U.S. FOOD & DRUG ADMINISTRATION

NEW REQUIREMENTS FOR THE ELECTRONIC SUBMISSION OF MFs

MF Requirements

The Electronic Common Technical Document (eCTD) is the standard method for submitting applications, amendments, supplements, reports, and master files (MF) to FDA's Center for Biologics Evaluation and Research (CBER) and Center for Drug Evaluation and Research (CDER).

Converting existing MFs to eCTD format

If you currently hold a MF in paper form, you are not required to resubmit it in eCTD format. However, you may convert an existing paper MF into eCTD format if you wish. When submitting your first eCTD submission to a MF, you will use the existing MF number. If the existing number is four digits, you will need to add zeros on the left to convert it to a six-digit format. For example, 1234 would become 001234.

If you choose to resubmit a paper MF in electronic format and there are changes in the content of the MF, such as new or updated information, you must list the changes in the cover letter for the submission.

Starting **May 5, 2018,** new MFs and any submissions to existing MFs (e.g., amendments, annual reports, letters of authorization (LOAs)) must be submitted using eCTD. All submissions must be submitted electronically, even if the remainder of the MF is on paper. MF submissions that are not submitted in eCTD format starting May 5, 2018, will not be filed or received. The eCTD standard will be updated in the future. The current requirements and supported versions can be found in the FDA Data Standards Catalog at www.fda.gov/eStudyResources.

Submitting MFs electronically

Implementing electronic MFs will improve the efficiency of the MF review process. This will make it easier for FDA to review applications supported by MFs. The first step to submitting MFs electronically through the FDA Electronic Submissions Gateway (ESG) is to request an ESG test account. Refer to the FDA ESG User Guide at www.fda.gov/esg for information on how to submit the registration request. Setting up an ESG account is a multi-step process and should be started well before you intend to make your first electronic submission.

Additional information

For more information on eCTD requirements, please visit www.fda.gov/ectd.

If you have **questions about MFs**, please write to dmfquestion@cder.fda.gov and visit the Drug Master Files website at www.fda.gov/DMF.

Contact information

If you have questions about **MFs filed under the Generic Drug User Fee Amendments of 2012**, please write to AskGDUFA@fda.hhs.gov.

If you have questions about **electronic submissions to CBER**, please write to esubprep@fda.hhs.gov.

If you have questions about **electronic submissions to CDER**, please write to esub@fda.hhs.gov.

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES/U.S. FOOD & DRUG ADMINISTRATION
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