POLICY AND PROCEDURES

Office of Generic Drugs and Office of Pharmaceutical Quality

Communications with Industry with respect to pre-GDUFA Year Three Abbreviated New Drug Applications

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PURPOSE

This Manual of Policies and Procedures (MAPP) clarifies the general principles and certain procedures for generic drug program staff communications with the authorized representative for an abbreviated new drug application (ANDA) applicant (the Authorized Representative) regarding pre-Generic Drug User Fee Amendments of 2012 (GDUFA) Year Three ANDA submissions (pre-Year 3 submissions).

BACKGROUND

The Center for Drug Evaluation and Research (CDER) believes it is important to timely respond to industry inquiries with respect to ANDA submissions. Prior to 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 and potential timing of FDA action on submissions (review status). This was resource intensive for the generic drug program staff, and the review status information FDA provided varied by generic drug program staff. To improve review efficiency and ensure consistency, the Office of Generic Drugs (OGD) issued MAPP 5200.3 in September 2013, stating that OGD Regulatory Project Managers (RPMs) should field all applicant inquiries concerning review status of submissions.

Due in part to stakeholder feedback, this revised MAPP substantially expands and sets forth responsibilities and procedures for communications between generic drug program staff and Authorized Representatives concerning the review status of pre-Year 3

submissions. The MAPP also discusses communications concerning Information Requests (IRs).

Although GDUFA requires FDA to take action on 90% of the submissions in the pre-GDUFA backlog cohort by September 30, 2017, individual pre-Year 3 submissions lack goal dates. This makes it hard for applicants to plan product launches and conduct other business planning that affects generic drug availability. To facilitate launch planning – and help ensure public access to affordable, quality generic medicines at the earliest legally available date – we intend to provide information concerning the review status of pre-Year 3 submissions down to the discipline and sub-quality discipline levels.

POLICY

Our policy is to provide prompt and accurate responses to any inquiry regarding review status from the Authorized Representative while maintaining appropriate confidentiality related to other stakeholders in the generic review process, including the existence of and information contained in other ANDAs and information contained in a referenced Drug Master File. Generally, inquiries should be responded to within two business days of receipt.

As set forth below, generic drug program staff will provide certain communications regarding review status, and advance notification of regulatory correspondences (including Refusal-to-Receive Letters, Filing Acknowledgement Letters, Complete Response Letters, Approval Letters, Tentative Approval Letters), IRs, and TADs.

None of the communications described in this MAPP may be construed as final agency action on an ANDA.

RESPONSIBILITIES

- The **OGD** Division of Project Management (DPM) **RPMs** (in contrast to reviewers, team leaders, discipline project managers, division directors, deputy division directors, other CDER management, or any other CDER staff) are responsible for communicating with the Authorized Representative concerning the **review status** of ANDAs they manage on behalf of the generic drug program.

- **Discipline Project Managers** are responsible for issuing **IRs and Easily Correctible Deficiencies (ECDs).** The discipline project manager is to notify the OGD RPM prior to issuing an IR/ECD to confirm that an IR/ECD is appropriate.

- **Office of Pharmaceutical Quality (OPQ) Regulatory Business Process Managers** (RBPMs) are responsible for issuing all **quality related IRs and ECDs**. When a TAD is closely approaching, the RBPM is to notify the OGD RPM prior to issuing an IR/ECD to confirm that issuing an IR/ECD is appropriate.

PROCEDURES

The following procedures should be used when responding to review status inquiries.

1. All FDA staff other than the OGD RPM for the submission
    a. Refer all inquiries concerning the review status of a submission to the OGD RPM for that submission.

2. Discipline Project Managers
    a. Refer all non-IR/ECD inquiries to the OGD RPM for that submission.
    b. Provide advance informal notification, by phone or email, of all anticipated IRs. If the Authorized Representative raises concerns or seeks additional information regarding the anticipated IR, remind the Authorized Representative that you are providing advance informal notice as a courtesy, and encourage the Authorized Representative to review the actual IR upon receiving it.
    c. Issue IRs/ECDs.
    d. Document and archive all discussions with the Authorized Representative, including advance notifications of IRs/ECDs, in the administrative file for the submission in the archival system.

