POLICY AND PROCEDURES

OFFICE OF GENERIC DRUGS

Evaluating Requests for and Conducting Product Development and Pre-Submission Pre-ANDA Meetings

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PURPOSE

This Manual of Policies and Procedures (MAPP) outlines the policies and procedures of the Office of Generic Drugs (OGD) and the Office of Pharmaceutical Quality (OPQ) for both:

- Evaluating requests from prospective abbreviated new drug application (ANDA) applicants (prospective applicants) for a product development or a pre-submission pre-ANDA meeting.[1]

- Conducting such meetings.

BACKGROUND

In the GDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2018-2022 letter (GDUFA II Commitment Letter),[2] the Food and Drug

[1] Product development and pre-submission meetings, which are both part of the pre-ANDA program at the Food and Drug Administration (FDA), are conducted before prospective applicants submit an ANDA. Mid-review-cycle meetings, which are also part of the pre-ANDA program, are for applicants who have submitted an ANDA and have participated in a product development or pre-submission meeting. This MAPP applies only to product development and pre-submission meetings and not to mid-review-cycle meetings.

[2] The GDUFA II Commitment Letter is available at https://www.fda.gov/media/101052/download.

Administration (FDA) committed to establish a program to, among other things, "clarify regulatory expectations for prospective applicants" and "assist [these] applicants to develop more complete [ANDA] submissions."[3] As part of this program, FDA agreed to conduct a series of meetings with prospective applicants within specific time frames.[4] The meetings relevant to this MAPP include both product development meetings and pre-submission meetings, which are intended to allow prospective applicants to discuss their development of these products before they submit an ANDA. In particular, for prospective applicants developing complex generic drug products:[5]

- Product development meetings provide an opportunity for these applicants to discuss specific issues or questions and for FDA to provide targeted advice regarding these applicants' ongoing ANDA development programs

- Pre-submission meetings provide an opportunity for these applicants to discuss and explain the format and content of the ANDA to be submitted

POLICY

A prospective applicant may request a product development or pre-submission meeting through email to the Office of Generic Drugs[6] or the CDER Next Gen Collaboration Portal (portal).[7] Once received, OGD and OPQ will evaluate the request and determine whether it should be granted or denied. If either OGD or OPQ or agree to grant the meeting request, the meeting will be held.

- **Criteria for Granting a Product Development Meeting Request**

FDA will grant a product development meeting if, in FDA's judgment, the prospective applicant's meeting package is complete and the requested meeting concerns either:

- The development of a complex product for which FDA has not issued a product-specific guidance[8]

[3] GDUFA II Commitment Letter at 14.

[4] See GDUFA II Commitment Letter at 16-17; Draft guidance for industry *Formal Meetings Between FDA and ANDA Applicants of Complex Products Under GDUFA* (October 2017) (Formal Meetings draft guidance) at 2. When final, this guidance will represent the FDA's current thinking on this topic. For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

[5] See the GDUFA II Commitment Letter for FDA's definition of a *complex product*.

[6] See Formal Meetings draft guidance at 7.

[7] The portal is accessible at https://edm.fda.gov/.

[8] Product-specific guidances describe FDA's "current thinking and expectations on how to develop generic drug products therapeutically equivalent to specific reference listed drugs." Product-Specific Guidances for

- An alternative equivalence evaluation (i.e., change in study type, such as clinical to in vitro)[9] for a complex product for which FDA has issued a product-specific guidance

FDA may grant a product development meeting, dependent on available resources, if:

- The requested meeting concerns complex product development issues other than those identified above (e.g., if FDA has developed a product-specific guidance and the prospective applicant is not proposing an alternative equivalence evaluation)

- FDA determines the prospective applicant's meeting package is complete and a controlled correspondence response would not adequately address the prospective applicant's questions

- A product development meeting would significantly improve ANDA review efficiency[10]

- **Criteria for Granting a Pre-Submission Meeting Request**

FDA ***will generally*** grant pre-submission meetings for prospective applicants that have had a product development meeting (i.e., face-to-face, teleconference or written response). FDA ***may*** grant a pre-submission meeting to a prospective applicant of a complex product that did not have a product development meeting if FDA decides the pre-submission meeting would improve the efficiency of the ANDA assessment.

- **Notification of the Meeting Request Decision**

If FDA decides to grant the meeting request, FDA will notify the prospective applicant via the portal that the meeting has been granted and will occur in the agreed-upon meeting format (i.e., a written response, a face-to-face meeting, or a teleconference).[11] If FDA decides to deny the meeting request, FDA will notify the prospective applicant via the portal that the meeting has been denied. The denial will state why the meeting has been denied and will generally provide a path forward for future communication with FDA (e.g., a controlled correspondence or a revised meeting package).

Generic Drug Development web page, available at https://www.fda.gov/drugs/guidances-drugs/product-specific-guidances-generic-drug-development.

[9] GDUFA II Commitment Letter at 15.

[10] Id.

