OFFICE OF GENERIC DRUGS

TELEPHONE REQUESTS BY THE DIVISION OF BIOEQUIVALENCE

CONTENTS

PURPOSE

- This MAPP outlines the policy and procedures for making telephone requests for additional bioequivalence information during the review of abbreviated new drug applications (ANDAs) by Division of Bioequivalence (DBE) reviewers and project managers (PM).

BACKGROUND

- Bioequivalence reviewers often need additional information or clarification to be able to complete the review of an ANDA. Requesting this information by telephone expedites the review process, may eliminate a second review cycle, and possibly precludes the need for issuing a request by letter. This can reduce the workload of DBE. This MAPP describes when such requests are appropriate and how they are documented.

- Examples of minor deficiencies that can be addressed by a telephone request include:

  Missing lot numbers and expiration dates.

  Typographical errors.

  Information firms may have available but failed to submit or points that need clarification. This might include the names of primary investigators, a complete study protocol, or a copy of the standard operating procedures.

  Additional dissolution testing data resulting from a slight modification of a method (such as different speed or ½ tablet dissolution).

- In general, telephone requests should not require the applicant to generate new data. Examples of requests that are not appropriate to handle by telephone include:

  Development of a new dissolution method.

  Additional bioequivalence studies.

  A large number of complex issues requiring clarification.

POLICY

- When a reviewer identifies a need for information that can be resolved by a telephone request, the reviewer must obtain concurrence from the team leader that a telephone request is appropriate.

- The Project Manager (PM) attempts to communicate appropriate requests by telephone.

- Applicants are notified during the telephone conversation that they have 10 working days to respond to the information request. After 10 days without a response, the review is finalized and closed by issuing a standard deficiency letter.

RESPONSIBILITIES

- Bioequivalence Reviewers

  Identify a need for information that can be resolved by a telephone request.

  Seek team leader concurrence for making a telephone request.

  Communicate the decision to the PM so the applicant can be contacted.

- Team Leader/Deputy Division Director/Division Director

  Concurs, if appropriate, with the determination to make a telephone request.

  Discusses any nonconcurrence with the reviewer.

  Ensures consistent and appropriate use of the policy for requesting information by telephone.

- Project Manager

Contacts the applicant on behalf of the reviewer.

Documents the content of the telephone request and files electronic and hard copies of the documentation.

Monitors the 10 working day response time.

Initiates closing the review and forwards the written request to the review support staff to process by fax when the applicant does not meet the 10-day time frame.

PROCEDURES

- To avoid repeated calls to the firm, the DBE reviewer should complete the review to the extent possible and identify all issues that might be resolved by telephone before initiating the request.

- The reviewer communicates the need for a telephone request for information to a PM with concurrence by the team leader.

- The DBE PM calls the applicant to request the information. This is done in the presence of the reviewer and/or team leader. During the telephone conversation, the applicant will be advised to clearly identify the resulting submission as a ***bioequivalence telephone amendment*** in the cover letter. The PM also emphasizes to the applicant that the response must be received in 10 working days. If the response is not received within 10 days, the bioequivalence review is finalized and comments will be issued in writing.

EFFECTIVE DATE

This MAPP is effective upon date of publication.