SOPP 8113: Handling of Regulatory Faxes in CBER

Version #2

Effective Date: May 18, 2015

I. Purpose

This Standard Operating Policy and Procedure (SOPP) provides guidance to the Center for Biologics Evaluation and Research (CBER) staff on the handling of regulatory facsimiles (faxes) received from or sent to sponsors/applicants.

II. Scope

This SOPP applies to incoming and outgoing faxes related to specific existing regulatory submissions: **pre-submissions, investigational, marketing, and post-marketing submissions.**

III. Background

The Office of Chief Counsel (OCC), Food and Drug Administration (FDA) determined that faxes are legal documents acceptable as regulatory documents upon which decisions can be made and transmitted. These documents must be in a form that FDA can process, review, and archive (21 CFR 601.14). OCC has determined that CBER can decide what submission type or criteria can be used for accepting such regulatory faxes.

IV. Definitions

A. Regulatory Facsimile (fax) - An electronic transmission of an exact copy of incoming or outgoing formal correspondence between FDA and a sponsor/applicant.

B. Administrative Record - The documents in the administrative file of a particular administrative action on which the Commissioner relies to support the action (21 CFR 10.3). Administrative records include sponsor/applicant submissions, CBER/FDA generated documents, and CBER/FDA database records.

V. Policy

A. It is CBER policy that incoming regulatory faxes for pending submissions:

1. Are treated as official correspondence and entered into the administrative record and the appropriate regulatory database if CBER either requests the fax or the sponsor/applicant and CBER reached an agreement on the acceptance of the fax as the official document.

a. Faxes that are not requested or agreed to as part of the administrative record for the submission may not be accepted. Regulatory decisions/actions will **not** be made on the basis of these types of faxes.

b. Incoming faxes should include the content, formal CBER address, sponsor/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.

2. Are not accepted by CBER *in lieu* of submitting a formal initial/*original* investigational or marketing submission.

3. Are not accepted by CBER for any eCTD submissions or for medical device eCopies.

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 fax. The fax must be received before 4:30 PM EST (DST) on a regular business day in order for the received date to be the same date. If the fax is received after that time or on a non-business day, the receipt date will be the next business day.

5. The faxed submission should be complete. It should not be a partial submission with additional pages on a subsequent fax.

6. The faxed submission should be readable. Faxes with color original photos or graphics will not be accepted.

7. The sponsor/applicant will be notified by phone within one business day of receipt if CBER receives incomplete or illegible faxes. CBER and the sponsor/applicant will reach a decision on whether the fax should be re-sent or the response should be submitted in another format, for example, electronic or hard copy.

8. Follow-up copies of documents faxed to CBER are discouraged; they are not necessary.

a. Any subsequent follow up documents sent in by a firm once a fax is received are treated as a new submission, e.g., new amendment.

b. The follow-up paper copy will receive a CBER tracking Document Accountability and Tracking System (DATS) Number, and must also receive an appropriate submission number, for example, an RMS-BLA third level number or IND/IDE amendment number.

i. Both the follow-up copy and the fax are included in the administrative record. As such, both the fax and the follow-up copy must be filed in DCC following the procedures for the appropriate submission type.

ii. For the purposes of formal decision-making and the administrative record, when both a fax and follow-up 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/Follow-up Copy used by (name of reviewer) as the (a) basis of my "discipline review memoranda" dated XX/XX/XX.*

9. If a fax is sent to anyone other than the RPM assigned to the file, then the CBER fax recipient is obligated to transmit a copy to the RPM for processing. If the CBER fax recipient does not notify the RPM, that person is responsible for all administrative processing including data entry in the appropriate regulatory database, and distribution of all copies.

B. It is CBER policy that outgoing regulatory faxes for pending submissions:

1. Are treated as regulatory communications 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.

2. With the exception of regulatory action letters and lot release notifications, once a fax is sent to a sponsor/applicant, a hard copy will **not** be sent unless requested by the sponsor/applicant. **All regulatory action letters will be mailed to the sponsor/applicant.**

3. All regulatory communications not followed-up by a hard copy will be treated as official correspondence, and entered as part of the administrative file.

