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

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, ANDAs and master files.

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

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

CDER:

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

U. S. Food and Drug Administration
Office of Generic Drugs – HFD-600
Center for Drug Evaluation and Research
Metro Park North VII
7620 Standish Place
Rockville, MD 20855-2773

B. Types of physical electronic media accepted

See the following table:

Media Type	**Format**	**Submission Size**
CD ROM	CD-R	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 45 GB only 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. IMPORTANT: DO NOT SUBMIT USB DRIVES FOR SUBMISSIONS UNDER 45 GB

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

CBER: ESUBPREP@fda.hhs.gov