

Office of Generic Drugs

Telephone Requests by the Divisions of Chemistry

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PURPOSE

This MAPP outlines the Office of Generic Drugs' (OGD) policy and procedures in the Divisions of Chemistry regarding telephone requests for clarification or additional information about chemistry, manufacturing and controls (CMC) during the review of original and supplemental abbreviated new drug applications (ANDAs) and drug master files (DMFs).

BACKGROUND

A chemistry reviewer often needs additional information or clarification to complete the review of an ANDA, an ANDA supplement, or an associated DMF. In some cases, requesting this information by telephone may expedite the review process. This MAPP describes how to determine with consistency when such requests are appropriate and how to document them.

There are two types of telephone communication:

- **Type 1 telephone communication:**

Clarification or location of information and/or data, but resulting in no immediate new submission from the applicant

- The reviewer may place a phone call to the applicant during the review of an application to obtain a needed explanation — that can be provided by telephone within 2 working days — to continue and finalize an initial review.
- To streamline FDA's document processing, no new submission is to be made by the applicant immediately following the telephone response.

- If, as a result of the telephone communication, the reviewer determines that there is missing and/or incorrect information in the application, this deficiency will be included as an item in a request for a major, minor, or telephone amendment upon completion of the review.
- If the review concludes without any additional deficiencies, another phone call is made to the applicant requesting a telephone amendment to correct any significant typographical errors or submit the missing information discussed during the initial call.
- **Type 2 telephone communication:**

Final resolution of technical issues at the team level, resulting in a telephone amendment

- This type of request for an amendment by telephone to resolve technical issues often follows the review of a minor amendment. It may also follow the review of a major amendment or an original ANDA.
 - Type 2 communication should be used when minor deficiencies can be resolved within 10 working days.
 - Reviewers should obtain team leader concurrence for Type 2 communication.
 - During the first review cycle, the division director or deputy division director should also concur for a Type 2 phone call.
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POLICY

- For **Type 1** telephone communication, the reviewer, at his or her discretion, will call the applicant during the review of an application for clarification and/or location of information and data to facilitate and complete the review documentation.
- For **Type 2** telephone communication, when a team leader determines that a telephone amendment is appropriate, the reviewer will communicate the appropriate request by telephone. Only if the applicant cannot be reached or fails to respond within 10 days should the request be communicated in writing.

The reviewer will notify the applicant during the telephone communication that the applicant will have 10 working days to respond to the information request. If the applicant does not respond within 10 days, the review will be finalized and closed by issuing written communication.

RESPONSIBILITIES

The chemistry reviewer will:

- Identify information needs that may be resolved by either a Type 1 or Type 2 telephone request
- Ensure that the Type 1 telephone request is documented electronically and by a hard copy filed in the application
- Seek team leader concurrence for making a Type 2 telephone request

The team leader will:

- Determine whether a Type 2 telephone request is appropriate
- Ensure consistent and appropriate use of the policy within the team for requesting telephone information

The division director or deputy division director will:

- Determine whether a Type 2 telephone request is appropriate in the first review cycle
- Ensure consistent and appropriate use of the policy within the division for requesting telephone information

The project manager will:

- Contact the applicant and take part in the telephone call when appropriate
- Ensure that a Type 2 telephone request is documented electronically and by a hard copy filed in the application

PROCEDURES

Type 1 telephone communication:

- The reviewer may call the applicant or DMF holder during the review of a submission for clarification or location of information or data. The reviewer should exercise discretion to avoid repeated calls to the firm.
- At the start of the telephone conversation, the reviewer will advise the applicant of the purpose of the call. The reviewer will also notify the applicant that if there are any deficiencies in the application, those deficiencies will be transmitted by the appropriate communication. Additional topics or issues will not be discussed during the telephone call.

- Upon completion of the telephone call, the reviewer will document the discussion electronically and by a hard copy filed in the application.

Type 2 telephone communication:

- When a telephone amendment is determined to be appropriate, the reviewer and/or team leader will contact the applicant by phone.
- Upon completion of a first review cycle, when a telephone amendment appears to be appropriate, the division director or deputy division director should provide concurrence before the call is placed.
- Upon completion of the telephone call, the reviewer or project manager should document the discussion electronically and by a hard copy filed in the application.

EFFECTIVE DATE

This MAPP is effective upon date of publication.