VI. Responsibilities

A. Regulatory Project Manager (RPM) or Designee - works with the sponsor/applicant on submitting their fax. The RPM enters the fax in the appropriate regulatory database, and ensures that the fax and the follow-up copy are the same document (if the sponsor/applicant submits a follow-up copy).

B. Document Control Center (DCC) - receives and processes incoming submissions.

C. Review Committee Members - reviews the fax to determine its adequacy and the regulatory action to be taken based on the content.

VII. Procedures

A. Incoming Regulatory Facsimiles (faxes)

1. Instructs a firm requesting to communicate with CBER via *incoming* regulatory fax that the fax must be an exact copy of the firm's formal correspondence that would

have been mailed to the CBER DCC. The fax must include content, formal CBER address, applicant signature, appropriate FDA forms, etc. **[RPM]**

2. Instructs the firm to send the fax directly to the RPM or regulatory point of contact in the appropriate CBER Office/Division **[RPM]**

3. Notifies the RPM or regulatory point of contact if an agreement was reached with the sponsor/applicant to communicate via fax **[Review Committee Member]**

4. Reviews the incoming fax within one business day of receipt to determine its adequacy as outlined in Section V of this SOPP **[Review Committee Member]** NOTE: Even though the official receipt date is the date CBER acknowledges acceptability of the fax, the sponsor/applicant will be aware of when the fax arrived based on their fax records. It is imperative that processing of the fax be completed within one business day.

5. Data Entry: **[RPM or Designee]**

a. Enters the fax into the appropriate regulatory database under the appropriate document type, e.g., resubmission, response to a clinical hold, meeting request, response to Complete Response Letter, requested information or revisions.

b. Refers 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.

6. Follow-up copies of documents:

a. Note: Any subsequent follow-up documents sent in by an applicant/sponsor once a fax is received, is treated as a new submission, e.g., new amendment.

b. Ensures that the follow-up copy receives a DATS Log Number and an appropriate submission number, for example, an RMS-BLA third level number or IND/IDE amendment number **[DCC]**

c. Ensures that both the follow-up copy and the fax are included in the administrative record. As such, both the fax and the follow-up copy are filed in DCC following the procedures for the appropriate submission type **[DCC]**

d. Documents in the review memo and appropriate regulatory database summary the document used to make the regulatory decision, if a fax and follow-up copy of the same document are received **[Review Committee Member]**

B. Outgoing Regulatory Facsimiles (faxes)

1. Faxes information to the sponsor/applicant **[RPM]**

    a. Do not mail a hard copy of the document to the sponsor/applicant except for regulatory action letters and lot release notifications.

    b. Do not fax documents to a sponsor/applicant from a fax machine other than an FDA machine. Note: one point of verification for the receiver to know it was submitted from the FDA is from the transmission (FDA fax).

2. Includes the fax in the administrative record **[RPM]**

3. Enters the outgoing fax in the appropriate regulatory database. **[RPM or designee]**

    a. Enters the outgoing fax under the document type rather than "fax," for example: letter, memo, meeting minutes, etc. Depending on the regulatory database, enter a communication with the notation that a fax was sent. Enter the notation of "fax" in the Comments field.

    b. Ensures the date of the outgoing fax and the date the action was taken are entered

    c. Note: Follow the appropriate regulatory database User Guide for data entry procedures.

VIII. Appendix

N/A

IX. References

A. References below are located on CBER's Intranet Web Page (unless otherwise noted)

1. DCC Procedure Guide #21: Process for Handling Faxed Documents for IRA, Marketing and Pre-Application Submissions

2. DCC Procedure Guide #22: Procedure for Processing, Routing, and Storing Electronic Submissions

B. Web links to the references below can be found in the list following the History Table.

1. Draft Guidance for Industry: Providing Regulatory Submissions in Electronic Format--Annual Reports for New Drug Applications and Abbreviated New Drug Applications – **August 2003**

2. Guidance for Industry: Providing Regulatory Submissions to CBER in Electronic Format - Investigational New Drug Applications (INDs) – **March 2002**

X. History

Written/ Revised	Approved By	Approval Date	Version Number	Comment
Yvette Coleman-Cheng/ ADRM	Chris Joneckis, PhD	May 7. 2015	2	Revised to update procedures
RMCC	Robert A. Yetter, PhD	October 9, 2009	1	First Issuance of this SOPP