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**POLICY AND PROCEDURES**

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**OFFICE OF GENERIC DRUGS****Communicating Abbreviated New Drug  
Application Review Status Updates with Industry**

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**PURPOSE**

This Manual of Policies and Procedures (MAPP) clarifies the general principles and certain procedures for communicating abbreviated new drug application (ANDA) review status updates with the applicant consistent with the commitments agreed to as part of the second reauthorization of the Generic Drug User Fee Amendments (GDUFA III).<sup>1</sup> This MAPP contains revisions to a prior version that reflected the general principles and procedures under the Generic Drug User Fee Amendments of 2017 (GDUFA II).<sup>2</sup>

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**BACKGROUND**

The Center for Drug Evaluation and Research (CDER) believes it is important to respond in a timely manner to applicant inquiries with respect to ANDA submissions. Before GDUFA, a wide range of generic drug program staff responded to a high volume of ad hoc inquiries from multiple representatives of applicants regarding the review status of their ANDA submissions, including the potential timing of FDA action. These responses

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<sup>1</sup> Generic Drug User Fee Amendments of 2022.

<sup>2</sup> Public Law 115-52.

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were resource intensive for FDA, and the review status information FDA provided applicants varied by generic drug program staff.<sup>3</sup>

Under GDUFA III, FDA agreed to provide timely ANDA review status updates for all pending ANDAs, in response to an applicant's periodic request, to further facilitate planning and to help ensure public access to affordable, quality generic medicines at the earliest legally available date.<sup>4</sup> FDA has also agreed to provide certain communications regarding deficiencies and actions, including with respect to imminent actions, major deficiencies, and delays in taking an action.<sup>5</sup>

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## **POLICY**

FDA will provide prompt and accurate responses to inquiries regarding review status from the applicants while maintaining appropriate confidentiality related to (1) other stakeholders in the generic review process, (2) the existence of and information contained in other ANDAs, and (3) information contained in a referenced Drug Master File. Generally, FDA should respond to inquiries within 2 business days of receipt.

FDA will communicate with applicants regarding their ANDA review status, including through the issuance of Information Requests (IRs) and Discipline Review Letters (DRLs)<sup>6</sup>, and provide applicants with an advance notification of regulatory correspondences (including Refuse-to-Receive Letters, Filing Acknowledgement Letters, any forthcoming action letter without disclosing whether that letter is an Approval Letter, Tentative Approval Letter, or CRL). Also, if an RPM learns that FDA is likely to miss the goal date for an ANDA, the Regulatory Project Manager (RPM) will notify the applicant of the delay in taking an action, identify the general reason for the delay including the outstanding discipline(s), if any, and the estimated time for FDA's action on the application. In addition, if the RPM learns that a major deficiency is likely forthcoming, the RPM will notify the applicant, but will not discuss the nature of the specific forthcoming deficiencies prior to the issuance of a CRL.

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<sup>3</sup> Under GDUFA I, to improve review efficiency and ensure consistency, the Office of Generic Drugs (OGD) issued MAPP 5200.3 *Responding to Industry Inquiries with respect to Abbreviated New Drug Applications in the Office of Generic Drugs* in September 2013, stating that OGD Regulatory Project Managers (RPMs) should field all applicant inquiries concerning the review status of submissions. That MAPP was revised in August 2015, changing the title to *Communications with Industry with respect to pre- GDUFA Year Three Abbreviated New Drug Applications* and setting forth the responsibilities and procedures for communications between FDA and applicants concerning the review status of pre-GDUFA I Year 3 submissions (i.e., applications not approved or withdrawn as of the close of business, September 30, 2014).

<sup>4</sup> See the definition of *review status update* in the GDUFA III Commitment Letter, section XI.C.

<sup>5</sup> See the GDUFA III Commitment Letter, available at <https://www.fda.gov/media/153631/download>, section II.B.6.

<sup>6</sup> Please see MAPP 5220.5 Rev. 2 Issuance of Information Requests and/or Discipline Review Letters for Abbreviated New Drug Applications for further information.

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With respect to imminent actions, FDA will promptly respond to applicant inquiries seeking information as to whether FDA intends to work through the goal date for an imminent action. These communications will be preliminary and subject to change.

FDA will disclose information related to an ANDA only to the applicants or to an alternate that the applicant identified to act on that ANDA in the absence of that applicant.

Communications described in this MAPP do not represent final FDA action.

