

Specification for 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

Specifications for Transmitting Electronic Submissions using eCTD Specifications

This document provides specification for transmitting electronic submissions using eCTD specifications. Details are included for transmitting the electronic submission on physical media or electronically.

I. PHYSICAL MEDIA

A. Address for electronic submissions on physical media

CBER

Center for Biologics Evaluation and Research
 Document Control Center, HFM-99
 Food and Drug Administration
 1401 Rockville Pike
 Rockville, MD 20832-1448

CDER

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

B. Type of media

See the following table:

Type of media	Format	Size
Floppy Disk	3.5 inch 1.44 MB	Up to 14.4 MB (10 disks)
CD ROM	CD-R Joliet Specification	Up to 3 GB (1- 5 CDs)
DVD	DVD-RAM DVD-R DVD+R DVD+/-R	Up to 45 GB (1 to 6 DVDs)
Digital Linear Tape	35/70 or 40/80 DLT tapes using <ul style="list-style-type: none"> • Veritas backup exec, • Win2000 native backup. do not use compression	No limit
Linear Tape Open	LTO 1 (100/200 GB) or LTO	No limit

Specification for Transmitting Electronic Submissions using eCTD Specifications

	2 (200/400 GB)tapes using <ul style="list-style-type: none">• Veritas backup exec• Win2000 native backup uncompressed	
--	--	--

C. Media preparation

Send all electronic media adequately secured in a standard binder marked clearly on the outside ELECTRONIC REGULATORY SUBMISSION FOR ARCHIVE. 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., IND number)

Submission date (dd-mmm-yyyy)

Media series (e.g., "1 of 1", "1 of 2")

II. ELECTRONIC TRANSMISSION

FDA is currently working on updating its capabilities to receive submissions electronically. Contact the appropriate centers for details on alternatives for sending in electronic submissions.