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**POLICY AND PROCEDURES**

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**OFFICE OF GENERIC DRUGS**

Prioritization of the Review of Original ANDAs, Amendments, and Supplements

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**PURPOSE**

This MAPP describes how the review of original abbreviated new drug applications (ANDAs), ANDA amendments, and ANDA supplements will be prioritized for review within the Office of Generic Drugs (OGD) and the Office of Pharmaceutical Quality (OPQ).<sup>1</sup> This MAPP is a revision of MAPP 5240.3 Rev. 3 *Prioritization of the Review of Original ANDAs, Amendments, and Supplements* (June 27, 2017).

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**BACKGROUND**

On October 18, 2006, OGD issued MAPP 5240.3 *Review Order of Original ANDAs, Amendments, and Supplements*. That MAPP set forth certain modifications to OGD’s earlier “first-in, first-reviewed” approach to the review of ANDAs, amendments, and supplements. The Food and Drug Administration (FDA) continued to revise that MAPP to reflect approaches to the review of ANDAs, amendments, and supplements designed to prioritize submissions that would have a meaningful impact on generic drug access. These approaches stem from a variety of legislative and regulatory initiatives including the Food and Drug Administration Safety and

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<sup>1</sup> Prioritization in accordance with this MAPP may qualify an original ANDA for 8-month priority review under section 505(j)(11) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(11)) if a pre-submission of facility information is made in accordance with that provision. This MAPP does not describe the pre-submission of facility information or procedures for determining qualification for the 8-month review period.

Innovation Act (FDASIA),<sup>2</sup> the FDA Reauthorization Act of 2017 (FDARA),<sup>3</sup> and the Commissioner's Drug Competition Action Plan.

This MAPP establishes public health priorities (or "prioritization factors") that may qualify an original ANDA, amendment, or supplement for a priority review.

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## POLICY

Prioritization of the review of submissions to OGD will be carried out as described in the numbered paragraphs below.

- If an original ANDA, amendment, or supplement meets one of the prioritization factors in this MAPP, the submission will be eligible for a "priority review." Submissions that are eligible for a priority review may receive either a shorter goal date or an expedited review, as defined below in this MAPP.
- A priority review may be granted following a request from the applicant (including when the request is for a supplemental ANDA under 21 CFR 314.70(b)(4))<sup>4</sup> or at FDA's initiative. In either case, the granting of a priority review must be consistent with the criteria set forth in this MAPP.
- Inquiries about priority review should be handled in accordance with the procedures described in MAPP 5200.3 *Communications With Industry With Respect to Abbreviated New Drug Applications*.<sup>5</sup>
- The prioritization criteria outlined below apply at all stages of review. Determinations about priority reviews may be made at the time a submission is received or thereafter.
- Submissions involving facilities that are subject to a recommendation of official action indicated will not be considered for a priority review, except in certain cases in which it

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<sup>2</sup> Public Law 112-144. FDASIA includes the Generic Drug User Fee Amendments of 2012 (GDUFA I) and, by reference, the Generic Drug User Fee Act Program Performance Goals and Procedures (GDUFA I Commitment Letter).

<sup>3</sup> Public Law 115-201. FDARA includes the Generic Drug User Fee Amendments Act of 2017 (GDUFA II) and, by reference, the GDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2018-2022 (GDUFA II Commitment Letter).

<sup>4</sup> In accordance with 21 CFR 314.97, 21 CFR 314.70(b)(4) applies to ANDAs.

<sup>5</sup> We update MAPPs periodically. To make sure you have the most recent version of a MAPP, check the CDER MAPP web page at <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ManualofPoliciesProcedures/default.htm>.

is determined that the submission must be prioritized to address a public health concern. These determinations will be made by the OGD Regulatory Project Manager (RPM) and OGD management in consultation with other FDA personnel as necessary.

- All determinations regarding the priority of submissions within the review process will be consistent with FDA's GDUFA II review metrics.

