

Prioritization Requests

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Learning Objectives

- What is Priority Review and the benefits
- Describe process for prioritizing original ANDAs, amendments and supplements
- Roles and Responsibilities
- List Common Mistakes to Avoid when submitting a prioritization request

Poll Question



Which of the following is not true?

- A. Original ANDA or amendment must meet one of the prioritization factors in MAPP 5240.3 to qualify for priority review
- B. An ANDA supplement that addresses a public health emergency qualifies for priority review
- C. FDA will evaluate whether a priority review will be granted without an explicit request from applicant at time of submission
- D. Submissions that are eligible for priority review may receive a shorter goal date or expedited review

Key Points



- What is Priority Review
- Benefits
- How to Request Priority Review

Benefits



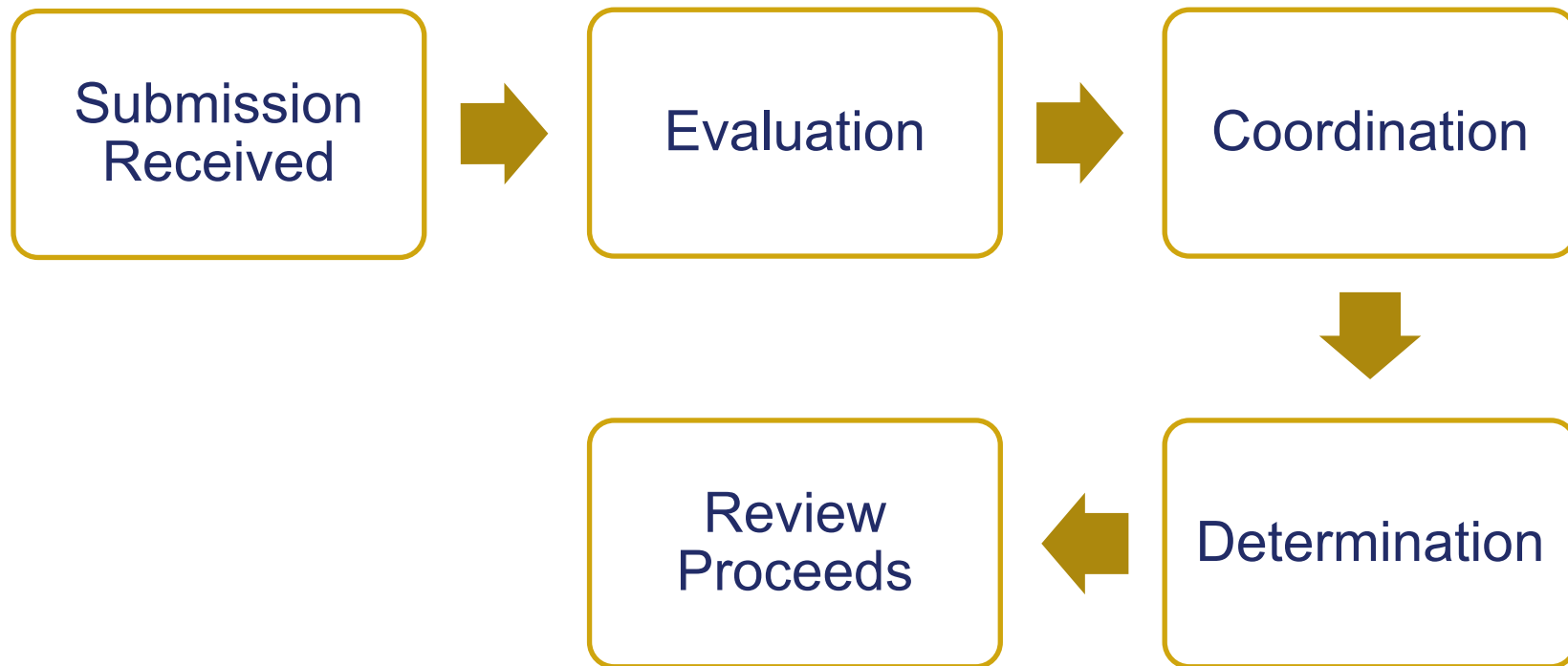
Shorter Goal Dates (GDUFA III):

- Original ANDAs: 8-month goal date
- Major Amendments: 6- or 8-month goal date
- Prior Approval Supplements: 4- or 8-month goal date

Expedited Review (No change to Goal Date):

- FDA strives to act as soon as possible
- May complete review prior to goal date

Priority Review Process



Roles and Responsibilities



- OGD RPMs
- OPQ RBPMs & OGD Labeling PM
- OGD Division of Filing Review
- Office of Generic Drug Policy

Common Mistakes



- Timing
- Request priority review with each cycle
- Facilities
- Cover letter

Summary



- Shorter Goal Date or Expedited review
- Limitations
- Review classification changes
- Manage expectations

Resources



- [MAPP 5240.3 Rev.6 Prioritization of the Review of Original ANDAs, Amendments, and Supplements](#)
- [GDUFA Reauthorization Performance Goals and Program](#)
- [Domestic Onshoring Pilot Announcement \(October 3, 2025\)](#)