U.S. FOOD & DRUG ADMINISTRATION

AS OF MAY 5, 2018, MASTER FILE (MF) SUBMISSIONS MUST BE IN eCTD FORMAT

MF Tips

Tips on getting started

- All submissions to the MF that are received starting May 5, 2018 (e.g., amendment, annual report, letter of authorization), must be in Electronic Common Technical Document (eCTD) format.
  - Use the same MF application number when converting from paper to eCTD.

    Note: eCTD format requires the application number to be 6 digits (e.g., MF 1234 should be MF 001234 in eCTD).
  - If FDA received non-eCTD submissions prior to May 5, 2018, it is not necessary or encouraged to resubmit same material in eCTD format.

ESG tips

- Submissions of 10 GB or less must use the Electronic Submission Gateway (ESG).
- Obtain an ESG account early!
  - The ESG account setup/test/approval process can take several weeks and can reveal gaps in your eCTD publishing process when the test submission is validated.
  - There is no cost for an ESG account, but you must obtain a digital certificate for each person in your organization who will be sending files through the ESG.
  - For complete instructions, see www.fda.gov/esg.

Cover letter tips

- Provide a clear, concise description of the submission. If providing a response to an information request, include a hyperlink to the location of the response document.
- Always include the U.S. agent's information in case we need to contact the sponsor.
- Provide a point of contact for technical issues with electronic submissions.
- Provide the correct email address and fax number for technical rejection notices.

Tips on documents

- PDFs must follow the FDA PDF Specifications (located under the eCTD Submission Standards link at www.fda.gov/ectd).
- Do not submit paper copies of the application when submitting in eCTD format.

  Note: This includes review and desk copies.
- For documents of five pages or longer, provide proper bookmarks, tables of contents, and hyperlinks.
- Try to avoid scanning documents; it is better to convert from native format to PDF.
- Make sure pages are properly oriented.
- Leaf titles of documents should be clear and indicative of the content.

Tips on submitting

- Request an application number from Center for Biologics Evaluation and Research (CBER) or Center for Drug Evaluation and Research (CDER) when planning to submit a new MF (see www.fda.gov/ectd for instructions).
- When submitting a MF to CBER via ESG, choose "CBER" as the center and "eCTD" as the submission type.

- When submitting a MF to CDER via ESG, choose "CDER" as the center and "eCTD" as the submission type.
- When replacing a document submitted in a previous sequence, use the eCTD *replace* life cycle operation rather than submitting the file as *new*.
- If a MF holder is transitioning from paper to eCTD, using v2.01 document type definition (DTD), and submitting an amendment to the original application, the submission type to use is "original-application." Subsequent amendments to the original application should be coded as "amendment" and relate back to the sequence number of the "original-application" submission type.
  - If transitioning from paper to eCTD, using v3.3 DTD, and submitting an amendment to the original application, use "original-application" as the submission type, "application" as the submission subtype, "0001" as the sequence number, and "0001" as the submission ID. Subsequent amendments to the original application should use "original-application" as the submission type, "amendment" as the submission subtype, the next available sequence number, and "0001" as the submission ID.
  - If this is your first eCTD submission, you may provide an eCTD sample to the electronic submission team to get feedback before you send in your official submission. See the Sample Submission Validation Process for details (please note that it can take up to 30 days for feedback).

Additional resources

- See the Drug Master Files (DMF) website at www.fda.gov/dmf for information specific to DMF organization and submission.
- See the eCTD website at www.fda.gov/ectd for eCTD guidance, specifications, and other helpful information for getting started.

For more information, see the **eCTD Web page** and the binding guidance ***Providing Regulatory Submissions in Electronic Format—Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications: Guidance for Industry***.

Any questions? For technical eCTD clarifications, contact **esub@fda.hhs.gov**. For MF content- and policy-related questions, contact **dmfquestion@fda.hhs.gov** in advance.