
Manual of Standard Operating Procedures and Policies

Regulatory - Communication

Handling of Regulatory Faxes

SOPP 8113

Version #1

October 15, 2007

1. Purpose

The purpose of this SOPP is to describe the policies and procedures for the Center for Biologics Evaluation and Research (CBER) staff on the handling of regulatory facsimiles (faxes) received from or sent to sponsors/applicants.

Incoming facsimiles will ordinarily contain responses to information requests or meeting requests related to specific existing submissions, e.g., IND, BLA, 510(k), PMA, IDE or to pre-application submissions.

Outgoing facsimiles could be letters such as notifications that an action was taken, telecon/meeting minutes, review comments, or preliminary meeting comments, for example, answers to questions asked in a meeting package from a sponsor/applicant.

2. Definitions

Regulatory Facsimile

A regulatory facsimile is an electronic transmission of an exact copy of a firm's formal correspondence including content, formal CBER address, applicant signature, appropriate FDA forms, etc. that would have been mailed to the CBER Document Control Center (DCC) as part of an investigational or marketing application or pre-application.

Administrative Record

All documents and data that together represent the activity, substantive communication, and basis for decision-making related to an investigational or marketing application. Administrative records include sponsor/applicant submissions, CBER-generated documents, and CBER database records. Administrative records may also be referred to as administrative files.

3. Background

Increasing overall review efficiency was a significant component of the Prescription Drug User Fee Act (PDUFA) at its inception. Additional efforts to increase review efficiency, including the Medical Device User Fee Modernization Act (MDUFMA), PDUFA reauthorizations, development of electronic submission infrastructure such as the CBER Electronic Document Room (EDR) and the Agency Electronic Submission Gateway (ESG), necessitate streamlining the review process steps.

This streamlining in no way mitigates our responsibility to maintain a complete and accurate administrative record ensuring that all our actions are appropriately documented. The Office of Chief Counsel (OCC), Food

and Drug Administration (FDA) determined that facsimiles are legal documents acceptable as regulatory documents upon which decisions can be made and transmitted. The OCC advised that CBER should follow the guidelines in 21 CFR 601.14.

4. Policy

It is CBER policy that incoming regulatory facsimiles:

1. Will be treated as official correspondence and will be entered into the administrative record and regulatory database
if CBER either requests the facsimile or the sponsor/applicant and CBER reached an agreement on the acceptance of the facsimile as the official document.
 - a. Faxes received that were not requested or agreed to will not be acknowledged as part of the administrative record for the submission. Regulatory decisions/actions will **not** be made on the basis of these types of facsimiles.
2. Will not be accepted by CBER in lieu of submitting a formal initial/original investigational or marketing submission.
3. Should be sent to the following CBER personnel who will be responsible for the further processing of incoming facsimiles:
 - a. the Regulatory Project Manager (RPM) in the appropriate product Application Division, or
 - b. the Division of Manufacturing and Product Quality (DMPQ) in the Office of Compliance and Biologics Quality (OCBQ) or
 - c. Consumer Safety Officer (CSO) in the Advertising and Promotional Labeling Branch (APLB)/Division of Case Management (DCM/OCBQ), or the
 - d. Regulatory Management Staff in the Office of Cellular, Tissue, and Gene Therapies (OCTGT).
4. The FDA/CBER receipt date will be the date acknowledged by CBER staff. In most cases this date will be consistent with the date on the facsimile. The facsimile must be received before 4:30 PM (16:30) EST(DST) on a regular business day in order for the received date to be the same date. If the facsimile is received after that time or on a non-business day, the receipt date will be the next business day.
5. If CBER receives a facsimile that is incomplete or cannot be read, the sponsor/applicant will be notified by phone within one working day of receipt. CBER and the sponsor/applicant will reach a decision on whether the facsimile should be resent or the response should be submitted in hard copy.
6. The facsimile submission should be complete. It cannot be a partial submission with additional pages on a subsequent facsimile.
7. Facsimiles with color original photos or graphics will not be accepted.

5. Responsibilities and Procedures

Incoming Regulatory Facsimiles

1. When a sponsor/applicant is requesting to communicate with CBER via facsimile the RPM must instruct the firm that:
 - The facsimile must be an exact copy of the firm's formal correspondence that would have been mailed to the CBER Document Control Center (DCC), including content, formal CBER address, applicant signature, appropriate FDA forms etc.
 - The facsimile must be sent only to the RPM in the appropriate product Application Division, DMPQ/OCBQ, or APLB/DCM/OCBQ or the Regulatory Management Staff in OCTGT to ensure records management integrity.
 - If a CBER reviewer other than the RPM agrees with a sponsor/applicant to communicate via facsimile, that person is responsible for notifying the RPM immediately of the decision.

