

SOPP 8116: Use of Electronic Signatures for Regulatory Documents

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I. Purpose

This Standard Operating Policy and Procedure (SOPP) serves as a guide for Center for Biologics Evaluation and Research (CBER) staff for the electronic signature of CBER generated regulatory documents.

II. Scope

This SOPP applies to all CBER generated regulatory documents that are considered original documents. It does not apply to draft documents.

III. Background

A. During the conduct of its business, CBER staff create a wide variety of regulatory documents including review memorandums, memorandums of meetings and conversations, regulatory letters, etc. requiring signatures. The ability of employees to electronically sign documents is vital to day-to-day operations. 21 CFR Part 11, regarding electronic records and electronic signatures outlines the criteria for executed electronic records and signatures to be deemed trustworthy, reliable, and generally equivalent to paper records and handwritten signatures. It requires that electronic records are controlled to ensure the authenticity, integrity, and confidentiality and that the signer cannot readily repudiate the signed

records as not genuine. It also outlines requirements for procedures and controls of electronic signatures.

- B.** The Office of Management and Budget (OMB) publication, Use of Electronic Signatures in Federal Organization Transactions, January 25, 2013, outlines important requirements for legally binding electronic signatures, which includes the following:
- A person (i.e., the signer) must use an acceptable electronic form of signature;
 - The electronic form of signature must be executed or adopted by a person with the intent to sign the electronic record (e.g., to indicate a person's approval of the information contained in the electronic records);
 - The electronic form of signature must be attached to or associated with the electronic record being signed;
 - There must be a means to identify and authenticate a particular person as the signer; and
 - There must be a means to preserve the integrity of the signed record.
- C.** Electronically signing documents with an HHS issued Personal Identity Verification (PIV) certificate, i.e., the FDA identification badge, meets these requirements.

IV. Definitions

- A. Administrative File** – The file or files containing all documents pertaining to a particular administrative action, including internal working memoranda, and recommendations (21 CFR 10.3).
- 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). Note: Administrative records include sponsor/applicant submissions, CBER/FDA generated documents, and CBER/FDA database records.
- C. Digital signature** – An electronic signature based upon cryptographic methods of originator authentication, computed by using a set of rules and a set of parameters such that the identity of the signer and the integrity of the data can be verified (21 CFR 11.3).
- D. Electronic signature** – A computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be

- the legally binding equivalent of the individual's handwritten signature (21 CFR 11.3).
- E. Final Action package** – The documents routed to the signatory for the sole purpose of a final action on a pending marketing application or supplement.
 - F. Record Copy** – The document that is kept on file as an original or official master record for the total retention period. According to FDA's Office of Chief Council, the outgoing correspondence record copy must be an exact duplication of what the sponsor/applicant receives. Record copies are sometimes referred to as the archival copy.
 - G. Regulatory Document** – All CBER generated official correspondence, including but not limited to, review memorandum, teleconference memorandum, meeting summaries and letters related to an investigational or marketing application, supplement, or amendment.
 - H. Secure Email** – An electronic message sent from a sponsor/applicant that has exchanged secure certificates with FDA. Secure certificates typically include the entire corporate or organization structure of a sponsor/applicant or a subset of users. Secure email makes use of encryption technology during transmission and decryption upon receipt using a public key within the certificate.

V. Policy

- A.** All CBER generated final regulatory documents shall be signed electronically using an HHS issued PIV certificate, i.e., the FDA identification badge (see *JA 820.01: Guide for CBER's Electronic Signature Process*). Note: CBER generated final regulatory documents should not be scanned for inclusion in an administrative record.
- B.** CBER generated regulatory letters follow *JA 820.01: Guide for CBER's Electronic Signature Process* and *JA 900.16: Regulatory Letter Processing for All Submissions*. CBER generated regulatory letters that are PIV signed may be issued to the sponsor/applicant by secure email. The email sent to the applicant or sponsor should not be uploaded to the CBER's Electronic Document Room (EDR).
 - 1.** In accordance with *SOPP 8119: Use of Email for Regulatory Communications*, if a sponsor/applicant does not have secure email, the final electronically signed version of a letter must be printed and sent to a sponsor/applicant via regular mail (see *JA 900.16: Regulatory Letter Processing for All Submissions* for additional information). A follow-up facsimile is allowed as a rapid means of transmitting the information.

- C. All CBER generated final regulatory documents will be uploaded in CBER's EDR.
- D. Draft documents are exempt from the requirements of this SOPP. It is expected that drafts will be circulated for comments before the final sign off. Examples of these document types include:
 - 1. The first version of a letter/review memo sent to the committee/participants/supervisors for review/edits before sending the letter/review memo for concurrence/signature.
 - 2. Draft meeting summaries before the issuance of the final meeting summary.

VI. Responsibilities

A. CBER personnel who generate CBER final regulatory documents:

- 1. Sign final regulatory documents electronically using the PIV badge.
- 2. Upload final regulatory documents to the appropriate database.

B. CBER personnel who are responsible for signing CBER final regulatory documents

- 1. Sign final regulatory documents electronically using the PIV badge.

VII. Procedures

A. Follow *JA 820.01: Guide for CBER's Electronic Signature Process* for specific technical instructions on signing and locking documents. **[Review committee Members, RPM, Signatory Authority]**

B. Upload signed documents to the EDR. **[Review Committee Members, RPM]**

VIII. Appendix

N/A

IX. References

A. References below are CBER internal:

- 1. JA 820.01: Guide for CBER's Electronic Signature Process
- 2. JA 900.16: Regulatory Letter Processing for All Submissions

B. References below can be found on the Internet:

1. [SOPP 8119: Use of Email for Regulatory Communications](#)

X. History

Written/ Revised	Approved	Approval Date	Version Number	Comment
Monser	Reviewed by Template Coordinator	November 14, 2019	7	Technical Update to current format/font and to correct typographical errors.
Rehkopf	Christopher Joneckis, PhD	April 14, 2019	6	Revised to incorporate current procedures.
Dixon/Perkins	R. A. Yetter, PhD	April 16 2012	5	Revised to incorporate procedures for using the PIV badge and make technical corrections; appendices removed
Dixon	R.A. Yetter, PhD	July 29, 2010	4	Revised to make the document security password definition consistent with SOPP 8401.7
Dixon	R.A. Yetter, PhD	July 15, 2009	3	Revised to clarify procedures for signing review memos
Dixon	R.A. Yetter, PhD	Sept 12, 2008	2	Revised to include new procedures for the Common Communication Module
BPWG/RMCC	R. A. Yetter, PhD	October 10, 2007	1	First version of this SOPP