Office of Review Management

Processing an Electronic New Drug Application

CONTENTS

PURPOSE

This MAPP describes the procedures involved in processing an electronic new drug application (NDA).

BACKGROUND

An applicant can submit some or all of the archival copy of an NDA in electronic format. This MAPP describes the steps for processing an NDA with an electronic component. [1]

REFERENCES

- *Guidance for Industry: Providing Regulatory Submission in Electronic Format — General Considerations*
- *Guidance for Industry: Providing Regulatory Submission in Electronic Format — New Drug Applications*

[1] These procedures are discussed in more detail in the guidance for industry on *Providing Regulatory Submission in Electronic Format – New Drug Applications.*

DEFINITIONS

The different types of submissions to the NDA and the corresponding electronic folder names are summarized in the following table. Aside from the original NDA and new correspondence, subsequent submissions are numbered sequentially.

Submission type	Folder name
Original NDA	N_000
All New correspondence	C_000
Initial presubmission	M_000
First periodic safety report	P_001
First supplement	S_001
First annual report	Y_001

POLICY

- All NDAs with an electronic component are processed through the Central Document Room (CDR).

- NDAs with electronic components are maintained in the Electronic Document Room (EDR).

RESPONSIBILITIES

- **Central Document Room**

  - Receive the NDA submission with electronic components from the applicant
  - Enter submission data into COMIS
  - Send the paper portion of the submission to the appropriate Division Document Room (DDR). If there is no paper portion, send cover letter and 356h form
  - Send the electronic component to the EDR

- **Electronic Document Room**

  - Load the submission onto the server

- Update the electronic document room
- Inform the assigned project manager and reviewers of the submission
- Check submission for consistency with guidance for electronic submissions
- Create archive tapes of the electronic submission
- Save media sent by applicant
- Following approval or withdrawal of the submission, or if the submission has been inactive for 1 year following an FDA action letter, remove applicable sections from the server
- Reinstate a previously removed submission section from an archive tape upon request

- **Division Document Room**

  - Receive and process the paper component of the NDA in accordance with standard operating procedures
  - Update the submission data in COMIS as directed by the project manager (PM) and inform EDR of any changes
  - Update the assignment table in COMIS as directed by the PM

- **Project Managers (PM)**

  - Inform DDR of any corrections to assignments or submission data in COMIS
  - Inform additional reviewers of submission as needed

PROCEDURES

- **Central Document Room**

  - Receive the NDA with electronic components from the applicant
  - Enter submission data into COMIS
  - Make copies of the cover letter and 356h form
  - If amendment, supplement, or amendment to supplement, call appropriate DDR for volume number and document coding; if electronic components are present, the CDR will enter this data immediately into COMIS.
  - Send the original cover letter, 356h form and any paper portion of the submission to the appropriate DDR
  - Send the electronic component to the EDR with copies of the cover letter and 356h

- **Electronic Document Room**

    - Obtain reviewer assignments from assignment table in COMIS
    - Phone DDR for NDA reviewer assignments, if not in assignment table
    - Determine if submission can be archived
    - Load archival submission onto staging server
    - Check for data integrity
    - Review for consistency with guidance for electronic submissions
    - Notify PM, or supervisory project manager if PM is not available, of any problem with submission as received, including unreadable media, problems with electronic archival criteria, and archival status
    - Load the conforming submissions onto the EDR server, following the folder naming convention:
        - First level = NDA number
        - Second level = submission type
        - Third level = amendment or correspondence submission date
        - Fourth level = amendment content
- Update the electronic document room submission database
- E-mail the assigned PM and the appropriate assigned reviewers of submission:
    - All reviewers if only summary or labeling folder
    - Chemistry reviewer if cmc folder
    - Pharmtox reviewer if pharmtox folder
    - Biopharm reviewer if biopharm folder
    - Medical officer and statistician if clinstat folder
    - Microbiology reviewer if micro folder
- Create the archive tapes of the electronic submission
- Save the media sent by the applicant
- Three months following approval or withdrawal of an NDA or if an application has been inactive for 1 year following an action letter:
    - After E-mailing appropriate PM, remove the submission from the server except:
        - ndatoc.pdf
        - 356h.pdf
        - cover.pdf
        - summary folder and contents
        - labeling folder and contents
        - chemistry section
    - Update the EDR to show submission has been removed and provide an automated means to request submission to be reinstated.
- Reinstate the submission from the archive to the server following a request
- Track reinstated submissions so they can be removed when no longer needed

Division Document Room

- Receive and process the paper component of the NDA
- Update the COMIS assignment table as directed by the PM
- Update any changes to document classification as directed by PM
- Notify EDR if any changes are made

- **Project Manager**

  - Notify the DDR of corrections/additions of assigned NDA reviewers as needed
  - Inform additional reviewers on availability of submission as needed
  - Contact applicant if submission cannot be archived

EFFECTIVE DATE

This MAPP is effective upon date of publication.