - a. Telephone and minor amendments to unapproved ANDAs will be the highest priority in a reviewer's work queue (unless management assigns other work as a higher priority, e.g. an expedited review). If multiple telephone or minor amendments are in the reviewer's queue, review will proceed according to days pending, if possible.
    - b. Original applications and major amendments to original applications will remain in the team queue for assignment to the next available reviewer.
    - c. The review priority for supplements will be based on the date the supplement is submitted. Minor amendments to supplements are high priority as are minor amendments to original applications.
    - d. The review policy on global supplements (multiple supplements from a firm) will continue as described in MAPP 5240.9, *Handling and Processing Requests for Global Reviews*.
    - e. Similarly, multiple supplements from the same firm that require review by both OGD and the Office of New Drug Quality Assessment will be assigned to one office. These reviews are also described in the MAPP referenced above (2.d.).
  3. Other approaches to review order will be used as necessary to enhance efficiency, productivity and/or to incorporate new understanding of the product's risk-based assessment. Examples of such alternative approaches include:

- a. When there is a cluster of applications for the same drug product, the drug master file(s) (DMF) should be obtained so that review can be started before the ANDA is assigned.
- b. Early DMF review will also apply to expedited reviews of ANDAs.
- c. A cluster of applications for the same drug product may be assigned to a specific group/team of reviewers, including the related team leader and project manager, to ensure both consistency and efficiency.
- d. With the increasing complexity of products, not all reviewers will have the necessary expertise to conduct certain reviews. Applications will be assigned for review to staff with special expertise while still adhering to the “first-in; first-reviewed” procedure to the extent possible.

---

## **RESPONSIBILITIES**

- Reviewers will adhere to the procedures delineated in this MAPP for conducting reviews of applications, amendments and supplements.
  - Team leaders and managers will assure that applications are addressed in the order described in this MAPP.
  - The Regulatory Support Branch will identify applications that qualify for expedited review.
- 

## **PROCEDURES**

OGD remains committed to the “first-in, first-reviewed” review order unless there are specific reasons to expedite an application. The Director of the Office of Generic Drugs will provide memoranda to the staff documenting the basis for expediting the review of an application or group of applications and authorizing such expedited review.

- After an application has been submitted, the filing review will be completed and the application placed into the work queue for the appropriate review team.
  - If the application relates to a product that is (1) responsive to a current or anticipated public health emergency, (2) a product under a special review program such as PEPFAR, (3) determined to be in nationwide shortage, or (4) a first generic product for which there are no blocking patents or exclusivities, and the Director of the Office of Generic Drugs has authorized expedited review in writing, the application will be placed at the head of the review queue for the appropriate team.
  - The review staff in each discipline will conduct reviews as efficiently as possible, using mechanisms that will assure a full assessment of the applications.
- 

## **AUTHORITY**

- The Director, Center for Drug Evaluation and Research has authorized the Director of the Office of Generic Drugs to implement this modification to the first-in, first-reviewed procedure.
- 

**EFFECTIVE DATE**

This MAPP is effective upon date of publication.