

# 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](mailto:esub@fda.hhs.gov) or CBER at [esubprep@fda.hhs.gov](mailto: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)**

## Transmitting Electronic Submissions Using eCTD Specifications

### 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

## **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) and on physical media.

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

### **I. ELECTRONIC TRANSMISSION**

FDA recommends the use of the Electronic Submissions Gateway (ESG). See <http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm> for more information.

#### **NOTE:**

**Beginning May 5, 2017, the ESG must be used for eCTD submission sizes of 10 GB or less for NDAs, BLAs, and ANDAs.**

**Beginning May 5, 2018, the ESG must be used for eCTD submission sizes of 10 GB or less for commercial INDs and master files.**

Please see <http://www.fda.gov/ectd> for additional eCTD requirements.

### **II. PHYSICAL ELECTRONIC MEDIA**

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

#### **A. 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

## Transmitting Electronic Submissions Using eCTD Specifications

CDER:

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

### B. Types of physical electronic media accepted

See the following table:

Media Type	Format	Submission Size
CD ROM	CD-R	Over 10 GB to 45 GB
DVD	DVD-R DVD+R DVD+/-R	
USB drive	<ul style="list-style-type: none"><li>• Device Type: External hard drive, including “thumb” drive Size not to exceed: Width: 4 in Depth: 5 in Height: 1 in</li><li>• Interface: Hi-Speed USB 3.0 (preferred) or 2.0 with Type A plug</li><li>• Optional passcode: use 6 to 24 digits</li><li>• Driverless operation</li></ul>	Over 10 GB  Contact the Agency Center by email in advance for specific instructions on how to send. For CDER, contact <a href="mailto:ESUB@fda.hhs.gov">ESUB@fda.hhs.gov</a> . For CBER, contact <a href="mailto:ESUBPREP@fda.hhs.gov">ESUBPREP@fda.hhs.gov</a> .

### **C. 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”)

*To obtain instructions for sending  
USB drives and to ask general  
questions, please contact us:*

CDER: [ESUB@fda.hhs.gov](mailto:ESUB@fda.hhs.gov)

CBER: [ESUBPREP@fda.hhs.gov](mailto:ESUBPREP@fda.hhs.gov)