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## **RESPONSIBILITIES**

- The OGD Division of Filing Review Project Managers communicate with the applicant during the filing review of ANDAs.
- The OGD Division of Project Management RPMs (in contrast to assessors, team leads, discipline project managers,<sup>7</sup> division directors, deputy division directors, other CDER management, or any other CDER staff) communicate with the applicant concerning the review status of ANDAs they manage on behalf of the generic drug program.
- Discipline project managers issue all non-quality related IRs and DRLs. The discipline project manager notifies the OGD RPM when issuing an IR or DRL when appropriate.
- Office of Pharmaceutical Quality (OPQ) Regulatory Business Process Managers (RBPMs) issue all quality-related IRs and DRLs. These RBPMs notify the OGD RPM when issuing an IR or DRL when appropriate.

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## **PROCEDURES**

1. For non-OPQ assessors, team leads, discipline project managers, division directors, deputy division directors, other CDER management, or any other CDER staff, refer all inquiries concerning the review status of a submission to the

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<sup>7</sup> The Division of Labeling Review (DLR) project managers and Office of Pharmaceutical Quality (OPQ) Regulatory Business Process Managers (RBPMs) communicate with the applicant concerning the review status of labeling-only and quality-only prior approval supplements (PASs) they manage on behalf of the generic drug program. (The DLR project managers manage labeling-only PASs, and OPQ RBPMs manage quality-only PASs.)

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OGD RPM for that submission. OPQ staff should refer all inquiries concerning the review status of the original submission to the OPQ RBPM.<sup>8</sup>

## **2. OGD DIVISION OF FILING REVIEW (DFR) PROJECT MANAGERS**

- a. Provide advance notification to the applicant that FDA will be sending the applicant a filing action letter without disclosing whether that letter is a Refuse-to-Receive Letter or a Filing Acknowledgement Letter.
- b. Issue Filing IRs. If the applicant raises concerns or seeks additional information regarding an anticipated Filing IR, the DFR Project Managers remind the applicant that they are providing advance informal notice as a courtesy and encourage the applicant to review the actual Filing IR upon receipt.
- c. Serve as the point of contact for questions from the applicant regarding Filing IRs.
- d. Document and archive communications with the applicant, including advance notifications of Filing IRs in the most recent administrative file for submission in the archival system.
- e. Provide a written notification to the applicant when a DFR Request for Reconsideration/Reclassification is granted or denied.

## **3. DISCIPLINE PROJECT MANAGERS AND OPQ RBPMS**

- a. Refer all non-IR or non-DRL inquiries related to an ANDA to the assigned OGD RPM.
- b. Discipline PMs, including OPQ RBPMS, should respond to inquiries regarding IRs/DRLs issued by their discipline.
- c. Issue IRs and/or DRLs, as appropriate, and provide notification to the OGD RPM of any such issuance.
- d. Document and archive telephone discussions and email communications with the applicant in the most recent administrative file for the submission in the archival system.

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<sup>8</sup> The DLR project managers and OPQ RBPMS will forward all requests regarding original ANDAs to the OGD RPM. For requests regarding labeling-only, quality-only PASs or Changes Being Effected, the DLR project manager or OPQ RBPM, respectively, will inform the applicant of the review status.

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- e. Provide a written notification to the applicant when a Request for Reconsideration/Reclassification<sup>9</sup> is granted or denied for discipline-specific prior approval supplements.<sup>10</sup>

**4. OGD RPMS**

- a. Notify any unauthorized inquirers that status inquiries should only be made by the applicant or their identified alternate.<sup>11</sup>
- b. Respond to inquiries from the applicant within 2 business days of receipt. If OGD RPMS anticipate being out of the office and that their absence may prevent them from responding within those 2 business days, the OGD RPMS should make arrangements to forward the applicant's inquiry to a colleague who will be able to respond within that time frame.
- c. May encourage the applicant to be proactive about their ongoing obligations with respect to received submissions. For example, the OGD RPM should encourage the applicant to ensure that all facilities are ready for inspection; that applications are updated in a timely manner to address labeling changes, product-specific guidances, or compendial changes; and administrative amendments (such as amendments concerning the impending expiration of a blocking patent or the favorable conclusion of patent litigation) are submitted in a timely manner.
- d. Communicate to the applicant that a newly filed ANDA or a reassigned ANDA has been assigned to them.
- e. Update the applicant concerning the status of relevant review disciplines at the time of the applicant's inquiry and advise the applicant that the update is *preliminary only and subject to change at any time*.
- f. If an RPM learns that a major deficiency is likely forthcoming, the RPM will notify the applicant. Per the GDUFA III Commitment Letter, the RPM is not expected to discuss the nature of the specific forthcoming deficiencies prior to issuance of the CRL.
- g. Document and archive inquiries about the review status of a specific

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<sup>9</sup> Please see the guidance for industry *ANDA Submissions – Prior Approval Supplements Under GDUFA* for further information.

