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

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I. Purpose

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,INTERACT, 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 and Meetings for Medical Device Submissions: The Q-Submission Program - 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 extensible markup language (XML) backbone and on FDA’s fillable-PDF version of Form FDA 356h or Form FDA 1571, FORM FDA 3938 for eBLA, eIRA, and eMF submissions, respectively. The fillable-PDF versions of these FDA forms are called PDF “SmartForms.”

C. The CBER Electronic Repository’s (CER) 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 CER 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 eight weeks in advance of the target receipt date for the electronic submission. If an STN is required in advance of the eight weeks, please include a justification for the extended time which will be evaluated on a case-by-case basis.

B. When a sponsor/applicant requests a tracking number for an electronic submission in eCTD format, CBER's Regulatory Information Branch (RIB) within the Division of Informatics (DI), Office of Regulatory Operations (ORO) should provide the number within two business days of the request.

C. Sponsor/applicant requests should be sent by email to CBERRIB@fda.hhs.gov. The request should include the sponsor/applicant name and address, the primary point of contact's name, phone number, email address and address if different from the sponsor/applicant's, the biologic product name, indication, the reviewing office (if known), 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. Sponsors/applicants should determine if their submission is commercial or research.

a. All commercial submissions must use eCTD through the ESG and the sponsor/applicant should request a pre-assigned tracking number.

b. Research submissions may use eCTD through the ESG with a provided pre-assigned tracking number or be submitted by email to CBER DCC at CBERDCC_eMailSub@fda.hhs.gov.

i. Sponsors emailing research submissions to CBER DCC should NOT request a pre-assigned tracking number when planning to submit to CBER DCC through email. CBER DCC will assign a tracking number upon receipt.

2. The pre-assigned number allows the CER to automatically process, load and notify reviewers of the receipt of a new regulatory submission.

3. If a submission does not have a pre-assigned number and is submitted through the ESG, it fails the automated process and must be loaded manually by CBER's DCC or CER Support Team.

4. The sponsor/applicant will be automatically notified by the system upon receipt of the submission. If the submission failed to load, the automatic receipt would alert the sponsor/applicant.

5. If a sponsor has questions regarding the ESG or if issues are encountered, such as not receiving the third acknowledgment they can contact esubprep@fda.hhs.gov.

F. Tracking numbers are not pre-assigned for non-eCTD submissions.

1. Non-eCTD submissions can be emailed to CBERDCC_eMailSub@FDA.HHS.GOV, and the submission will be processed manually. Additionally paper submissions (especially large submissions) can be mailed to the CBER DCC.

a. The mailing address is: 10903 New Hampshire Avenue, WO71, G112 (for regulatory submissions), Silver Spring, MD 20993-0002

VI. Responsibilities

A. Office of Regulatory Operations (ORO), Division of Informatics (DI), Regulatory Information Branch (RIB)

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 system.

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, or when a sponsor/applicant no longer intends to submit one.

B. Review Office

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

VII. Procedures

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

1. Generate the submission's tracking number (STN number) in the appropriate regulatory system based on a request from the applicant; provide the number to the applicant within two business days of the request. **[RIB]**

   a. Forward the request to RIB if a request is received in the review office. **[Review Office]**

2. Notify the applicant and the appropriate product review office of the STN assignment. **[RIB]**

3. Advise the applicant to notify CBER RIB if plans change and there will not be a submission within the targeted submission date. **[RIB]**

4. Instruct 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. **[RIB]**

5. Check the regulatory system periodically for pre-assigned STNs that are outdated and not received. **[RIB]**

6. If pre-assigned STNs are outdated, contact the review office to verify submission status. **[RIB]**

   a. If submission status is unknown, contact the applicant to verify status. **[RIB or RPM]**

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

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

1. Generate the submission's tracking number (IRA number) in the appropriate regulatory system based on a request from the sponsor; provides the IRA number to the sponsor within two business days of the tracking number request. **[RIB]**

    a. Forward the request to RIB, if a request is received in the review office. **[Review Office]**

2. Notify the sponsor and the appropriate product review office of the IRA number assignment. **[RIB]**

3. Advise the sponsor to notify CBER RIB if plans change and there will not be a submission within the targeted submission date. **[RIB]**

4. Instruct the sponsor to include the IRA number on the cover page of the submission, on PDF SmartForm FDA 1571 (INDs and EUA Submissions), or on PDF Smart Form FDA 3938 (MFs), and in the XML backbone. **[RIB]**

    a. **Note:** Form FDA 3938 should be used for Master Files, including device MF when submitting device MFs to CBER, despite the name "Drug Master File." For addition information on MFs, refer to *SOPP 8301: Receipt and Processing of Master Files*.

