

SOPP 8117: Issuing Tracking Numbers in Advance of Electronic Submissions in eCTD Format

Version: 4

Effective Date: October 1, 2018

I. Purpose

- A.** This Standard Operating Policy and Procedure (SOPP) serves as a guide for the Center for Biologics Evaluation and Research (CBER) staff on issuing a tracking number in advance of receiving an electronic submission in Electronic Common Technical Document (eCTD) format.

II. Scope

- A.** This SOPP applies only to eCTD documents for drug and biologic submissions, i.e., Biologics License Applications (BLA), New Drug Applications (NDA), Abbreviated New Drug Applications (ANDA), and related supplements (BLS, sNDA, sANDA), non-device pre-application submissions (e.g. pre-IND, etc.), and Investigational and Related Applications (IRA), which include electronically submitted Investigational New Drugs (IND), Master Files (MF), and Emergency Use Authorizations (EUA).
- B.** This SOPP does not apply to **any** medical device submissions, some of which are subject to the requirements in the eCopy Guidance. Medical device submissions include Requests for FDA Feedback (Q-Subs, Pre-Subs, etc., as described in “Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff - Guidance for Industry and Food and Drug Administration Staff”), Investigational Device Exemptions (IDE), pre-market notification submissions/510(k), De Novo requests, Premarket Approval Applications (PMA) and related supplements and annual reports, Device Master Files (DMF), and some BLA and related supplements and annual reports.

III. Background

- A.** The International Council on Harmonisation (ICH) developed a standard format for regulatory submissions called the Common Technical Document (CTD) and a standard for electronic regulatory submissions called the Electronic Common Technical Document (eCTD). A tracking number is pre-assigned by CBER prior to receiving an eCTD

submitted original application or supplement to automate receipt and processing of the submission.

- B.** The tracking number is included within the electronic submission's XML backbone and on FDA's fillable-PDF version of Form FDA 356h or Form FDA 1571, for eBLA and eIRA submissions, respectively. The fillable-PDF versions of these FDA forms are called PDF "SmartForms."
- C.** The CBER Electronic Document Room's (EDR) automated loading process reads the tracking number associated with the submission from the PDF SmartForm and executes automated loading and routing of the submission. If the tracking number is missing in the XML backbone, errors are generated and the automated loading and validation process fails. Submissions that fail the automated loading process are sent to CBER's Document Control Center (DCC) or the EDR Support Team for manual loading.

IV. Definitions

- A. Common Technical Document (CTD)** - A standardized format developed by the ICH for submitting applications to the FDA.
- B. eCTD** - A CTD submitted in electronic form with an extensible markup language (XML) backbone.
- C. eCTD XML Backbone** - An XML file that serves as a hyperlinked table of contents for the eCTD.
- D. Electronic Submissions Gateway (ESG)** - The Agency Secure Portal through which electronic submissions are received from sponsors/applicants.
- E. PDF SmartForm** - Forms that have embedded XML coding that facilitate the machine reading to automate loading and routing of the electronic submission process. **Note:** this includes the recovery of information supplied by the sponsor/applicant (Forms FDA 1571 and 356h). These forms can be obtained from the FDA forms webpage.

V. Policy

- A.** When requested, CBER will issue the tracking number to a sponsor/applicant no earlier than four weeks in advance of the target receipt date for the electronic submission.
- B.** When a sponsor/applicant requests a tracking number for an electronic submission in eCTD format, CBER's Regulatory Information

Management Staff (RIMS) should provide the number within two business days of the request.

- C.** Sponsor/Applicant requests should be made by email to cberrims@fda.hhs.gov. The request should include the Sponsor/Applicant name and address, primary point of contact name and phone number, the biologic product name, and the anticipated submission date.
- D.** In order for FDA to send regulatory information via email, the email must be sent to a secure email partner, to allow FDA to digitally sign and the encrypt message. This includes CBER's response to the Sponsor/Applicant's request for a tracking number for an electronic submission in eCTD format. Requests to establish secure email with FDA should be sent to SecureEmail@fda.hhs.gov. Adequate time should be allotted for secure email set-up prior to making a request for a tracking number. For further information regarding secure email, please refer to the *Guidance for Industry and Review Staff: Best Practices for Communication Between IND Sponsors and FDA During Drug Development* and CBER's *SOPP 8119: Use of Email for Regulatory Communications*.
- E.** All electronic original and related supplemental submissions received in eCTD format through the Agency's ESG, should contain a pre-assigned tracking number.
 - 1.** The pre-assigned number allows CBER's EDR to automatically process, load and notify reviewers of the receipt of a new regulatory submission.
 - 2.** If a submission does not have a pre-assigned number, it fails the automated process and must be loaded manually by CBER's DCC or EDR Support Team.
 - 3.** The Sponsor/Applicant will be automatically notified by the system upon receipt of the submission. If the submission failed to load, the automatic receipt will alert the sponsor/applicant.
- F.** Tracking numbers are not pre-assigned for paper based submissions.

VI. Responsibilities

A. Regulatory Information Management Staff (RIMS)

- 1.** Processes request from sponsor/applicant for a pre-assigned tracking number.

2. Enters the essential application information required in order to generate the tracking number in the appropriate CBER database.
3. Notifies the sponsor/applicant and the product review office of the pre-assigned tracking number.
4. Periodically voids tracking numbers that are pre-assigned when the submission is not received.