### **Prioritization of Review**

#### **1. Submissions containing certain patent certifications and exclusivity statements**

- Submissions for drug products for which there are not more than three approved drug products listed in FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book")<sup>6</sup> and for which there are no blocking patents or exclusivities listed for the reference listed drug (RLD) may receive a priority review. For purposes of this MAPP, a patent to which an applicant has solely submitted a statement under section 505(j)(2)(A)(viii) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)(2)(A)(viii)) will not be considered a blocking patent.
- Submissions that contain a paragraph IV certification but become eligible for approval during the review period as a result of no blocking patents or exclusivities (including 180-day exclusivity under section 505(j)(5)(B)(iv) of the FD&C Act (180-day exclusivity)) and no applicable stays may receive a priority review if no other generic version of the same RLD has been brought to market under an approved ANDA. The absence of any blocking patent, exclusivity period, or stay must be appropriately documented in order for a priority review to be granted. For 180-day exclusivity, "no exclusivity" means (1) that the 180-day exclusivity has either been relinquished or waived or (2) that FDA has determined that a forfeiture of the exclusivity has occurred.
- Submissions that (1) contain a paragraph IV certification, (2) are submitted on the first day that any valid paragraph IV application for the drug in question is submitted, and (3) are received as substantially complete (i.e., submissions that have "first filer" status) may receive a priority review.
  - i. OGD and OPQ will seek to complete review of these submissions in a manner that would permit a tentative or final approval within 30 months of filing.

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<sup>6</sup> The Orange Book is available at <https://www.accessdata.fda.gov/scripts/cder/ob/>.

- ii. If a submission (1) contains a paragraph IV certification and has “first filer” status as described above and (2) contains a paragraph III certification, the “first filer” status will govern for purposes of granting the priority review.
- Submissions for drug products blocked by 180-day exclusivity that have been tentatively approved or submissions for drug products blocked by 180-day exclusivity that OGD determines will likely be ready for approval upon or shortly after expiration of the 180-day exclusivity may receive a priority review when such exclusivity is triggered.
- If approval of a submission either is dependent on the expiration of a patent (i.e., the submission contains a paragraph III certification) or is dependent on the expiration of an exclusivity period, OGD and OPQ will seek to complete the review of the submission in a manner that would permit approval by the last applicable patent expiration date or exclusivity date. However, with regard to ANDAs submitted on or after October 1, 2014:
  - i. ANDAs submitted within 1 year of the last applicable patent expiration date or exclusivity date will not be considered for priority review, and FDA can provide no assurances that the review will be completed in a manner that would permit approval by the last applicable patent expiration date or exclusivity date. However, this provision may be subject to an exception when it is determined that the submission should be granted a priority review to address a public health concern. These determinations will be made by the OGD regulatory project manager (RPM) and OGD management in consultation with other FDA personnel as necessary.
  - ii. ANDAs submitted more than 30 months in advance of the last applicable patent expiration date or exclusivity date will not be considered for a priority review.

## **2. Submissions related to drug shortages**

Submissions that could help mitigate or resolve a drug shortage and prevent future shortages, including submissions related to products that are listed on FDA’s Current Drug Shortages Index at the time of the submission, may receive a priority review.

## **3. Submissions that are subject to special review programs such as the President’s Emergency Plan for AIDS Relief**

Submissions in this category may receive a priority review.

**4. Submissions related to public health emergencies**

Submissions that either could help address a public health emergency declared by the Secretary of the U.S. Department of Health and Human Services, or anticipated under the same criteria as apply to such a declaration, may receive a priority review.

**5. Submissions related to certain government purchasing programs**

Submissions related to certain government purchasing or procurement activities, including expiration-date extensions or packaging changes usually requested by the Government-Wide Quality Assurance Program, may receive a priority review.

**6. Submissions subject to statutory mandates or other legal requirements**

Submissions that are subject to federal or state mandates or other legal or regulatory actions may receive a priority review as necessary to comply with those requirements. Note: This category includes legally required changes in formulation or labeling. However, supplements submitted following actions taken by FDA field staff against applicants who put changes into effect that are required to have approved supplements under 21 CFR 314.70(b) will not be considered for a priority review.

