

**Office of Generic Drugs**

---

**Reassignment of Bioequivalence Reviews**

---

**CONTENTS**

**PURPOSE**

**BACKGROUND**

**POLICY**

**RESPONSIBILITIES**

**EFFECTIVE DATE**

**ATTACHMENT – A**

---

**PURPOSE**

- This MAPP explains the procedures for transferring the review of a submission from one reviewer to another in the Division of Bioequivalence (DBE) to prevent a delay in completing that review.
- 

**BACKGROUND**

- It is DBE policy to assign abbreviated new drug applications (ANDA) and related documents (generic drug submissions) to bioequivalence reviewers according to the Office of Generic Drugs random assignment policy. Reviewers are occasionally unable to review an assigned submission in a timely manner. This may be due to the reviewer's unexpected absence, a planned extended absence, or the need to work on a top priority special assignment. In such instances, the reassignment procedures outlined in this MAPP should be followed.
- 

**POLICY**

- If at any time a reviewer is unable to initiate or complete the review of a bioequivalence application, amendment, or other review assignment within a specified time period, it should be reassigned to the next available reviewer according to the schedule below.
-

<u>Generic Drug Submission Status</u>	<u>Time Reviewer Unavailable</u>
Original application	2 weeks (or more)
Major amendment	2 weeks (or more)
Minor amendment	1 week
FAX amendment	1 week
Telephone amendment	1 week

The need for reassignment will be determined by the status of the submission and the period of time that the reviewer will be unavailable. If the reviewer has been able to complete a draft review, it is left to the discretion of the team leader whether to complete the review instead of reassigning it. If a team leader completes the review, another team leader or the deputy division director should do the secondary review.

The reassignment determination and rationale must be documented in a memorandum to the file of the reassigned application (see Attachment A).

## RESPONSIBILITIES

### Division Director

- ! Concurs in reassignments, when appropriate, by signing the Application Reassignment Authorization Form (see Attachment A).

### Team Leader

- ! Monitors work queues and reviewer absences to determine if reassignment is appropriate. Alerts Division Director to the need for reassignment of review work.
- ! Prepares the Application Reassignment Authorization Form, stating the reason for the reassignment, and obtains the Division Director's concurrence and signature on the form.
- ! Forwards signed memorandum to the DBE Project Manager.
- ! Provides secondary review for work reassigned to any member of the team.

### DBE Project Managers

- ! Maintain the DBE review queue and related files.
  
  - ! Change the computer management information system (OGD MIS) to reflect reassignments and forward the signed authorization form to the document room for filing.
  
  - ! Place a copy of the form in the DBE Reassignment Authorization File.
- 

**EFFECTIVE DATE**

This MAPP is effective upon date of publication.

ATTACHMENT A

APPLICATION REASSIGNMENT AUTHORIZATION FORM  
OFFICE OF GENERIC DRUGS

ANDA #	DRUG	FIRM

1. REASSIGN FROM: \_\_\_\_\_

DATE OF ORIGINAL ASSIGNMENT: \_\_\_\_\_

2. DATE OF REASSIGNMENT: \_\_\_\_\_

REASON FOR REASSIGNMENT: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_ DATE: \_\_\_\_\_  
TEAM LEADER (SIGNATURE)

\_\_\_\_\_ CONCUR: \_\_\_\_\_ NOT CONCUR: \_\_\_\_\_  
BIOEQUIVALENCE DIVISION  
DIRECTOR (SIGNATURE) DATE: \_\_\_\_\_

A COPY OF THIS FORM SHOULD BE PLACED IN EACH APPLICATION AND IN THE DIVISION FILE