B. Review Office

1. Forwards all requests for a tracking number to RIMS, if received in the review office.

VII. Procedures

A. Electronic BLAs, NDAs and ANDAs, and related supplements

1. Generates the submission's tracking number (STN number) in the Regulatory Management System-Biologics License Application (RMS-BLA) based on a request from the applicant; provides the number to the applicant within two business days of the request. **[RIMS]**
 - a. Forward the request to RIMS, if a request is received in the review office. **[Review Office]**
2. Notifies the applicant and the appropriate product review office of the STN assignment. **[RIMS]**
3. Advises the applicant to notify CBER RIMS if plans change and there will not be a submission within the targeted submission date. **[RIMS]**
4. Instructs the applicant to include the STN on the cover page of the submission, on the PDF SmartForm FDA 356(h) and in the XML backbone for a submission in the eCTD format. **[RIMS]**
5. Checks RMS-BLA periodically for pre-assigned STNs that are outdated and not received. **[RIMS]**
6. If pre-assigned STNs are outdated, contacts the review office to verify submission status. **[RIMS]**
 - a. If submission status is unknown, contacts the applicant to verify status. **[RIMS or RPM]**

- b.** In consultation with the RPM, voids pre-assigned STNs for submissions where receipt is no longer anticipated or delay is substantial. **[RIMS]**

B. Electronic Original IRAs (IND, MF, EUA)

- 1.** Generates the submission's tracking number (IRA number) in the Biologics Investigational and Related Applications Management System (BIRAMS) based on a request from the sponsor; provides the IRA number to the sponsor within two business days of the tracking number request. **[RIMS]**
 - a.** Forward the request to RIMS, if a request is received in the review office. **[Review Office]**
- 2.** Notifies the sponsor and the appropriate product review office of the IRA number assignment. **[RIMS]**
- 3.** Advises the sponsor to notify CBER RIMS if plans change and there will not be a submission within the targeted submission date. **[RIMS]**
- 4.** Instructs the sponsor to include the IRA number on the cover page of the submission, on PDF SmartForm FDA 1571 and in the XML backbone. **[RIMS]**
- 5.** Checks BIRAMS periodically for pre-assigned IRA numbers that are outdated and not received. **[RIMS]**
- 6.** If pre-assigned IRAs are outdated, contacts the product review office to verify submission status. **[RIMS]**
 - a.** If submission status is unknown, contacts the sponsor to verify status. **[RIMS or RPM]**
 - b.** In consultation with the RPM, voids pre-assigned IRA numbers for submissions where receipt is no longer anticipated or delay is substantial. **[RIMS]**

C. Electronic, non-device pre-application submissions (pre-IND etc.)

- 1.** Generates the submission's tracking number (PS number) in the BITS-Pre-Application Tracking System (PTS) based on a request from the requestor; provides the PS number to the requestor within two business days of the tracking number request. **[RIMS]**

- a. Forward the request to RIMS, if a request is received in the review office. **[Review Office]**
2. Notifies the requestor and the appropriate review office of the PS number assignment. **[RIMS]**
3. Advises the requestor to notify CBER RIMS if plans change and there will not be a submission within the targeted submission date. **[RIMS]**
4. Instructs the requestor to include the PS number on the cover page of the submission and on PDF SmartForm, if available, as well as in the XML backbone. **[RIMS]**
5. Instructs the requestor to contact CBER RIMS, in the future, to request an IRA number, per this procedure, if they intend to submit an IRA (e.g., IND). **[RIMS]**
6. Checks PTS periodically for pre-assigned PS numbers that are outdated and not received. **[RIMS]**
7. If pre-assigned PS numbers are outdated, contacts the review office to verify submission status. **[RIMS]**
 - a. If submission status is unknown, contacts the sponsor to verify status **[RIMS or RPM]**
 - b. In consultation with the RPM, voids pre-assigned PS numbers for submissions where receipt is no longer anticipated or delay is substantial. **[RIMS]**

VIII. Appendices

A. N/A

IX. References

A. References below can be found on the Internet:

1. [Electronic Submissions Gateway](#)
2. [Draft Guidance for Industry: Providing Regulatory Submissions in Electronic Format – Submission of Manufacturing Establishment Information](#)
3. [Guidance for Industry: Providing Regulatory Submissions in Electronic Format – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications](#)

4. [Guidance for Industry: Providing Regulatory Submissions in Electronic Format – Submissions under Section 745A\(a\) of the Federal Food, Drug, and Cosmetic Act](#)
5. [Guidance for Industry: Providing Regulatory Submissions in Electronic Format – Standardized Study Data](#)
6. [Guidance for Industry: Providing Regulatory Submissions in Electronic Format – Receipt Dates](#)
7. [Guidance for Industry: Providing Regulatory Submission in Electronic Format – Content of Labeling](#)
8. [Guidance for Industry: Providing Regulatory Submissions to CBER in Electronic Format – Investigational New Drug Applications \(INDs\)](#)
9. [Guidance for Industry and Food and Drug Administration Staff: Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff](#)
10. [Guidance for Industry: Providing Regulatory Submissions to the Center for Biologics Evaluation and Research \(CBER\) in Electronic Format - Biologics Marketing Applications](#)
11. [Guidance for Industry and Review Staff: Best Practices for Communication Between IND Sponsors and FDA During Drug Development](#)
12. [SOPP 8119: Use of Email for Regulatory Communications](#)

X. History

Written/Revised By	Approved By	Approval Date	Version Number	Comment
Heather Erdman	C. Joneckis	September 27, 2018	4	Revised to include Secure E-mail requirements
Heather Erdman Linda Dixon	C. Joneckis	January 29, 2018	3	Revised to include pre-application submissions

Heather Erdman Carla Vincent BPS/RMCC	C. Joneckis	Aug 30, 2015	2	Updated to reflect process changes, including transferring responsibility of STN pre-assignment from the review offices to RIMS
BPWG/RMCC	R. Yetter	Sept 18, 2007	1	First issuance of this SOPP