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**POLICY AND PROCEDURES**

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**Office of Generic Drugs and Office of Pharmaceutical Quality**

**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<sup>1</sup> with the authorized representative for an ANDA applicant (Authorized Representative) in accordance with commitments made under the Generic Drug User Fee Amendments (GDUFA) of 2012 (GDUFA I),<sup>2</sup> as reauthorized and amended by the Generic Drug User Fee Amendments of 2017 (GDUFA II).<sup>3</sup>

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<sup>1</sup> This MAPP applies only to Food and Drug Administration (FDA) communications regarding ANDAs currently pending with the FDA. General inquiries specific to pre-ANDA submission requirements must be linked to a reference listed drug and should be submitted to the FDA in a controlled correspondence. Similarly, general, non-specific inquiries regarding ANDA post-approval submission requirements should be submitted to FDA in a controlled correspondence. See Guidance for industry *Controlled Correspondence Related to Generic Drug Development*.

<sup>2</sup> Public Law 112-144.

<sup>3</sup> Public Law 115-52.

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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 Food and Drug Administration (FDA) action. These responses were resource intensive for FDA, and the review status information FDA provided applicants varied by generic drug program staff. 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 Authorized Representatives 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).

Consistent with the GDUFA II Commitment Letter,<sup>4</sup> OGD is issuing this MAPP to promote consistency between pre- and post-GDUFA I Year 3 submissions and to streamline the FDA and applicant communications process.

Originally, one of the primary reasons for FDA to provide ANDA review status update communications to applicants was to provide them information regarding their pre-GDUFA I Year 3 submissions that could assist them with product launch and business planning in an effort to increase generic drug availability because these submissions lacked a GDUFA goal date. Under GDUFA II, FDA agreed to provide timely ANDA review status updates for all pending ANDAs, in response to an Authorized Representative's periodic request, to further facilitate planning and to help ensure public access to affordable, quality generic medicines at the earliest legally available date. These updates will span discipline and sub-discipline levels.<sup>5</sup>

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**POLICY**

FDA will provide prompt and accurate responses to any inquiry regarding review status from the Authorized Representative while maintaining appropriate confidentiality related to (1) other stakeholders in the generic review process, (2) the existence of and

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<sup>4</sup> See the GDUFA II Commitment Letter, available at <https://www.fda.gov/downloads/forindustry/userfees/genericdruguserfees/ucm525234.pdf>.

<sup>5</sup> See the definition of *review status update* in the GDUFA II Commitment Letter, see footnote 4, at 27.

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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), and provide applicants with an advance notification of regulatory correspondences (including Refuse-to-Receive Letters, Filing Acknowledgement Letters, Complete Response Letters (CRLs), Approval Letters, and Tentative Approval Letters).

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

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

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## RESPONSIBILITIES

- The OGD Division of Project Management RPMs (in contrast to reviewers, team leaders, discipline project managers,<sup>6</sup> division directors, deputy division directors, other CDER management, or any other CDER staff) communicate with the Authorized Representative 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 before issuing an IR or DRL only if the IR or DRL is being issued within 2 months of the goal date to confirm that an IR or DRL is appropriate.
- Office of Pharmaceutical Quality (OPQ) Regulatory Business Process Managers (RBPMs) issue all quality-related IRs and DRLs. These RBPMs notify the OGD RPM before issuing an IR or DRL only if the IR or DRL is being issued within 2 months of the goal date to confirm that an IR or DRL is appropriate.

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<sup>6</sup> The Division of Labeling Review project managers and Office of Pharmaceutical Quality (OPQ) Regulatory Business Process Managers (RBPMs) communicate with the Authorized Representative concerning the review status of labeling-only and quality-only prior approval supplements (PASs) they manage on behalf of the generic drug program. (The Division of Labeling Review project managers manage labeling-only PASs, and OPQ RBPMs manage quality-only PASs.)

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**PROCEDURES**

1. Reviewers, team leaders, 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 OGD RPM for that submission.<sup>7</sup>
  
2. **OGD Division of Filing Review (DFR) Project Managers**
  - a. Provide advance notification to the Authorized Representative 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 Authorized Representative raises concerns or seeks additional information regarding the anticipated Filing IR, the DFR Project Managers remind the Authorized Representative that they are providing advance informal notice as a courtesy and encourage the Authorized Representative to review the actual Filing IR upon receipt.
  
  - c. Serve as the point of contact for questions from the Authorized Representative regarding Filing IRs.
  
