TRANSMITTING ELECTRONIC SUBMISSIONS USING eCTD SPECIFICATIONS

Technical Specifications Document

This document is incorporated by reference into the following guidance document:

Guidance for Industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*

For questions regarding this technical specifications document, contact CDER at esub@fda.hhs.gov or CBER at esubprep@fda.hhs.gov

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

Revision History

Date	Version	Summary of Changes
2005-05-25	1.0	Original version
2005-06-14	1.1	Correction of typographical error in Type of Media table
2009-08-27	1.2	Removal of Media Type Floppy Disk Updated LTO specifications Added information regarding ESG
2010-08-02	1.3	Change to Address for electronic submission sent on physical media CDER Office of Generic Drugs address change
2011-12-28	1.4	Added information regarding USB media format Added retirement date for Tape options Added email address for Questions/Communication with Centers
2012-07-26	1.5	Clarification that USB encryption is optional Rewording information regarding password protection of data vs. USB drive
2016-03-04	1.6	Addition of coversheet Change of document title Update to include ESG requirements and deadlines Change to address for electronic submission sent on physical media Removal of tape options Update to CD ROM, DVD, and USB drive specifications Update to media preparation instructions
2017-06-22	1.7	Update to electronic submission date requirements, following update to the eCTD Guidance Update to CD ROM, DVD, and USB drive specifications
2019-04-01	1.8	Update to Physical Electronic Media addresses for submission from NPN7 to Central Document Room
2021-06-14	1.9	Clarified instructions on use of the ESG Added retirement date for CD-ROM and DVD options

Transmitting Electronic Submissions Using eCTD Specifications

This document provides a specification for transmitting electronic submissions using eCTD specifications. Details are included for transmitting electronically via the FDA Electronic Submission Gateway (ESG), our preferred method of transmission, and on physical media, when the ESG cannot be used.

Electronic submissions that do not comply with this specification cannot be processed for review and are subject to rejection.

I. ELECTRONIC TRANSMISSION

The ESG must be used for eCTD submission sizes of 10 GB or less. This applies to eCTD submissions types (NDA, BLA, ANDA, commercial IND and master files).

> The 10 GB requirement does apply to non-commercial/research IND, Type III master file, and EUA submissions. For more information on eCTD requirements, including exemptions to the eCTD requirements, please see http://www.fda.gov/ectd.

We also recommend the use of the ESG for submissions greater than 10 GB when possible. For guidance, please refer to the ESG User Guide regarding sending large submissions and/or contact the ESG Helpdesk at ESGHelpDesk@fda.hhs.gov.

For general information on the ESG, including how to set up an account, outages, submission acknowledgements, and how to submit a ticket, see: https://www.fda.gov/industry/electronic-submissions-gateway.

For ESG frequently asked questions, see: https://www.fda.gov/industry/create-esg-account/frequently-asked-questions.

II. PHYSICAL ELECTRONIC MEDIA

Physical electronic media should not be used for submissions that are 10 GB or less in size.

A. Type of physical electronic media accepted

Note: CD ROM and DVD options will be retired as of 12/31/2021.

Media Type	Format	Submission Size
CD ROM	CD-R	Over 10 GB to 45 GB
DVD	DVD-R DVD+R DVD+/-R	
USB drive	• Device Type: External hard drive, including "thumb" drive Size not to exceed: Width: 4 in Depth: 5 in Height: 1 in • Interface: Hi-Speed USB 3.0 (preferred) or 2.0 with Type A plug • Optional passcode: use 6 to 24 digits • Driverless operation	Over 10 GB Contact the Agency Center by email in advance for specific instructions on how to send. For CDER, contact ESUB@fda.hhs.gov. For CBER, contact ESUBPREP@fda.hhs.gov.

B. Media preparation

Send all physical electronic media in an adequately secured protective case or sleeve to avoid damage during transport.

The following information should be included on the media labels:

Sponsor, applicant or company name
Name of the product, chemical or ingredient
Appropriate regulatory ID number (e.g., NDA application number)
Submission date (dd-mm-yyyy)
Media series (e.g., "1 of 1", "1 of 2")

C. Addresses for submission

CBER:

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

CDER:

U.S. Food and Drug Administration
Center for Drug Evaluation and
Research Central Document Room
5901-B Ammendale Rd.
Beltsville, MD 20705-1266