Prioritizing Original and Supplemental ANDAs

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Learning Objectives

- Review criteria that OGD uses to assess a valid prioritization request
- Recognize the most commonly used Prioritization Factors from Manual of Policies and Procedures (MAPP) 5240.3 Rev. 6
- Discuss key considerations when selecting a prioritization factor
- Provide an overview of the new Onshoring Prioritization Pilot

The Following Criteria Must be Met to be Considered

1. The cover letter to the submission clearly states “Priority Review Requested” and references the ANDA number
2. The basis for the request is consistent with MAPP 5240.3, Prioritization of the Review of Original ANDAs, Amendments, and Supplements
3. The applicant clearly and briefly states the basis for the request, including the prioritization factor(s)
4. The applicant includes sufficient supporting documentation for the request

Or, in the absence of an explicit request, FDA determines the submission relates to a drug shortage, public health emergency, or meets the requirements of section 505(j)(11)(A) of the FD&C Act

Common Prioritization Factors

- Submissions for which there are not more than three approved drug products
- Applications containing a paragraph IV certification

Prioritization Factors

Submissions for which there are not more than three approved drug products:

- No blocking patents or exclusivities listed for the reference listed drug (RLD) at the time FDA makes the prioritization determination
  - **Blocking Patent:** any patent that an ANDA applicant is required to address with a paragraph III or paragraph IV patent certification, *no matter the status of litigation*
- Includes drug products listed in both the "Active Section" and the "Discontinued Section" of the Orange Book
- Applies to original ANDA submissions and amendments to original ANDA submissions

Prioritization Factors (cont.)

Applications containing a paragraph IV (PIV) certification

- The ANDA must be ready for final approval at or before the goal date for that submission and fit within one of three sub-categories described on next slide
  - Reminder: Paragraph IV Certifications List is updated regularly and useful reference for status of 180-day exclusivity
- Must provide adequate documentation to show that the application will be eligible for final approval on or before the goal date for that submission

Three Circumstances Where the PIV Factor Applies

1. First Applicant and 180-day exclusivity has not been extinguished
2. Subsequent Applicant and 180-day exclusivity is triggered but not expired
3. Other ANDAs with PIV certifications if there are fewer than four approved drug products in the Orange Book (including the RLD)
   - E.g., 180-day exclusivity is extinguished but still fewer than four approved drug products

Helpful Tips for Prioritization Requests

- Make sure you are selecting the right prioritization factor with clear justification
- Not an additional benefit to meeting multiple prioritization factors
- There generally must be an explicit request at the time of submission that includes the prioritization factor or factors under which the applicant believes the submission qualifies for priority review

Tips (cont.)

- ANDA ***supplements*** or amendments to ANDA supplements can only qualify for priority review under the following factors:
  - drug shortage,
  - public health emergency,
  - submissions related to certain government purchasing programs,
  - Submissions subject to statutory mandates or other legal requirements, or
  - requests pursuant to 21 CFR 314.70(b)(4) (extraordinary hardship)

New ANDA Prioritization Pilot to Support U.S. Generic Drug Manufacturing and Testing

Prioritization Pilot: Criteria

- Finished Dosage Form (FDF) manufacturer(s) is located in the U.S.
- Active Pharmaceutical Ingredient (API) supplier(s) is located in the U.S.
- Either the pivotal bioequivalence (BE) testing was conducted in the U.S. or the ANDA qualifies for a waiver of bioequivalence testing
- **All three** (U.S. BE, U.S. FDF, U.S. API) must be met to qualify

A Request for Priority Review Must Have Which of the Following?

A. A cover letter that clearly states “Priority Review Requested”

B. A clear statement of the basis for the request, including prioritization factor(s) (or the Onshoring Prioritization Pilot)

C. Supporting documentation for the request

D. A basis for the request that is consistent with the MAPP or Onshoring Prioritization Pilot

E. All of the above