  - d. Document and archive all communications with the Authorized Representative, 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 Authorized Representative 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. Issue IRs and/or DRLs, as appropriate, and provide notification to the OGD RPM of any such issuance.
  
  - c. Document and archive all telephone discussions with the Authorized Representative in the most recent administrative file for the submission in the archival system.

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<sup>7</sup> The Division of Labeling Review project managers and OPQ RBPMs will forward all requests regarding original ANDAs to the OGD RPM. For requests regarding labeling-only or quality-only PASs, the Division of Labeling Review or OPQ, respectively, will inform the Authorized Representative of the review status.

- d. Provide a written notification to the Authorized Representative when a Request for Reconsideration/Reclassification<sup>8</sup> is granted or denied for discipline-specific prior approval supplements.<sup>9</sup>

#### 4. OGD RPMs

- a. Notify any unauthorized inquirers that status inquiries should only be made by the Authorized Representative or their identified alternate.
- b. Respond to inquiries from the Authorized Representatives 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 Authorized Representative's inquiry to a colleague who will be able to respond within that time frame.
- c. Encourage the Authorized Representative to be vigilant about their ongoing obligations with respect to received submissions. For example, the OGD RPM should encourage the Authorized Representative 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 Authorized Representative that a newly filed ANDA or a reassigned ANDA has been assigned to them.
- e. Update the Authorized Representative concerning the status of relevant review disciplines (including the facility status) at the time of the Authorized Representative's inquiry and advise that Authorized Representative that the update is *preliminary only and subject to change at any time*.
- f. Informally advise the Authorized Representative if a major deficiency is identified by a review discipline during a preliminary review, that a formal communication describing that major deficiency will likely be forthcoming. If the Authorized Representative raises concerns or seeks additional information regarding that major deficiency, the OGD RPM should remind the Authorized

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<sup>8</sup> Please see the guidance for industry *ANDA Submissions – Prior Approval Supplements Under GDUFA* for further information.

<sup>9</sup> OGD RPMs will provide written notification to the Authorized Representative for Office of Bioequivalence-only PASs.

Representative that the advance informal notice was provided to them as a courtesy and encourage the Authorized Representative to review the forthcoming formal communication upon receipt.

- g. Document and archive inquiries about the review status of a specific 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 Authorized Representative to schedule and conduct mid-review cycle meetings for complex products.
- i. Provide advance notification to the Authorized Representative of any forthcoming action letter without disclosing whether that letter is an Approval Letter, Tentative Approval Letter, or CRL.
- j. Advise the Authorized Representative whether a request for a post-CRL meeting is granted or denied.
- k. Provide written notification to the Authorized Representative that the applicant's complete response to a CRL has been received.
- l. Issue the Approval Letter, Tentative Approval Letter, or CRL to the Authorized Representative.
- m. Provide a written notification to the Authorized Representative when a Request for Reconsideration/Reclassification is granted or denied for ANDAs, multidisciplinary PASs, or Office of Bioequivalence-only PASs.

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## REFERENCES

1. Public Law 112-144.
2. Public Law 115-52.
3. Guidance for industry *Controlled Correspondence Related to Generic Drug Development*.
4. Draft guidance for industry *Formal Meetings Between FDA and ANDA Applicants of Complex Products Under GDUFA*.
5. Guidance for industry *ANDA Submissions – Refuse-to-Receive Standards* (Rev. 2).
6. Guidance for industry *ANDA Submissions – Prior Approval Supplements Under*

*GDUFA.*

7. MAPP 5220.3 *Communicating Certain Deficiencies Identified During Filing Review of ANDAs.*
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**DEFINITIONS**

1. **Authorized Representative:** Authorized point of contact identified in the applicant's U.S. Agent Appointment Letter or Form FDA 356h. An Authorized Representative may designate an alternate to act in the Authorized Representative's absence.
2. **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.
3. **Information Request (IR):** A letter sent to an applicant during an application review to request further information or clarification that is needed or would be helpful to allow completion of the discipline review.
4. **Discipline Review Letter (DRL):** A letter used to convey preliminary thoughts on possible deficiencies found by a discipline reviewer and/or review team for its portion of the pending application at the conclusion of the discipline review.
5. **Mid-Review Cycle Meeting:** A teleconference meeting with the applicant to discuss current concerns with the application and next steps. CDER will schedule a mid-review cycle meeting after the last key discipline has issued its IR and/or DRL for ANDAs that were the subject of prior Product Development Meetings or pre-submission meetings.
6. **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
10/6/17	Initial	N/A