**7. Supplements for which a priority review is requested under 21 CFR 314.70(b)(4)**

- Under 21 CFR 314.70(b)(4), an applicant may ask FDA to grant a priority review to “a supplement for public health reasons or if a delay in making the change described in [the supplement] would impose an extraordinary hardship on the applicant.” For priority reviews, “extraordinary hardship on the applicant” will be interpreted to include the following:
  - i. Catastrophic events such as explosion, fire, or storm damage to manufacturing facilities.
  - ii. Events that could not have been reasonably foreseen by the applicant and for which the applicant could not have planned. Examples include:
    1. An abrupt discontinuation of the supply of an active ingredient, packaging material, or container closure system.
    2. The relocation of a facility or a change in an existing facility because of a catastrophic event. (In the absence of a catastrophic event, the applicant should contact OGD early in the planning stage of a contemplated relocation or change.)

## 8. Submissions for “sole source” drug products

Submissions for drug products for which there is only one approved drug product listed in the Prescription Drug Product List (i.e., the “active section”) of the Orange Book and for which there are no blocking patents or exclusivities may receive a priority review, except when the approved drug product was approved pursuant to a suitability petition under section 505(j)(2)(C) of the FD&C Act.

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## RESPONSIBILITIES

- OGD RPMs and OPQ Regulatory Project Business Managers (RBPMs) will have the overall responsibility for applying the prioritization policy outlined in this MAPP to the review of specific submissions within OGD and OPQ.
  - OGD RPMs will coordinate the prioritization of OGD reviews with the OGD disciplines.
  - OGD RPMs will coordinate the prioritization of an original ANDA or supplement containing the quality review (chemistry, microbiology, etc.) with the OPQ RBPMs to ensure consistent prioritizations across offices.
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## PROCEDURES

- During a filing review within OGD, the OGD Division of Filing Review staff will identify submissions that request prioritization based on one of the criteria set forth in this MAPP and communicate that information to the relevant OGD staff, including the OGD RPM.
- Submissions that do not go through a filing review within OGD will be assessed for prioritization purposes at the time they are submitted, either by the OGD RPM or the OPQ RBPM. To ensure consistent reviews and prioritizations across offices, the OGD RPM and OPQ RBPM will communicate prioritization information to each another and to the relevant OGD and OPQ staff.
- During the filing review, OGD and OPQ staff may also identify submissions that appear to meet the criteria for prioritization set forth in this MAPP and will communicate that information to the relevant OGD RPM and OPQ RBPM.
- Determinations about prioritizing a review will not be made until a submission is received for review as discussed in 21 CFR 314.101(b).

- OGD RPMs will coordinate with the OGD Policy office, OGD review disciplines, and the OPQ RBPMs to ensure that submissions are prioritized according to this MAPP.
- FDA will only consider a priority request when (1) the submission and cover letter clearly state “Priority Review Requested” and reference the ANDA number (when applicable), (2) the basis for the request is consistent with this MAPP, (3) the applicant clearly and briefly states the basis of the request, and (4) the applicant includes sufficient supporting documentation for the request.

**DEFINITIONS**

**Expedited Review:** FDA will strive to act on an ANDA as soon as possible, including prior to the goal date if possible. An expedited review, though, does not result in a shorter goal date.

**Priority Review:** FDA will either (1) give a shorter goal date or (2) grant an expedited review.

**Shorter Goal Date:** In accordance with the GDUFA II Commitment Letter, FDA commits to one of the following (1) for original ANDAs, an 8-month goal date; (2) for major amendments, a 6- or 8-month goal date; or (3) for prior approval supplements, a 4- or 8-month goal date.

**EFFECTIVE DATE**

This MAPP becomes effective upon the date of publication and applies to all submissions, including those pending with FDA as of that date, unless otherwise noted.

**CHANGE CONTROL TABLE**

Effective Date	Revision Number	Revisions
08/01/2014	1	Updated to describe how the review of ANDAs, ANDA amendments, and ANDA supplements will be prioritized for review within OGD and OPQ.
03/07/2016	2	Updated to include the prioritization of sole source drug products, reflect the reorganization of OPQ, and revise certain forfeiture time frames consistent with FDASIA.

MANUAL OF POLICIES AND PROCEDURES

CENTER FOR DRUG EVALUATION AND RESEARCH

MAPP 5240.3 Rev. 4

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06/27/2017	3	Updated to include (1) the prioritization of generic products for which there are fewer than three ANDAs approved for the RLD and (2) certain external references.
Xx/xx/2017	4	Updated to revise responsibilities and procedures; modernize language; and add a new prioritization factor, prioritization policy, and definitions section.