SOPP 8110: Submission of Regulatory Applications -- Exempt from eCTD Requirements

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I. Purpose

A. This Standard Operating Policy and Procedure serves as a guide for the Center for Biologics Evaluation and Research staff on the acceptable formats and procedure for the submission of regulatory applications to CBER that are exempt from electronic submission requirements.

B. This SOPP will aid CBER staff when responding to inquiries from applicants and sponsors on how to submit non-eCTD applications both directly to the CBER Document Control Center (DCC) and via the Electronic Submissions Gateway (ESG).

II. Scope

A. This SOPP applies to all non-device biologic application types that are exempt from the electronic submission requirements. Exemptions may include pre-application submissions, non-commercial Investigational New Drug applications, emergency use requests for individual use under expanded access provisions [see 21 CFR 312.310(d)], pre-Emergency Use Authorizations and Emergency Use Authorizations, emergency alternative procedures or exemptions under 21 CFR 640.120, and submissions described in section 361 of the Federal Food, Drug, and Cosmetic Act.

Biologic License Applications and Supplements for non-PDUFA products, except for allergenic products, are also exempt. Applications for allergenic products must comply with the electronic submission requirement.

B. This SOPP does not apply to device applications handled under the FDA eCopy Guidance.

C. This SOPP does not specifically address the submission of genomic sequencing and other types of scientific big data.

III. Background

A. CBER staff frequently receive inquiries from sponsors and applicants about the preparation of regulatory submissions. This SOPP contains information on the preferred method for submissions that are not required to be submitted through the ESG in the eCTD format (see the *Guidance for Industry: Providing Regulatory Submissions in Electronic Format—Submissions Under Section 745A(a) of the Federal Food, Drug, and Cosmetic Act* and *Guidance for Industry*: *Providing Regulatory Submissions in Electronic Format—Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications* for more information).

IV. Definitions

A. Investigational and Related Applications (IRA): IRAs include all original and amendments for application types that CBER receives from sponsors which are tracked in CBER's Biologics Investigational and Related Applications Management System (BIRAMS), including Investigational New Drug Applications (INDs), Investigational Device Exemptions (IDEs), Master Files (MFs), and Emergency Use Authorizations (EUAs).

B. Marketing submission: Marketing submissions include all original and supplemental applications/notifications that CBER receives from applicants intending to market products regulated by CBER. Marketing submissions include Biologic License Applications (BLA) and supplements (BLS), Premarket Notifications [510(k)], Premarket Approval Applications (PMA) and supplements (PMS), Product Development Protocols (PDP), New Drug Applications (NDA) and supplements (NDS), and Abbreviated New Drug Applications (ANDA) and supplements (ANDS).

V. Policy

A. All biologic regulatory submissions must follow the *Guidance for Industry: Providing Regulatory Submissions in Electronic Format—Submissions Under Section 745A(a) of the Federal Food, Drug, and Cosmetic Act* and *Guidance for Industry*: *Providing Regulatory Submissions in Electronic Format—Certain Human Pharmaceutical Product Applications and Related Submissions Using*

the eCTD Specifications. Regulatory submissions that fall outside of these guidances can be submitted to CBER through its Document Control Center. However, sponsors/applicants are encouraged to submit in accordance with the eCTD specifications, using the FDA Electronic Submissions Gateway (ESG).

B. It is the responsibility of all CBER personnel who receive a request for information on the preparation of regulatory submissions to provide the following instructions contained in this SOPP to sponsors and applicants.

C. Submissions that are not required to be submitted in accordance with the eCTD specifications should be submitted following the *Draft Guidance for Industry: Providing Regulatory Submissions in Alternate Electronic Format* via the FDA ESG, on electronic media or in paper. CBER prefers electronic submission via ESG over paper and electronic media.

1. The sponsor/applicant will submit one complete copy of the submission.

2. If submitting electronic media, the sponsor/applicant will submit one (original on electronic media (DVD, Disc or USB drive).

