FDA/CDER
SMALL BUSINESS CHRONICLES
JUNE 14, 2012

Go Green – Submit Electronically

Inside This Issue

Paper NDA

Electronic Submission
The equivalent of 50,000 pages of data

FDA is going green! Did you know that you can send investigational new drug applications (INDs), new drug applications (NDAs), abbreviated new drug applications (ANDAs), biologics license applications (BLAs) and drug master files (DMFs) to FDA/CDER electronically?

FDA encourages sponsors to file electronically using the electronic common technical document (eCTD) format. In January 2008, eCTD became CDER's standard for electronic submission. Although CDER still accepts paper submissions during this transition time, we are rapidly moving towards an all-electronic environment. In the future, electronic submission will be mandatory. FDA advises applicants to convert to eCTD format now.

Why? CDER prefers electronic submissions over paper, and you should too! Here are just a few of the reasons:

Faster: Automated processing for eCTDs sent via the Electronic Secure Gateway (ESG) allows your submission to be in reviewer's hands in as little as 15 minutes!

More efficient: FDA reviewers can simultaneously search and view your application, finding documents in standardized locations

Concurrent review: Electronic records enable concurrent review by multiple reviewers

Version control: Eliminates outdated documents

Easy cross-referencing: Certain documents can be re-used using cross-application hyperlinks

Standardized process: eCTD is a global standard that can facilitate a global submissions strategy

Better for the environment: Fewer trees used for paper

Cheaper: Printing, shipping and storage costs are reduced for industry and the FDA

FDA reviewers prefer eCTD!

The eCTD webpage outlines the basics of getting started with eCTD, such as the following:

- Review the Published Guidance and Specifications documents
- View recent eCTD presentations by FDA staff
- Refer to the Comprehensive Table of Contents Headings and Hierarchy
- Send an eCTD sample for evaluation before sending an actual eCTD submission

How? There are two ways you can electronically transmit a submission to CDER:

- Electronic Submissions Gateway (ESG) - preferred
- Physical Media (CD\DVD) or USB drive

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Electronic Submissions Gateway The FDA Electronic Submissions Gateway (also known as the FDA ESG) is an Agency-wide solution for accepting electronic regulatory submissions. The FDA enables the secure submission of regulatory information and is a conduit or "highway" along which submissions travel to reach their final destination. It does not open or review submissions; it automatically routes them to the selected FDA Center or Office.

Before using the ESG, the sponsor needs to create a WebTrader account. For policy questions and to request a WebTrader account, you may contact esgprep@fda.hhs.gov. For help with registration or testing, contact esgreg@gnsi.com.

Physical Media (CD\DVD) or USB Drive Sponsors can also send their submission by physical media. FDA requires only one electronic copy and recommends that you send a paper copy of the cover letter including the contact information and FDA form, in case the media is unreadable. Please refer to the Transmission Specification for details.

eCTD Software You will need specialized software to compile documents into eCTD format for submission. This usually involves software that will allow publishing, validating and viewing of the eCTD submission. Some companies choose to outsource this process. If you use a major search engine and type in eCTD applications, eCTD tools, eCTD viewers, you will find vendors. FDA does not endorse software or outsourcing solutions.

Validation is an important processing component to ensure compliance with the eCTD specification and improve the availability and reviewability of individual submissions and applications throughout their lifecycle. Validation should be done on all eCTD submissions regardless of the method of transmission, before sending to the FDA. FDA may perform additional validation checks for both eCTD and non-eCTD submissions. These validation checks are intended to ensure that submissions are processed and routed accurately and in a timely fashion.

In the future, electronic submission will be mandatory

Forms Just as with paper submissions, all electronic application submissions to FDA should include an FDA form depending on the application and submission type. You do not have to file any extra forms with an electronic submission versus paper submission. For example, sponsors filing INDs should include FDA Form 1571 and sponsors filing NDAs, BLAs and ANDAs should include FDA Form 356h. We prefer that you use fillable forms rather than sending scanned forms, as our automated software cannot read scanned forms.

Transitioning to eCTD format If you have an existing application that you submitted in paper format, you do have the opportunity to switch from paper or non-eCTD format to the eCTD format. Generally, resubmission of previously submitted information is unnecessary when converting to eCTD format. If you have never submitted eCTD before, we recommend that you contact the ESUB group at esub@fda.hhs.gov when converting to eCTD format for specific advice and help, prior to submitting your eCTD.

We are developing a CDERLearn course to guide you through the eCTD and electronic submissions process, which we anticipate delivering by year's end. If you have questions along the way, please contact the CDER Electronic Submission (CDER ESUB) Support Team at esub@fda.hhs.gov.

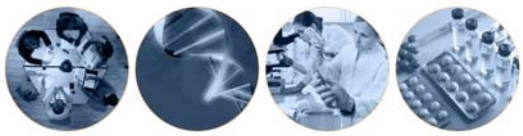
So save your time and energy, and save the planet at the same time. File electronically! And as always, please email us with any topics of interest for future newsletters.

Until next month,

The CDER Small Business Assistance Team

Issues of this newsletter are archived at http://www.fda.gov/cdersmallbusinesschronicles

This communication is consistent with 21CFR10.85(k) and constitutes an informal communication that represents our best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of the FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.



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