3. Division of Filing Review Project Managers
    a. Provide advance notification that FDA will be sending applicant a filing action letter, without disclosing whether that letter is a Refusal-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, remind the Authorized Representative that you are providing advance informal notice as a courtesy, and encourage the Authorized Representative to review the actual Filing IR upon receiving it.
    c. Serve as the point of contact for questions from the Authorized Representative regarding Filing IRs.
    d. Document and archive all discussions with the Authorized Representative, including advance notifications of Filing IRs in the administrative file for the submission in the archival system.

4. OGD Regulatory Project Managers

    a. Should not disclose any information related to the ANDA to anyone other than the Authorized Representative or his or her alternate. If an OGD RPM receives an inquiry from an unauthorized representative, the OGD RPM should notify the unauthorized inquirer that status inquiries should only be made by the Authorized Representative or his/her identified alternate.

    b. Should respond to inquiries within 2 business days. If an OGD RPM anticipates an absence that might prevent him or her from responding to the Authorized Representative for 2 business days, he or she should make arrangements to forward the Authorized Representative's inquiry to a colleague who will be able to respond within 2 business days.

    c. When communicating with Authorized Representatives, OGD RPMs should encourage them to be vigilant about their ongoing obligations with respect to received submissions – for example, assuring that facilities are ready for inspection, that applications are timely updated to address labeling and compendial changes, and that administrative amendments are timely submitted concerning information such as the impending expiration of a blocking patent or the favorable conclusion of patent litigation.

    d. Communicate to the Authorized Representative that a newly filed ANDA has been assigned to him/her. Communicate to the Authorized Representative that a reassigned ANDA has been assigned to him/her.

    e. Communicate TADs in accordance with Center policy.

    f. Periodically update the Authorized Representative concerning the status of relevant review disciplines (including facility status) with respect to the submission *at that time*. Advise the Authorized Representative that the update is *preliminary only and subject to change at any time*.

    g. In response to a review status inquiry from the Authorized Representative, update the Authorized Representative concerning the status of relevant review disciplines (including facility status) *at that time*. Advise the Authorized Representative that the update is *preliminary only and subject to change at any time*.

    h. When managing submissions, if an OGD RPM learns that a major deficiency has been preliminarily identified by a review discipline, informally advise the Authorized Representative that a formal communication describing the major deficiency will likely be forthcoming. If the Authorized Representative raises concerns or seeks additional information regarding the forthcoming major deficiency, remind the Authorized Representative that you are providing advance informal notice as a courtesy, and encourage the Authorized Representative to review the forthcoming deficiency upon receiving it.

i. Document and archive inquires about the review status of a specific ANDA and/or other discussion regarding a specific ANDA in the administrative file for the submission in the archival system.

j. Directly before sending a signed Complete Response letter, provide notification of the forthcoming Complete Response letter to the Authorized Representative.

k. Provide notification to the Authorized Representative that a post-Complete Response teleconference or meeting request has been received and is being evaluated.

l. Advise the Authorized Representative whether a post-Complete Response teleconference or meeting is granted or denied. If a teleconference or meeting is granted, schedule and administer it.

m. Provide notification to the Authorized Representative that the applicant's complete response to FDA's Complete Response letter has been received.

n. Directly before sending a signed Approval Letter or Tentative Approval Letter, provide notification of the forthcoming letter to the Authorized Representative.

o. Issue the Approval Letter or Tentative Approval Letter to the Authorized Representative.

DEFINITIONS

Authorized Representative: Authorized point of contact identified in the applicant's letter of authorization or Form 356h. An Authorized Representative may designate an alternate to act in the Authorized Representative's absence.

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.

OPQ Regulatory Business Process Managers: OPQ Office of Program and Regulatory Operations staff who coordinate and manage quality discipline reviews.

Pre-GDUFA Backlog Submissions: Applications not approved or withdrawn as of October 1, 2012.

Pre-Year 3 Submissions: Applications not approved or withdrawn as of the close of business, September 30, 2014.

Target Action Date (TAD): An aspirational deadline for action on a pre-Year 3 submission. TADs are not GDUFA goal dates.

EFFECTIVE DATE

This MAPP is effective upon the date of publication.

CHANGE CONTROL TABLE

Effective Date	Revision Number	Revisions
8/17/15	Rev. 1	1. Revises title of the MAPP. 2. Revises responsibilities and procedures for communications between generic drug program staff and Authorized Representatives concerning the review status of pre-Year 3 submissions. 3. Discusses communications concerning IRs. 4. Adds definitions.