3. The media types must not require specialized software and **must not** be password protected.

4. The PDF content may be one or more files presented in a logical order.

5. For paper submissions, the sponsor/applicant will submit one original on standard office weight 8.5” x 11” white paper. This will allow for the submission to be “scanner” ready for digital imaging by the DCC. Oversized paper sheets for charts and graphs are allowed. Color graphics are also allowed.

C. Applications that are submitted to the CBER DCC must be sent to the address listed below. The CBER DCC is open Monday through Friday from 8:00 AM to 4:30 PM (U.S. Eastern time zone). The CBER DCC is not open weekends or on U.S. federal government holidays. The CBER DCC does not accept shipments after business hours.

U.S. Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Avenue
WO71, G112
Silver Spring, MD 20993-0002

VI. Responsibilities

A. Document Control Center – Receives and processes regulatory submissions for the Center.

B. CBER personnel who receive a request for information on the submission of regulatory documents **-** Provide the information in this SOPP to sponsors, prospective sponsors and applicants on how to submit regulatory documents to CBER.

C. Sponsors/applicants – CBER recommends that sponsors/applicants refer to these procedures when submitting regulatory documents to CBER to facilitate the efficient processing of their submissions.

VII. Procedures

A. Electronic Submissions Gateway (ESG)

1. Visit the ESG website to set up an account and ask questions. **[Sponsor/Applicant]**

B. Electronic Media

1. Submit the unstructured PDF on a common form of electronic media to DCC. **[Sponsor/Applicant] Note:** This includes Digital Video Disc (DVD), Compact Disc (CD), USB flash drive, or external hard drives.

C. Paper Based Submissions

1. Submit single paper applications on 8.5” x 11” white paper of a normal bond and weight for business documents to DCC. **[Sponsor/Applicant]**

a. The application must be three-hole punched on the left margin.

b. The application does not need to be jacketed but larger submissions must be grouped in volumes no larger than 2” and bound with binder clips, rubber bands, or like devices.

c. Each volume must be marked with the volume number and the total number of the volumes (i.e., 1 of 10, 2 of 10, etc.).

d. The applications should not have divider tabs. Sections can be divided by sheets of colored paper.

e. Oversized pages and foldouts are permitted.

f. Color graphics and charts are permitted.

g. Text must be black with a minimal amount of color text printing.

h. Text must be dark enough to allow for digital imaging.

i. It is recommended that documents not be printed with an inkjet printer.

VIII. Appendix

N/A

IX. References

A. References below can be found on the Internet:

1. Guidance for Industry: Providing Regulatory Submissions in Electronic Format – Submissions Under Section 745A(a) of the Federal Food, Drug, and Cosmetic Act
2. Guidance for Industry: Providing Regulatory Submissions in Electronic Format—Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications
3. Draft Guidance for Industry: Providing Regulatory Submissions in Alternate Electronic Format Guidance for Industry
4. FDA's Electronic Submission Gateway

X. History

Written/Revised	Approved	Approval Date	Version Number	Comment
Richard Thomas	Christopher Joneckis, PhD	August 23, 2020	5	Updated for changes in electronic submission requirements.
Richard Thomas	Christopher Joneckis, PhD	June 3, 2019	4	Updated for the electronic submission requirements. It simplifies the requirements and instructions for submitting non-eCTD applications to CBER.
Jules Meisler, RMS	Christopher Joneckis, PhD	October 21, 2014	3	Updated address and deliver procedures

Written/Revised	Approved	Approval Date	Version Number	Comment
Jules Meisler, BPS	Robert Yetter, PhD	April 5, 2010	2	Updated procedures
Jules Meisler; RMWG; RMCC	Robert Yetter, PhD	February 6, 2003	1	Original. It replaces and includes appropriate updated information from SOPP 8102, Submission of Electronic Media, issued April 30, 1997.