5. Check the regulatory system periodically for pre-assigned IRA numbers that are outdated and not received. **[RIB]**

6. If pre-assigned IRAs are outdated, contact the product review office to verify submission status. **[RIB]**

    a. If submission status is unknown, contact the sponsor to verify status. **[RIB or RPM]**

    b. In consultation with the RPM, void pre-assigned IRA numbers for submissions where receipt is no longer anticipated or delay is substantial. **[RIB]**

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

1. Generate the submission's tracking number (PS number) in the appropriate regulatory system based on a request from the requestor; provides the PS number to the requestor within two business days of the tracking number request. **[RIB]**

    a. Forward the request to RIB if a request is received in the review office. **[Review Office]**

2. Notify the requestor and the appropriate review office of the PS number assignment. **[RIB]**

3. Advise the requestor to notify CBER RIB if plans change and there will not be a submission within the targeted submission date. **[RIB]**

4. Instruct 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. **[RIB]**

5. Instruct the requestor to contact CBER RIB, in the future, to request an IRA number, per this procedure, if they intend to submit an IRA (e.g., IND). **[RIB]**

6. Check the regulatory system periodically for pre-assigned PS numbers that are outdated and not received. **[RIB]**

7. If pre-assigned PS numbers are outdated, contact the review office to verify submission status. **[RIB]**

   a. If submission status is unknown, contact the sponsor to verify status. **[RIB or RPM]**

   b. In consultation with the RPM, void pre-assigned PS numbers for submissions where receipt is no longer anticipated, or delay is substantial. **[RIB]**

VIII. Appendices

Not Applicable

IX. References

A. References below can be found on the Internet:

1. Electronic Submissions Gateway
2. Guidance for Industry: Providing Regulatory Submissions in Electronic Format – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications

3. Guidance for Industry: Providing Regulatory Submissions in Electronic Format – Submissions under Section 745A(a) of the Federal Food, Drug, and Cosmetic Act

4. Guidance for Industry: Providing Regulatory Submissions in Electronic Format – Standardized Study Data

5. Guidance for Industry: Providing Regulatory Submissions in Electronic Format – Receipt Dates

6. Guidance for Industry: Providing Regulatory Submission in Electronic Format – Content of Labeling

7. Guidance for Industry: Providing Regulatory Submissions to CBER in Electronic Format – Investigational New Drug Applications (INDs)

8. Guidance for Industry and Food and Drug Administration Staff: Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program

9. Guidance for Industry and Review Staff: Best Practices for Communication Between IND Sponsors and FDA During Drug Development

10. SOPP 8119: Use of Email for Regulatory Communications

11. SOPP 8301: Receipt and Processing of Master Files

X. History

Written/Revised By	Approved By	Approval Date	Version Number	Comment
Gates/Jefferson/Monser	Katie Rivers, MS Chief RABOB/DROP/ORO	October 30, 2025	10	Updated policy to indicate pre-assignment may occur up to 8 weeks in advance, clarified policy regarding pre-assignment for commercial vs research INDs and where to submit paper submissions; Updated procedures to clarify that form 3938 should be used for Master Files, added INTERACT as a pre-submission type, de-identified internal systems, and grammatical corrections
Martha Monser	N/A	February 27, 2023	9	Technical update for changes related to 2023 CBER reorganization
Martha Monser	N/A	February 27, 2022	8	Technical update for changes related to 2022 CBER reorganization

Written/Revised By	Approved By	Approval Date	Version Number	Comment
Martha Monser	N/A	December 11, 2020	7	Technical update for EDR retirement and replacement with CER and to replace “database” with “system”
Brien Hampton	Darlene Martin, MS, PMP	March 30, 2020	6	Minor update to policy to add that requestor also should specify indication with request
Martha Monser	N/A (Reviewed by Job Aid Coordinator)	January 9, 2020	5	Technical Update to current format/font and to update reference section.
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