eCTD Waivers:
What they are
When they are needed
How to obtain

Virginia Ventura
Office of Business Process Support
Center for Drug Evaluation and Research

DIA Electronic Document Management Conference
February 7th, 2008
Philadelphia, PA

Overview

- Background
  - Memorandum 27
  - CTD Hybrid
  - Memorandum 33
  - eCTD Waiver Process
    - When you need, when you don't, how to get
  - FAQs
  - References

The Public Docket

- Electronic Submissions Public Docket number 92-0251
  - provides a permanent location for a list of the Agency units that are prepared to receive electronic submissions, as well as a list of the specific types of regulatory records that can be accepted in electronic format (62 FR 13467, March 20, 1997).

Public Docket: Memo 27

- Published August 27, 2003
- Announced CDER's readiness for accepting eCTDs
- Technical specs posted on eCTD website
- CDER has received about 20,000 eCTD submissions since then

The Hybrid CTD

- An electronic application
- Not eCTD, not eNDA
- Folders arranged as per the eCTD Guidance, but with a TOC.pdf that acts as the "backbone," following the Table of Contents Headings and Hierarchy document, linking to the various documents contained in the submission

Public Docket: Memo 33

- Published September 13, 2007
- Announced acceptance of eCTD for IND, NDA, BLA, ANDA, Master Files and Annual Reports
- Withdrew Memos 6, 24 & 30, which made provisions for electronic acceptance of NDAs, ANDAs and their Annual Reports (governed by withdrawn guidances)* as of 12/31/07

**Guidances for these original formats were withdrawn per Federal Register 9/29/2006*

The Old eSubmissions Guidances in CDER

- 1999 – Providing Regulatory Submissions in Electronic Format – NDAs
- 2002 – Providing Regulatory Submissions in Electronic Format – ANDAs
- 2003 – Providing Regulatory Submissions in Electronic Format – Annual Reports for NDAs and ANDAs (*draft*)

Withdrawn 12/31/07

Memo 33: The Waiver Process

- Provides a way to keep submitting in eNDA or Hybrid format if you are not able to submit in eCTD format yet
- Allows CDER to understand your plans for conversion and an estimate of your timetable

Where We Are Now

- eNDA (old format, ok with waiver)
- Hybrid (transitioning format, preferred with waiver)
- eCTD (what you should be sending)

When you need a waiver

- You have not converted to eCTD format yet
- You are submitting an NDA, ANDA, BLA application, supplement, or annual report in electronic format
- Paper still ok, although discouraged

After you get a waiver

- Keep submitting in the format you had previously sent in
- If a new application, send in Hybrid format if possible
- If a BLA (with roadmap) continue to send in the CBER format

When you do not need a waiver

- NDA or ANDA original and supplemental application that is currently under active review
- Continue to send in the same format you have been using (i.e., do not convert to Hybrid if you've been using eNDA format or CBER Roadmap to Hybrid)

What about INDs and DMFs?

- No waiver for IND unless your IND was previously submitted in electronic format (no guidance for electronic IND other than eCTD)
- No waivers for DMF (no guidance for electronic IND other than eCTD). DMF must be in eCTD format.

Of Note in Memo 33

- Mix paper/electronic NDA/BLA/ANDA with SPL or datasets to an IND
- Only those electronic elements need to comply with Memo 27 (eCTD)
- Does not mean you need to convert entire submission to eCTD, just those electronic parts

How to obtain a waiver

- Instructions are found on both the ERSR and eCTD CDER websites: http://www.fda.gov/cder/regulatory/ersr/waiver.htm
- Submit the required contact info, along with your plans and timetable to convert ESUB@fda.hhs.gov
- Do not seek a waiver if you don't need one

FAQs

- Can I still submit paper applications after 12/31/2007?
  - *Yes. The withdrawal does not affect paper applications in any way. CDER prefers electronic submissions over paper.*
- What about eBLAs and the guidance on them?
  - *That is a CBER guidance. It has not been withdrawn. CBER has not announced plans to withdraw this guidance. However, electronic BLAs to CDER must be in eCTD format or a waiver must be sought.*

FAQs

- I want to send in a meeting request electronically. Do I need a waiver for this?
  - *Yes, you need a waiver.*
- Does a meeting package need to be in eCTD format?
  - *Yes, meeting packages are part of the eCTD, however you may also be requested to provide these in paper. See this link for info.*

Summary

- eCTD is the only acceptable eSubmission format as of 1/1/08
- Waivers are available if you haven't converted, but you must indicate your plans & timetable to convert in order to obtain one
- Waivers not needed for NDA and ANDA original and supplemental actions under active review at time of deadline
- Paper still okay (but strongly discouraged)

References

- Public Docket: http://www.fda.gov/ohrms/dockets/dockets/92s0251/92s0251.htm
- eCTD Guidance: http://www.fda.gov/cder/regulatory/ersr/ectd.htm
- TOC Headings and Hierarchy: http://www.fda.gov/cder/regulatory/ersr/5640CTOC-v1.2.pdf
- Waiver Instructions: http://www.fda.gov/cder/regulatory/ersr/waiver.htm
- Info Packages for Meetings: http://www.fda.gov/cder/regulatory/ersr/meetings_information.htm