<sup>10</sup> OGD RPMS will provide written notification to the applicant for Office of Bioequivalence-only PAs.

<sup>11</sup> FDA will not publicly disclose the existence of an ANDA before an approval letter or tentative approval letter is sent to the applicant, unless the existence of the application or abbreviated application has been previously publicly disclosed or acknowledged. See 21 CFR § 314.430. Responding to unauthorized inquirers could lead to disclosing the existence of an ANDA before approval or tentative approval, therefore, responses can only be provided to the applicant or their identified alternate.

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ANDA and/or other discussions regarding a specific ANDA in the most recent administrative file for the submission in the archival system.

- h. Collaborate with review disciplines and the applicant to schedule and conduct granted mid-cycle review meetings or enhanced mid-cycle review meetings.
- i. Provide advance notification to the applicant of any forthcoming action letter without disclosing whether that letter is an Approval Letter, Tentative Approval Letter, or CRL.
- j. Provide written notification to the applicant stating whether a request for a post-CRL clarification meeting or a post-CRL scientific meeting is granted or denied.
- k. Provide written notification to the applicant that the applicant's complete response to a CRL has been received.
- l. Issue the Approval Letter, Tentative Approval Letter, or CRL to the applicant.
- m. Provide a written notification to the applicant when a Request for Reconsideration/Reclassification is granted or denied for ANDAs, multidisciplinary PASs, or Office of Bioequivalence-only PASs.
- n. If an RPM learns that FDA is likely to miss the goal date for an ANDA, the RPM will notify the applicant of the delay in taking an action on or before the GDUFA goal date, identify the general reason for the delay including the outstanding discipline(s), if applicable, and the estimated time for FDA's action on the application if developing an accurate estimate is feasible.
- o. In response to an applicant inquiry regarding imminent action, update the applicant as to whether FDA intends to work through the goal date and advise the applicant that the update is *preliminary only and subject to change at any time*.
- p. Provide notification to the applicant within 14 days<sup>12</sup> of the date of an assessment classification change from Standard to Priority during the assessment of an ANDA, ANDA amendment, PAS, or PAS amendment.
- q. Provide written notification to the applicant when there is a change to the current assigned GDUFA goal date.

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<sup>12</sup> In this MAPP, unless otherwise specified, days means calendar days.

## **REFERENCES**

1. GDUFA Reauthorization Performance Goals and Program Enhancements, Fiscal Years 2023 through 2027.
  2. Guidance for industry *ANDA Submissions – Prior Approval Supplements Under GDUFA*.
  3. MAPP 5220.5 Rev. 2 *Issuance of Information Requests and/or Discipline Review Letters for Abbreviated New Drug Applications*.
  4. MAPP 5220.3 *Communicating Certain Deficiencies Identified During Filing Review of NDAs*.
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## **DEFINITIONS**

1. **Filing Information Request (Filing IR):** A correspondence sent to an applicant during the filing review of an ANDA that identifies nine or fewer minor filing deficiencies to be addressed for the ANDA to be considered substantially complete for discipline review.
2. **Information Request (IR):** A communication sent to an applicant during an assessment to request further information or clarification that is needed or would be helpful to allow completion of the discipline assessment.
3. **Discipline Review Letter (DRL):** A letter used to convey preliminary thoughts on possible deficiencies found by a discipline assessor and/or assessment team for its portion of the pending application at the conclusion of the discipline assessment.
4. **Mid-Cycle Review Meeting:** A meeting during which an applicant can ask for the rationale for any deficiency identified in the mid-cycle DRL(s), and/or ask questions related to FDA's assessment of the data or information in the ANDA. An applicant may not present any new data or information at this meeting.
6. **Enhanced Mid-Cycle Review Meeting:** A meeting in which the applicant has an opportunity to ask questions related to a proposed scientific path to address possible deficiencies identified in the mid-cycle DRL(s). An applicant may ask questions about potential new data or information to address any possible deficiencies identified in the mid-cycle DRL(s). FDA will discuss the data and

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information but will not provide substantive assessment of the data or information provided by the applicant at the meeting.

7. **OPQ Regulatory Business Process Managers (RBPMs):** OPQ Office of Program and Regulatory Operations staff who coordinate and manage quality discipline reviews.
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**EFFECTIVE DATE**

- This MAPP is effective upon date of publication.
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**CHANGE CONTROL TABLE**

Effective Date	Revision Number	Revisions
10/6/2017	Initial	N/A
10/5/2022	1	GDUFA III