[11] On occasion, a prospective applicant may request a written response, but FDA may determine that a face-to-face or teleconference meeting would promote discussion. If so, FDA may ask the prospective applicant to reconsider the original request for a written response.

PROCEDURES

OGD and OPQ[12] will evaluate requests for product development and pre-submission meetings and conduct these meetings by completing the following three stages.[13]

A. Stage 1

Within 14 calendar days from receiving the prospective applicant's meeting request, OGD and/or OPQ will complete the following actions.

1. The OGD Pre-ANDA Meeting Coordinator will perform a preliminary screening of the request to confirm that the prospective applicant:

    a. Included a pre-assigned ANDA number in the request

    b. Submitted a meeting package

2. Once the OGD Pre-ANDA Meeting Coordinator determines that the meeting package is acceptable for further assessment, he or she will assign the grant/deny assessment task to the Pre-ANDA Project Manager (Pre-ANDA PM) who will assign the meeting request assessment to the appropriate teams, which will consist of staff from OGD and OPQ.

3. The OGD and OPQ meeting request assessment teams will:

    a. Confirm the prospective applicant's eligibility for the product development or pre-submission meeting.

    b. Assess the meeting request and package, including the prospective applicant's proposed questions.

    c. Provide a recommendation on whether to grant or deny the request to the Meeting Project Manager (Meeting PM).[14]

        i. If the meeting is granted, the Meeting PM will send, via the portal, a letter (grant letter) indicating the grant decision

[12] The procedures in this MAPP generally apply to staff in OGD's Office of Research and Standards and OPQ's Immediate Office.

[13] The time frames for each stage are effective as of October 1, 2019.

[14] In general, the Meeting PM, who will manage meetings and communicate with the prospective applicants, will be from OGD.

and the agreed-upon meeting format to the prospective applicant.

ii. If the meeting is denied, the Meeting PM will send, via the portal, a letter indicating the denial (deny letter) to the prospective applicant, which generally provides advice on a path forward, and will close the meeting request project.

iii. If the meeting is granted but the request is withdrawn by the prospective applicant, the Meeting PM will send, via the portal, a letter confirming the withdrawal to the prospective applicant and will close the pre-ANDA meeting request project in the CDER Informatics Platform (the Platform).

B. Stage 2

Within 120 calendar days from granting the meeting request, OGD and/or OPQ will complete the following actions.

1. The meeting package assessment team[15] will convene and review the meeting package.

   If, during review of the meeting package, the meeting package assessment team identifies questions for the prospective applicant, the Meeting PM will send an information request, via the portal, to that applicant.

2. If a face-to-face or teleconference meeting will be held:

   a. The Meeting PM will send the prospective applicant a letter detailing the date and time of the meeting.

   b. The meeting package assessment team will prepare, before the meeting, preliminary comments, which are generally based on (1) FDA's current thinking and available information, (2) input from the involved disciplines, and (3) consultations with other offices/centers, as applicable.

   c. If the prospective applicant cancels the meeting before FDA issues the preliminary comments, the Meeting PM will close the pre-ANDA meeting project in the Platform without preparing and issuing the preliminary comments.

[15] The meeting package assessment team will include review staff from OGD, OPQ, and possibly other offices based upon the type of the proposed complex generic drug product and the questions included in the meeting package.

d. If the prospective applicant does not cancel the meeting before FDA issues the preliminary comments, the Meeting PM will send the preliminary comments, via the portal, to the applicant approximately 5 calendar days before the scheduled meeting.

e. If the prospective applicant cancels the meeting after receiving the preliminary comments, the preliminary comments will serve as the final response from FDA. The Meeting PM will close the pre-ANDA meeting project in the Platform.

f. If the prospective applicant does not cancel the meeting after receiving the preliminary comments, OGD and OPQ will meet with the prospective applicant.

3. If the meeting is granted as a written response, the meeting package assessment team will prepare the written response, which will serve as the final response from FDA.

   a. The Meeting PM will send that response, via the portal, to the prospective applicant.

   b. The Meeting PM will close the pre-ANDA meeting project in the Platform.

C. Stage 3

Within 30 calendar days from the face-to-face or teleconference meeting, the following actions will occur:

1. Within 7 calendar days from the face-to-face or teleconference meeting, the prospective applicant may submit, through the portal, its own post-meeting summary.

2. The Meeting PM will draft minutes of the meeting and circulate them, incorporating content, as appropriate, from any post-meeting summary submitted by the prospective applicant, to the meeting package assessment team, via the Platform, for review and comment.

3. The Meeting PM will send the final meeting minutes to the prospective applicant through the portal and the pre-ANDA meeting project will be closed in the Platform.

EFFECTIVE DATE

This MAPP is effective upon date of publication.

CHANGE CONTROL TABLE

Effective Date	Revision Number	Revisions
9/19/19	N/A	Initial

ATTACHMENT: Procedures for Evaluating Requests for and Conducting Product Development and Pre-Submission Pre-ANDA Meetings