U.S. FOOD & DRUG ADMINISTRATION

Recent Revisions to FDA's MAPP on Prioritization of Abbreviated New Drug Applications

Overview of Presentation

- Background on Prioritization
- Priority Review Basics
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Background on Prioritization

- Access to high-quality, affordable generic medications plays a vital role in advancing public health.

- In recognition of this, FDA offers certain ANDA submissions – those that could have a meaningful impact on generic drug access – a special review, known as *priority review*.

- Information on how FDA prioritizes review of ANDA submissions is outlined in MAPP 5240.3 *Prioritization of the Review of Original ANDAs, Amendments, and Supplements*, which was recently revised.

Priority Review Basics

- For an ANDA submission to be eligible for priority review, it must meet the criteria for one of several public health priorities — known as *prioritization factors* — identified by FDA in MAPP 5240.3.

- If an applicant believes that its submission is eligible for priority review, the applicant should explicitly request priority review at the time of submission.

- If FDA grants the request, the submission is designated as a *priority review*, and the submission is granted either (1) a shorter goal date or (2) an expedited review.

Priority Review Basics, cont.

- If one drug strength in an ANDA submission is eligible for a priority review, the entire submission will be eligible for priority review.
- The benefit of priority review does not vary based on the number of prioritization factors that an ANDA submission meets.
- Applicants should request priority review for every submission (including amendments) for which they are seeking such a review and provide the basis for each request, including the prioritization factor or factors under which the submission qualifies for priority review.

Requests for Priority Review

- Absent an explicit request for priority review from an applicant, FDA will not prioritize the review of a submission unless:

  (1) the submission relates to drug shortage;

  (2) the submission relates to a public health emergency; or

  (3) the submission meets the requirements of section 505(j)(11)(A) of the FD&C Act.

Supplements

- FDA will prioritize ANDA supplements:

  (1) if the submission relates to a drug shortage or public health emergency;

  (2) if the submission is subject to a statutory mandate or other legal requirement; or

  (3) where a delay in making the change described in the supplement would impose an extraordinary hardship on the applicant.

Not More Than Three Approved Drug Products

- FDA will continue to prioritize submissions for which there are not more than three approved drug products listed in the Orange Book, including the Reference Listed Drug (RLD), and for which there are no blocking patents or exclusivities listed for the RLD.

Not More Than Three Approved Drug Products, cont.

- "Approved drug products" include products listed in both the active section and discontinued section of the Orange Book unless voluntarily withdrawn under 21 CFR 314.150(c), with a published *Federal Register* notice.

Not More Than Three Approved Drug Products, cont.

- This prioritization factor only applies if there are no blocking patents or exclusivities listed for the RLD.
- This factor is distinct from the factor related to “sole source” drug products.

Applications Containing a Paragraph IV Certification

- FDA will prioritize certain submissions containing a paragraph IV certification from first applicants or subsequent applicants if the submission will be ready for final approval at or before the goal date for that submission and the submission fits within one of three categories.

Applications Containing a Paragraph IV Certification, cont.

The three circumstances under which FDA will prioritize submissions that will be ready for final approval at or before the goal date under this factor are:

- Submissions from applicants who satisfy the definition of first applicant at the time of submission, and for which the 180-day exclusivity period has not expired.
- Submissions from subsequent applicants who were blocked from final approval by 180-day exclusivity, once the relevant 180-day exclusivity period as been triggered.
- Other submissions containing a paragraph IV certification, if there are fewer than four approved therapeutically equivalent drug products listed in the Orange Book.

Submissions for Which Final Approval is Dependent on Expiration of Patent or NDA Exclusivity

- FDA will prioritize submissions dependent on the expiration of a patent or New Drug Application exclusivity period:
  - For noncomplex products, if the original submission is submitted between 24 to 36 months prior to the last applicable patent or exclusivity expiration date, and
  - For complex products (as defined in the GDUFA II Commitment Letter), if the original submission is submitted between 36 to 48 months prior to the last applicable patent or exclusivity expiration date

Submissions for Sole Source Drug Products

- FDA will continue to prioritize submissions for "sole source" drug products – i.e., submissions for which:
  - There is only one approved product in the active section of the Orange Book and that product is approved under an ANDA
  - That ANDA was not approved pursuant to a suitability petition
  - There are no blocking patents/exclusivities.

Key Takeaways

- Applicants should familiarize themselves with MAPP 5240.3 Rev. 5.
- If an applicant believes that its submission is eligible for priority review, the applicant should explicitly request priority review at the time of submission.
  - The submission cover letter should clearly state “Priority Review Requested.”
  - The applicant should clearly and briefly state the basis of the request, including the prioritization factor.
  - The applicant should include sufficient supporting documentation.

Resources

- GDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2018-2022 (GDUFA II Commitment Letter).
- CDER MAPP 5240.3 Rev. 5 *Prioritization of the Review of Original ANDAs, Amendments, and Supplements*.
- Food and Drug Administration Reauthorization Act (Public Law 115–52).
- Draft guidance for industry *ANDAs: Pre-Submission of Facility Information Related to Prioritized Generic Drug Applications (Pre-Submission Facility Correspondence)* (November 2017).

Questions?

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