NOTE: If a facsimile is sent to a reviewer rather than an RPM, then the CBER facsimile recipient is obligated to immediately transmit a copy to the RPM for processing. If the CBER recipient does not notify the RPM, that person is responsible for all administrative processing including data entry in the appropriate CBER regulatory database and distribution of all copies.

2. The RPM (or designee) receiving the facsimile should, within one working day of receipt,

- Review the incoming facsimile to determine its acceptability as outlined in Section 4 of this SOPP.
- Review the document to determine the regulatory action to be taken based on the content, e.g., resubmission, response to a clinical hold, meeting request, response to Complete Response Letter, requested information or revisions.
- The official received date of the facsimile is the date the facsimile is acknowledged as received by CBER. The official received date will be entered in the database the same as for a DCC received document.
- Enter the facsimile in the appropriate database and identify the submission as a facsimile.
 - RMS-BLA: A Document Accountability and Tracking System (DATS) number is not needed to enter the facsimile into the regulatory database. However, a DATS number is needed to create a second level STN.
 - BIRAMS: Per the DCC procedure guide, the receiving office will provide DCC with copies of the fax. As part of DCC processing, a BIRAMS number (usually an amendment number) as well as a DATS number will be assigned. The receiving office can then characterize the submission as a facsimile.
 - BLT: a DATS number is not needed to enter the facsimile into the regulatory database.
- Refer to DCC Procedure Guide #21: Process for Handling Faxed Documents for IRA and Marketing Submissions for details on obtaining a DATS number and further processing of all incoming faxes. The RPM will provide copies to the reviewers.

Note: Even though the official receipt date is the date CBER acknowledges receipt, the sponsor/applicant will be aware of when the facsimile arrived based on their facsimile records. It is imperative that processing of the facsimile be completed as soon as possible.

3. Follow-up hard copies:

- **Hard copies of documents faxed to CBER are not necessary and are to be discouraged.**
- If a firm decides to send in a hard copy once a facsimile is received, the subsequent hard copy will be treated as a new submission, e.g., new amendment.
- When a hard copy is received in the DCC, DCC will stamp the hard copy with the date on which the hard copy is received in the DCC and distribute one copy to the RPM unless more copies are requested.
 - The RPM is responsible for ensuring the facsimile and the hard copy are the same document.
- The hard copy will receive a DATS Log Number and must also receive an appropriate submission number, for example, an RMS-BLA third level number or IND/IDE amendment number.
 - Both the hard copy and the facsimile are included in the administrative record. As such, both the facsimile and the hard copy must be filed in DCC following the procedures for the appropriate submission type.
 - For the purposes of formal decision-making and the administrative record, when both a facsimile and hard copy of the same document are received, the actual document used to make a regulatory decision will be documented in the review memo/database summary by the reviewer as follows: *Fax/Hard Copy used by (name of reviewer) as the (a) basis of my "discipline review memoranda" dated XX/XX/XX.*

Outgoing Regulatory Faxes

- Outgoing facsimiles could be letters such as notifications that an action was taken, telecon minutes, review comments that are not hold issues, or preliminary meeting comments, for example, answers to questions asked in a meeting package from a sponsor/applicant.
 - With the exception of regulatory action letters, once a facsimile is sent to a sponsor/applicant, a hard copy will **not** be sent to the sponsor/applicant unless requested by the sponsor/applicant. **All regulatory action letters will be mailed to the sponsor/applicant.**
 - The facsimile will be included in the administrative record.
 - The outgoing facsimile should be entered in the appropriate regulatory database. The outgoing facsimile will be entered under the document type rather than "fax," for example,

letter, memo, meeting minutes, etc. Depending on the regulatory database, a telecon may need to be entered with the notation that a facsimile was sent. The “fax” indication should be noted in the Comments field.

- The date of the outgoing facsimile and the date the action was taken should be the same. If there is a difference, the date the action was taken is the date to be entered in the appropriate regulatory database.

6. References

21 CFR 601.14

DCC Procedure Guide #21: Process for Handling Faxed Documents for IRA and Marketing Submissions

7. Effective Date

This SOPP is effective immediately upon posting on CBER’s Internet.

8. History

Written/Revised	Approved	Approval Date	Version Number	Comment
RMCC	Robert A. Yetter, OHD	October 9, 2007	1	First issuance of this SOPP

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